Table of Abbreviations		
Category	**Abbreviation**	**Text**
Action - Subject	N	No action
	O	Other
	P	Drug withdrawn (study intervention discontinued)
	TC	Concomitant drug treatment given
	TCN	Concomitant non-drug treatment given
	W	Withdrawn from study
Toxicity Grade	1	Mild
	2	Moderate
	3	Severe
	4	Life-threatening
System Organ Class	BLOOD	Blood and lymphatic system disorders
	CARD	Cardiac disorders
	CONG	Congenital, familial and genetic disorders
	EAR	Ear and labyrinth disorders
	ENDO	Endocrine disorders
	EYE	Eye disorders
	GASTR	Gastrointestinal disorders
	GENRL	General disorders and administration site conditions
	HEPAT	Hepatobiliary disorders
	IMMUN	Immune system disorders
	INFEC	Infections and infestations
	INJ&P	Injury poisoning and procedural complications
	INV	Investigations
	METAB	Metabolism and nutrition disorders
	MUSC	Musculoskeletal and connective tissue disorders
	NEOPL	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
	NERV	Nervous system disorders
	PREG	Pregnancy, puerperium and perinatal conditions
	PSYCH	Psychiatric disorders
	RENAL	Renal and urinary disorders

Table of Abbreviations		
Category	**Abbreviation**	**Text**
	REPRO	Reproductive system and breast disorders
	RESP	Respiratory, thoracic and mediastinal disorders
	SKIN	Skin and subcutaneous tissue disorders
	SOCCI	Social circumstances
	SURG	Surgical and medical procedures
	VASC	Vascular disorders

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.5 cm	129.6 kg	46.2 kg/m2	30JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	2000	Present
Hypothyroidism	Hypothyroidism	NOV2007	Present
Depression	Depression	2008	Present
Asthma	Asthma	2009	Present
Sleep apnea	Sleep apnoea syndrome	2013	Present
Gastroesophageal reflux	Gastrooesophageal reflux disease	2018	Present
Gastric sleeve	Gastrectomy	SEP2019	Past
Supraventricular tachycardia	Supraventricular tachycardia	08OCT2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30JUL2020 (1)	13:11
2	BNT162b2	20AUG2020 (22)	11:45

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Cardiac arrest	Cardiac Arrest	18OCT2020 (81)		21OCT2020 (84)		4	4	W	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Fatal (21OCT2020)	NOT RELATED/OTHER: Heart attack. Occurred 2 months after last receipt of study agent	2	60	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30JUL2020	
Completed	VACCINATION	17SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	21OCT2020	DEATH

Narrative Comment
Subject C4591001 1007 10071101, a 56-year-old white female with a pertinent medical history of obesity (since 2000), hypothyroidism (since Nov 2007), depression (since 2008), asthma (since 2009), sleep apnea syndrome (since 2013), and supraventricular tachycardia (on 08 Oct 2019), received Dose 1 on 30 Jul 2020 and Dose 2 on 20 Aug 2020 (Day 22). The subject experienced cardiac arrest on 18 Oct 2020, 59 days after receiving Dose 2, and died of cardiac arrest on 21 Oct 2020, 62 days after receiving Dose 2. Concomitant medications included levothyroxine for hypothyroidism (since Nov 2007), albuterol for asthma (since 2016), citalopram for depression (since May 2017), metoprolol succinate for supraventricular tachycardia (since Oct 2019), and pantoprazole for gastroesophageal reflux disease (since Sep 2020). On 18 Oct 2020 (Day 81), the subject presented to the emergency room following an intubation prior to arrival after a cardiac arrest. It was reported by the nursing facility that the subject did not have neurologic response other than occasional movements and could breathe only with the help of ventilator settings. Her electrocardiogram was abnormal, with initial rhythm of pulseless electrical activity and ischemic changes. The downtime was reported as 15 minutes. On the same day (Day 81), a computed tomogram of the head showed cerebral edema. Emergency department personnel spoke with cardiology personnel, who deferred an intervention and a targeted temporal management (TTM) was ordered. The laboratory results on 18 Oct 2020 (Day 81) showed a blood chloride level of 124 mEq/L (normal range [NR]: 98-111 mEq/L), blood glucose of 393 mg/dL (NR: 70-99 mg/dL), blood potassium of 3.5 mEq/L (NR: 3.6-5.1 mEq/L), blood sodium of 155 mEq/L (NR: 135-145 mEq/L), carbon dioxide of 18 mmol/L (NR: 21-31 mmol/L), and glomerular filtration rate of 58 mL/min/1.73 m2 (NR: >59 mL/min/1.73 m2). Pressors were required, and the subject was admitted to the intensive care unit. On admission, the potassium level was low at 2.8 mEq/L. On 19 Oct 2020 (Day 82), the subject was on TTM with high urine output overnight, which was concerning for diabetes insipidus. On the same day (Day 82), the subject's troponin I was high at 491 ng/L (NR: <15 ng/L), which was considered critical. Her urine toxicology screening showed elevated ethanol at 109 mg/dL (upper limit of normal: 9.9 mg/dL) and was positive for amphetamines. The subject was an organ donor and her SARS-CoV-2 test was negative. On 20 Oct 2020 (Day 83), the subject was rewarmed and a magnetic resonance imaging showed anoxic brain injury with possible herniation, and an electroencephalogram showed absent brain activity. On 21 Oct 2020 (Day 84), the subject was pronounced dead at 1859 hours because of a cardiac arrest. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures, as the death occurred 2 months after receiving Dose 2. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.82 cm	116.18 kg	39.7 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Myopia	Myopia	1960	Present
Leg Cramps	Muscle spasms	1972	Present
asthma	Asthma	1985	Present
Allergic Rhinitis	Rhinitis allergic	1986	Present
Hemorrhoids	Haemorrhoids	1990	Present
Gastric Reflux	Gastrooesophageal reflux disease	2000	Present
Hypercholesterolemia	Hypercholesterolaemia	2002	Present
Recurrent Back pain	Back pain	2010	Present
Osteoarthritis- knees	Osteoarthritis	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2016	Present
Atrial Fibrillation	Atrial fibrillation	30OCT2019	Present
sleep apnea	Sleep apnoea syndrome	NOV2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	14:40
2	Placebo	22SEP2020 (22)	07:56

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Biliary cancer metastatic	Biliary Cancer Metastatic	27OCT2020 (57)		17DEC2020 (108)		52	4
2	NEOPL	Metastases to liver	Metastases to Liver	27OCT2020 (57)		17DEC2020 (108)		52	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (17DEC2020)	NOT RELATED/OTHER: Unknown	2	36	Y
2	W	Y	Fatal (17DEC2020)	NOT RELATED/OTHER: metastatic biliary cancer	2	36	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	27OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	17DEC2020	DEATH

Narrative Comment
Subject C4591001 1019 10191146, a 67-year-old white male with a pertinent medical history of gastroesophageal reflux disease (since 2000), hypercholesterolemia (since 2002), hypertension (since 2016), and atrial fibrillation (since 30 Oct 2019), received Dose 1 on 01 Sep 2020 and Dose 2 on 22 Sep 2020 (Day 22). The subject was diagnosed with metastatic biliary cancer with metastases to the liver on 27 Oct 2020, 35 days after receiving Dose 2. The subject was diagnosed with metastatic biliary cancer and metastases to the liver on 27 Oct 2020, 35 days after receiving Dose 2, and died of the events on 17 Dec 2020, 86 days after receiving Dose 2. On 16 Oct 2020 (Day 46), an ultrasound-guided core biopsy and liver biopsy revealed a poorly differentiated carcinoma in the liver, which led to a diagnosis of biliary cancer with metastases to the liver on 27 Oct 2020 (Day 57). On 29 Oct 2020 (Day 59), a positron emission tomography scan revealed no other organ involvement besides the liver. On 16 Nov 2020 (Day 77), the subject was scheduled for an oncology consultation (no further information reported). The subject had no reported predisposing factors and died on 17 Dec 2020 (Day 108) because of disease progression of biliary carcinoma metastatic to the liver. No autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the metastatic biliary cancer with metastases to the liver was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178.2 cm	70.3 kg	22.1 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Acid Reflux	Gastrooesophageal reflux disease	2013	Present
Hypertension	Hypertension	2013	Present
Bilateral Leg Edema	Oedema peripheral	2013	Present
Congestive Heart Failure	Cardiac failure congestive	2016	Present
Idiopathic Cardiomyopathy	Cardiomyopathy	2016	Present
Irregular Heartbeat	Heart rate irregular	2019	Present
Defibrillator Implant	Implantable defibrillator insertion	2019	Past
Chronic Obstructive Pulmonary Disease	Chronic obstructive pulmonary disease	DEC2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	17:49
2	BNT162b2	23SEP2020 (24)	10:56

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	CARD	Acute left ventricular failure	NYHA Class IV Acute on Chronic Systolic Heart Failure	19OCT2020 (50)		21OCT2020 (52)		3	3	TC
2	CARD	Cardiac failure congestive	Acute on Chronic Combined Systolic and Diastolic Congestive Heart Failure	30NOV2020 (92)		19DEC2020 (111)		20	4	TC/W
3	METAB	Hypokalaemia	Hypokalemia	19OCT2020 (50)		21OCT2020 (52)		3	3	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (21OCT2020)	NOT RELATED/OTHER: Not related to drug or non-drug treatments	2	27	Y
2	Y	Fatal (19DEC2020)	NOT RELATED/OTHER: Not related to drug or non-drug treatment	2	69	Y
3	N	Resolved (21OCT2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	27	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	19DEC2020	DEATH

Narrative Comment
Subject C4591001 1021 10211127, a 54-year-old black or African American male with a pertinent medical history of hypertension, peripheral edema (bilateral leg/foot edema), and gastroesophageal reflux disease (all since 2013); congestive cardiac failure and idiopathic cardiomyopathy (both since 2016); irregular heart rate (since 2019); defibrillator implant (in 2019); and chronic obstructive pulmonary disease (COPD; since Dec 2019), received Dose 1 on 31 Aug 2020 and Dose 2 on 23 Sep 2020 (Day 24). The subject was diagnosed with acute left ventricular failure on 19 Oct 2020 and congestive cardiac failure on 30 Nov 2020, 26 days and 68 days after receiving Dose 2, respectively. He died of congestive heart failure on 19 Dec 2020, 87 days after receiving Dose 2. Concomitant medications included acetylsalicylic acid (since 2013) for cardiac prophylaxis; cyanocobalamin, iron, folic acid, potassium chloride, and magnesium (all since 2013), all as supplements; pantoprazole (since 2013) for acid reflux; spironolactone (since 2013) for hypertension/bilateral foot edema; torasemide (since 2013) for bilateral foot edema; salbutamol and olodaterol hydrochloride/tiotropium bromide monohydrate (both since Dec 2019), both for COPD; and nicotine (since 10 Aug 2020) for smoking cessation. On 19 Oct 2020 (Day 50), the subject presented to the emergency room (ER) with severe hypokalemia (potassium values not provided) and was diagnosed with acute left ventricular failure (New York Heart Association Class 4 acute on chronic systolic heart failure), resulting in hospitalization. Hypokalemia was considered likely to be secondary to the need for aggressive diuresis with torasemide 200 mg twice a day and metolazone 5 mg 3 times a week (unspecified start dates). The subject's magnesium and potassium levels were restored. On 21 Oct 2020 (Day 52), the acute left ventricular failure and hypokalemia resolved, and the subject was discharged from the hospital. On 30 Nov 2020 (Day 92), the subject's ongoing history of peripheral edema worsened as a result of end-stage heart failure. The subject went to the ER and was diagnosed with congestive cardiac failure that resulted in hospitalization. A subsequent chest x-ray showed stable cardiac enlargement with a faint infiltrate and/or subsegmental atelectasis at the right lung base; however, there was no consolidation or edema observed. The venous/lower-extremity Doppler performed on 04 Dec 2020 (Day 96) showed no evidence of acute deep vein thrombosis. A peripherally inserted central catheter line was placed for dobutamine infusion. Per the cardiologist, the subject was only minimally responsive to aggressive medical therapy including intravenous (IV) diuretics and IV dobutamine because of idiopathic cardiomyopathy and severe left ventricular systolic dysfunction coupled with acute on chronic combined systolic and diastolic heart failure. Per the discharge summary, the subject was not a candidate for any advanced cardiac therapies. On 06 Dec 2020 (Day 98), the automatic implantable cardioverter defibrillator was turned off. On 08 Dec 2020 (Day 100), influenza and SARS-CoV-2 tests were negative. On the same day (Day 100), the subject was discharged to an inpatient hospice care facility. On 19 Dec 2020 (Day 111), the subject died of congestive cardiac failure (Stage IV) and disease progression. No autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the acute left ventricular failure and congestive cardiac failure were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168.91 cm	62.45 kg	21.8 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergy to cipro	Drug hypersensitivity	1975	Present
thyroid cancer	Thyroid cancer	1982	Past
thyroidectomy	Thyroidectomy	1982	Past
dysmenorrhea	Dysmenorrhoea	1990	Past
hysterectomy	Hysterectomy	1990	Past
hyperlipidemia	Hyperlipidaemia	2010	Present
hypertension	Hypertension	2013	Present
irritable bowel syndrome (IBS) - constipation	Irritable bowel syndrome	2014	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
emphysema	Emphysema	2017	Present
lung cancer	Lung neoplasm malignant	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	12:59
2	Placebo	02OCT2020 (22)	09:20

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Acute respiratory failure	Acute Hypoxic Respiratory Failure	12JAN2021 (124)		13FEB2021 (156)		33	4
2	INFEC	COVID-19	COVID-19	12JAN2021 (124)		13FEB2021 (156)		33	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN/W	Y	Fatal (13FEB2021)	NOT RELATED/OTHER: Diagnosis of COVID-19	2	103	Y
2	TC/TCN/W	Y	Fatal (13FEB2021)	NOT RELATED/OTHER: Viral Infection	2	103	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	02NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	13FEB2021	DEATH

Narrative Comment
Subject C4591001 1027 10271191, a 68-year-old black or African American female with a pertinent medical history of drug allergy to ciprofloxacin (since 1975), thyroid cancer and thyroidectomy (both in 1982), hyperlipidemia (since 2010), hypertension (since 2013), emphysema (since 2017), and malignant lung neoplasm (in 2017), received Dose 1 on 11 Sep 2020 and Dose 2 on 02 Oct 2020 (Day 22). The subject was diagnosed with acute respiratory failure and COVID-19 on 12 Jan 2021, 102 days after receiving Dose 2, and died of the events on 13 Feb 2021, 134 days after receiving Dose 2. On 13 Jan 2021 (Day 125), the subject completed a telehealth potential COVID-19 illness visit with a positive central laboratory COVID-19 test, and the subject's local COVID-19 test from 14 Jan 2021 (Day 126) was also positive. The subject's family informed the site that on 18 Jan 2021 (Day 130), the subject presented to the hospital via emergency medical services with shortness of breath, productive cough, headache, fever, myalgia, lack of taste, decreased appetite, and 2 syncopal episodes. According to the medical records, upon hospital admission, the subject was afebrile with a respiratory rate of 22 breaths/min. The subject was noted to be hypoxic with blood saturation levels in the 80s (%), with improvement on supplemental oxygen; her oxygen saturation was 95% on 3 L of supplemental oxygen via nasal cannula. The subject was diagnosed with acute hypoxic respiratory failure due to COVID-19 with an onset date of 12 Jan 2021 (Day 124). She was treated with 6 mg of intravenous dexamethasone. The subject remained on oxygen therapy, and was additionally treated with albuterol inhalation, remdesivir, ascorbic acid, zinc, and oral dexamethasone 6 mg daily. On 18 Jan 2021 (Day 130), the laboratory test results showed hemoglobin of 10.2, potassium of 3.1, calcium of 8.1, C-reactive protein of 2.8, and fibrinogen of 530 (units and normal ranges [NRs] not available). A computed tomography angiography of the chest with contrast revealed multifocal pneumonia, left upper lobe and right hilar/suprahilar postradiation changes, and emphysema with no evidence of large or central pulmonary artery embolus. On 20 Jan 2021 (Day 132), the laboratory test results showed leukocytes of 10.6 K/µL (NR: 4.0-10.5 K/µL) and neutrophils of 9.1 K/µL (NR: 1.7-7.7 K/µL). On 08 Feb 2021 (Day 151), the subject was moved to hospice care because of deterioration in health from acute hypoxic respiratory failure caused by COVID-19. On 15 Feb 2021 (Day 158), the subject's family informed the site that the subject had died on 13 Feb 2021 (Day 156) because of acute hypoxic respiratory failure caused by COVID-19. An autopsy was not performed. The subject had COVID-19 illness per study protocol criteria. In the opinion of the investigator, there was no reasonable possibility that the acute respiratory failure and COVID-19 were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	64	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.96 cm	106.82 kg	30.2 kg/m2	22OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
trouble sleeping	Insomnia	1989	Present
back surgery	Spinal operation	1990	Past
hypercholesterolemia	Hypercholesterolaemia	1995	Present
hypertension	Hypertension	1995	Present
back pain	Back pain	1996	Present
Barrett's esophagus	Barrett's oesophagus	1998	Present
urination frequency	Pollakiuria	2005	Present
scoliosis of the spine	Scoliosis	2010	Present
seasonal allergies	Seasonal allergy	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
osteoarthritis	Osteoarthritis	2015	Present
ringing in the left ear; tinnitus	Tinnitus	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	22OCT2020 (1)	14:46
2	BNT162b2	12NOV2020 (22)	13:50

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INJ&P	Injury	Traumatic Injuries	10FEB2021 (112)		10FEB2021 (112)		1	4	W
2	INJ&P	Road traffic accident	Motor Vehicle Accident	10FEB2021 (112)		10FEB2021 (112)		1	4	W

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Fatal (10FEB2021)	NOT RELATED/OTHER: car accident	2	91	Y
2	Y	Fatal (10FEB2021)	NOT RELATED/CONCOMITANT NON-DRUG TREATMENT	2	91	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22OCT2020	
Completed	VACCINATION	10DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	10FEB2021	DEATH

Narrative Comment
Subject C4591001 1036 10361140, a 64-year-old white male with a pertinent medical history of spinal operation (in 1990), scoliosis (since 2010), and osteoarthritis (since 2015), received Dose 1 on 22 Oct 2020 and Dose 2 on 12 Nov 2020 (Day 22). The subject died of traumatic injuries from a motor vehicle collision on 10 Feb 2021, 90 days after receiving Dose 2. On 10 Feb 2021 (Day 112), the subject was involved in a motor vehicle accident resulting in death of the subject on impact from traumatic injuries. The subject was the driver. No autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the traumatic injuries from the motor vehicle collision were related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1935	84	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
190.2 cm	88.88 kg	24.6 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis	Rhinitis allergic	1955	Present
high blood pressure	Hypertension	1960	Present
hyperlipidemia	Hyperlipidaemia	2000	Present
Hyperopia	Hypermetropia	2000	Present
oseoarthritis, thumbs and fingers	Osteoarthritis	2010	Present
torn left shoulder rotator cuff	Rotator cuff syndrome	2010	Past
cataracts	Cataract	2013	Past
carotid artery stenosis	Carotid artery stenosis	2016	Present
coronary artery disease	Coronary artery disease	JUL2016	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hearing problems	Auditory disorder	2020	Present
glasses wearer	Corrective lens user	2020	Present
GERD	Gastrooesophageal reflux disease	2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	10:59
2	BNT162b2	09SEP2020 (20)	12:54

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Arteriosclerosis	arthroscloratic cardiovascular disease	18NOV2020 (90)		18NOV2020 (90)		1	4
2	CARD	Hypertensive heart disease	hypertensive cardiovascular disease	18NOV2020 (90)		18NOV2020 (90)		1	4
3	GENRL	Injection site pain	INJECTION SITE PAIN	21AUG2020 (1)	19:00	23AUG2020 (3)	12:00	3	1
4	GENRL	Injection site pain	injection site pain	09SEP2020 (20)	19:00	11SEP2020 (22)		3	2
5	GENRL	Pyrexia	FEVER	10SEP2020 (21)	07:00	10SEP2020 (21)	19:00	1	1
6	INJ&P	Contusion	right arm bruising	21AUG2020 (1)	11:00	02SEP2020 (13)	11:00	13	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	W	Y	Fatal (18NOV2020)	NOT RELATED/OTHER: cardiovascular disease	2	71	Y
2	W	Y	Fatal (18NOV2020)	NOT RELATED/OTHER: cardiovascular disease	2	71	Y
3	N	N	Resolved (23AUG2020)	Study Treatment	1	1	N
4	N	N	Resolved (11SEP2020)	Study Treatment	2	1	N
5	TC	N	Resolved (10SEP2020)	Study Treatment	2	2	N
6	N	N	Resolved (02SEP2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21AUG2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	08OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	18NOV2020	DEATH

Narrative Comment
Subject C4591001 1039 10391010, an 84-year-old white male with a pertinent medical history of hypertension (since 1960), hyperlipidemia (since 2000), carotid artery stenosis (since 2016, stent placement in right carotid artery in 2016), coronary artery disease (since Jul 2016), and gastroesophageal reflux disease (since 2020), received Dose 1 on 21 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 20). The subject died of arteriosclerosis and hypertensive heart disease on 18 Nov 2020, 70 days after receiving Dose 2. Concomitant medications included acetylsalicylic acid (since 1990) for cardiac prophylaxis, multivitamin (since 1990) as a supplement, lovastatin (since 2014) for hyperlipidemia, Cernitin GBX, and Cernitin T60 (both since 2018), vitamin D (since 2019) as a supplement, and hydrochlorothiazide/olmesartan medoxomil (since 10 Sep 2020) for hypertension. The subject, with a history of extensive cardiovascular disease, lost consciousness on 18 Nov 2020 (Day 90). His family witnessed the event and attempted resuscitation, but it was unsuccessful. The subject was not taken to the emergency room or physician's office and he died on the same day (Day 90). The subject had regular follow-ups with his primary care physician, and there were no new complications or events reported prior to the subject's death. The cause of death was disease progression. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the arteriosclerosis and hypertensive heart disease were related to the study intervention, concomitant medications, or clinical trial procedures, but rather they were related to cardiovascular disease. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	84.23 kg	25.1 kg/m2	19OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
sulfa allergy	Drug hypersensitivity	1980	Present
morphine allergy	Drug hypersensitivity	1985	Present
anxiety	Anxiety	1990	Present
GERD	Gastrooesophageal reflux disease	2000	Present
hypertension	Hypertension	2000	Present
insomnia	Insomnia	2000	Present
L4-L5 laminotomy with diskectomy	Spinal laminectomy	2012	Past
spinal stenosis	Spinal stenosis	2012	Past
hyponatremia	Hyponatraemia	2015	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
history of seizure	Seizure	2015	Past
history of alcohol abuse	Alcohol abuse	2018	Past
cardiomyopathy	Cardiomyopathy	MAR2018	Present
myocardial infarction	Myocardial infarction	MAR2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19OCT2020 (1)	13:32

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Myocardial infarction	myocardial infarction	03NOV2020 (16)		03NOV2020 (16)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	P/W	Y	Fatal (03NOV2020)	NOT RELATED/OTHER: disease progression	1	16	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19OCT2020	
Withdrawn	VACCINATION	03NOV2020	DEATH
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	03NOV2020	DEATH

Narrative Comment
Subject C4591001 1066 10661350, a 58-year-old white male with a pertinent medical history of hypertension (since 2000), gastroesophageal reflux disease (since 2000), insomnia (since 2000), alcohol abuse (from 2010 to 2018), hyponatremia (since 2015), seizures (in 2015), myocardial infarction (in Mar 2018), and cardiomyopathy (since Mar 2018; coronary angiography, left ventriculography, and left heart catheterization), received Dose 1 on 19 Oct 2020. The subject died of a myocardial infarction on 03 Nov 2020, 15 days after receiving Dose 1. Concomitant medications included omeprazole (Protonix) (since 2015) for gastroesophageal reflux disease, trazodone (since 2015) for insomnia, Depade and acamprosate calcium (Campral) (since 2018), both for alcohol dependence, and levetiracetam (Keppra) (since 2018) for seizures. The subject's wife stated that the subject had suffered a heart attack and died in his sleep on 03 Nov 2020 (Day 16). An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the myocardial infarction was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to disease progression. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	51	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	95.82 kg	34 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	1995	Present
Allergy to Sulfa drugs	Drug hypersensitivity	2002	Present
Allergy to oral NSAIDs	Drug hypersensitivity	2007	Present
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2015	Present
Hypertension	Hypertension	2015	Present
Attention deficit disorder	Attention deficit hyperactivity disorder	2017	Present
Osteoarthritis of the knees	Osteoarthritis	2018	Present
Postmenopausal	Postmenopause	2018	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	10SEP2020 (1)	12:44
2	Placebo	29SEP2020 (20)	13:39

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	CARD	Myocardial infarction	Myocardial Infarction	04NOV2020 (56)		04NOV2020 (56)		1	4

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	W	Y	Fatal (04NOV2020)	NOT RELATED/OTHER: Hypertensive cardiovascular disease	2	37	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	27OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	04NOV2020	DEATH

Narrative Comment
Subject C4591001 1081 10811194, a 51-year-old white female with a medical history of hypothyroidism (since 1995), drug hypersensitivity (allergy to sulfa drugs since 2002 and allergy to oral nonsteroidal anti-inflammatory drugs [NSAIDs] since 2007), chronic obstructive pulmonary disease (COPD) and hypertension (both since 2015), attention deficit hyperactivity disorder (since 2017), and osteoarthritis and postmenopause (both since 2018), received Dose 1 on 10 Sep 2020 and Dose 2 on 29 Sep 2020 (Day 20). The subject died of a myocardial infarction on 04 Nov 2020, 36 days after receiving Dose 2. Concomitant medications included levothyroxine sodium (since 2015) for hypothyroidism; atomoxetine hydrochloride (since 2017) and bupropion hydrochloride (since 2018) for attention deficit disorder; salbutamol sulfate (since 2018) for COPD; diclofenac (since 2018) for osteoarthritis; and hydrochlorothiazide/lisinopril (since 01 Aug 2020) for hypertension. The subject was scheduled for a visit on 11 Nov 2020 but did not show up for her appointment. The family was contacted, and they reported that the subject was found deceased in her home on 04 Nov 2020 and had likely died 3 days prior on 01 Nov 2020. A family member had spoken with the subject on 01 Nov 2020 and the subject told her family member that she just got out of the shower and was going to go lie down because she had "stomach pains." This was the final conversation with the subject before she died. No autopsy was performed. The death certificate and toxicology report were received on 24 Nov 2020 and the date of death was 04 Nov 2020 per state regulations; the cause of death was reported as myocardial infarction due to hypertensive cardiovascular disease and disease progression. It was reported that the toxicology report was negative. In the opinion of the investigator, there was no reasonable possibility that the myocardial infarction was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to hypertensive cardiovascular disease. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	77	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166.4 cm	79 kg	28.5 kg/m2	22AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
environmental allergies	Hypersensitivity	1975	Present
Type 2 Diabetes	Type 2 diabetes mellitus	1980	Present
erectile dysfunction	Erectile dysfunction	1985	Present
Levaquin allergy	Drug hypersensitivity	2000	Present
Congestive Heart failure	Cardiac failure congestive	2005	Present
CORONARY ARTERIAL BYPASS GRAFTS	Coronary artery bypass	2005	Past
gangrene on all toes on right foot	Gangrene	2011	Past
amputation of 5 toes on right foot	Toe amputation	2011	Past
gangrene on left big toe	Gangrene	2012	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypercholesterolemia	Hypercholesterolaemia	2012	Present
Amputation of left big toe	Toe amputation	2012	Past
Bilateral Cataracts	Cataract	2015	Past
Cataract Removal	Cataract operation	2015	Past
gangrene on toe left foot	Gangrene	2017	Past
Amputation of toe on left foot	Toe amputation	2017	Past
Hypertension	Hypertension	2018	Present
Ocular hypertension	Ocular hypertension	JUN2020	Present
atrophy to left hand	Atrophy	22AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	22AUG2020 (1)	13:51
2	BNT162b2	14SEP2020 (24)	11:26

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	RENAL	Acute kidney injury	Acute Kidney Injury	03NOV2020 (74)		ONGOING			2	TCN
2	CARD	Atrial fibrillation	Atrial Fibrillation with RVR	03NOV2020 (74)		ONGOING			2	TC

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
3	INFEC	Emphysematous cholecystitis	Acute Emphysematous Cholecystitis	03NOV2020 (74)		12JAN2021 (144)		71	4	TC/TCN/W
4	MUSC	Muscular weakness	Left lower extremity weakness	28OCT2020 (68)		ONGOING			2	N
5	MUSC	Rhabdomyolysis	Rhabdomolysis	02NOV2020 (73)		13NOV2020 (84)		12	2	TCN
6	INFEC	Sepsis	Sepsis	03NOV2020 (74)		12JAN2021 (144)		71	4	TC/TCN/W

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Yes	NOT RELATED/OTHER: Dehydration	2	51	N
2	N	Yes	NOT RELATED/OTHER: CAD	2	51	N
3	Y	Fatal (12JAN2021)	NOT RELATED/OTHER: bacteria	2	51	Y
4	N	Yes	NOT RELATED/OTHER: sepsis	2	45	N
5	N	Resolved (13NOV2020)	NOT RELATED/OTHER: dehydration	2	50	N
6	Y	Fatal (12JAN2021)	NOT RELATED/OTHER: Klebsiella Oxytoca, Escherichia coli, Klebsiella pneumonia	2	51	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VIRUS VACCINE QUADRIVALENT 240 MCG IM	INFLUENZA VACCINE	08NOV2020
Pneumococcal Polysaccharide Vaccine 0.5mL IM	PNEUMOCOCCAL VACCINE POLYSACCH	08NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22AUG2020	
Completed	VACCINATION	12OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	12JAN2021	DEATH

Narrative Comment
Subject C4591001 1084 10841266, a 77-year-old white male with a pertinent medical history of type 2 diabetes mellitus (since 1980), erectile dysfunction (since 1985), drug hypersensitivity (Levaquin allergy, since 2000), congestive cardiac failure (since 2005; coronary artery bypass in 2005), gangrene and toe amputation (all toes on right foot in 2011, left big toe in 2012, and an unspecified left foot toe in 2017), hypercholesterolemia (since 2012), cataracts (bilateral; in 2015), hypertension (since 2018), ocular hypertension (since Jun 2020), and left hand atrophy (since 22 Aug 2020), received Dose 1 on 22 Aug 2020 and Dose 2 on 14 Sep 2020 (Day 24). The subject was diagnosed with emphysematous cholecystitis and sepsis on 03 Nov 2020, 50 days after receiving Dose 2, and died of the events on 12 Jan 2021, 120 days after receiving Dose 2.

Narrative Comment
Concomitant medications included metformin (since 1980) for type 2 diabetes mellitus; clopidogrel (since 2005) for congestive heart failure; atorvastatin (since 2012) for hypercholesterolemia; ubidecarenone (since 2012) and *Curcuma longa* rhizome (since 2018) as supplement; metoprolol (since 2018) for hypertension; chromium picolinate (since 2019) and magnesium (since 2020), both as supplement; latanoprost (since Jul 2020) for glaucoma; insulin human injection/isophane and insulin human (since 12 Sep 2020), both for type 2 diabetes mellitus; and *Aristotelia chilensis*/*Syzygium aromaticum* bud (since Aug 2020) as supplement. On 28 Oct 2020 (Day 68), the subject experienced muscular weakness in the left lower extremity and was subsequently diagnosed with rhabdomyolysis on 02 Nov 2020 (Day 73). On 02 Nov 2020 (Day 73), the subject was admitted to the hospital with weakness in the left lower extremity after being bedbound for 4 days. The subject could wiggle his toes but was unable to lift his left lower extremity. The laboratory results on 02 Nov 2020 (Day 73) included a creatine kinase level of 2849 U/L (normal range [NR]: 39-308 U/L), creatinine of 1.97 mg/dL (NR: 0.60-1.30 mg/dL), consistent with acute renal failure, brain natriuretic peptide (BNP) of 403 pg/mL (NR: 0 -100 pg/mL), white blood cell (WBC) count of $16.3 \times 10^3/mm^3$ (NR: $4.5\text{-}10.5 \times 10^3/mm^3$), and blood glucose of 379 and 342 (units and NR not reported), and the subject's blood pressure (BP) measurements were 134/74 mmHg, 135/68 mmHg, 136/63 mmHg, and 134/77 mmHg. On 03 Nov 2020, the subject was hospitalized and the laboratory tests included troponin of 14.13 ng/mL (NR: 0.00-0.04 ng/mL), consistent with a new non–ST-segment elevation myocardial infarction, and lactic acid of 2.8 mmol/L (NR: 0.4-2.0 mmol/L). On 03 Nov 2020 (Day 74), the subject was diagnosed with sepsis, emphysematous cholecystitis, acute kidney injury, dehydration, and atrial fibrillation with rapid ventricular response. A gallbladder drain was inserted for the acute emphysematous cholecystitis. A blood culture on 03 Nov 2020 (Day 74) showed no aerobic or anaerobic growth for 5 days. The subject's BP ranged from 67/30 mmHg to 188/72 mmHg, and the glucose values ranged from 134 to 346 (units and NR not reported). On 07 Nov 2020 (Day 78), the blood culture was reported positive for *Klebsiella oxytoca, Escherichia coli*, and *Klebsiella pneumoniae*. On 07 Nov 2020 and 08 Nov 2020 (Day 79), the subject's BP was between 90/57 mmHg and 104/72 mmHg. On 08 Nov 2020 (Day 79), the laboratory tests included blood glucose ranging from 213 to 280 (units and NR not reported), creatinine of 1.63 mg/dL, creatine kinase of 92 U/L, BNP of 586 pg/mL, WBC count of $7.9 \times 10^3/mm^3$, and troponin of 1.74 ng/mL. On the same day (Day 79), the subject received influenza virus vaccine and the pneumococcal polysaccharide vaccine. The subject's BP fluctuated from 94/58 mmHg to 118/72 mmHg from 11 Nov 2020 to 13 Nov 2020 (Days 82 to 84). On 13 Nov 2020 (Day 84), repeat laboratory test results showed creatinine of 0.99 mg/dL, glucose of 134 and 163, and WBC count of $6.33 \times 10^3/mm^3$. The subject was treated with sodium chloride, calcium gluconate, clopidogrel bisulfate, heparin sodium, docusate sodium, insulin human lispro, metoprolol tartrate, paracetamol, glucose, dextrose/water, glucagon, ondansetron, potassium chloride, atorvastatin calcium, acetylsalicylic acid, metformin, metronidazole, cefepime hydrochloride, and norepinephrine (all on 03 Nov 2020); lorazepam, iopamidol, magnesium oxide, docusate sodium, and piperacillin sodium/tazobactam sodium (all from 03 Nov 2020 to 09 Nov 2020); and metronidazole/sodium chloride, levofloxacin, and albuterol/ipratropium (unspecified dates). On 13 Nov 2020 (Day 84), the subject was discharged to a skilled nursing facility. The rhabdomyolysis resolved on the same day. The subject received levofloxacin, midodrine, and apixaban at the facility. A SARS-CoV-2 polymerase chain reaction test on 13 Nov 2020 was negative during hospitalization. On 12 Jan 2021 (Day 144), the subject died of the emphysematous cholecystitis. It was reported that the subject was on life support and the family requested that the subject be withdrawn from life support, as the subject's condition was not getting better and the physician informed the family that there was no real hope for recovery. It was unknown if an autopsy was performed, and the reported cause of death was disease progression (acute emphysematous cholecystitis and sepsis). The events atrial fibrillation, muscular weakness, and acute kidney injury were ongoing at the time of the subject's death. In the opinion of the investigator, there was no reasonable possibility that the emphysematous cholecystitis and sepsis were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	130.4 kg	41.2 kg/m2	30SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
gerd	Gastrooesophageal reflux disease	2010	Present
hyperlipidemia	Hyperlipidaemia	2010	Present
hypertension	Hypertension	2010	Present
insomnia	Insomnia	2010	Present
pulmonary fibrosis	Pulmonary fibrosis	2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30SEP2020 (1)	09:54
2	Placebo	21OCT2020 (22)	15:53

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	COVID-19	COVID-19 Infection	31DEC2020 (93)		11JAN2021 (104)		12
2	GENRL	Multiple organ dysfunction syndrome	Mutli-system organ failure	31DEC2020 (93)		11JAN2021 (104)		12

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/TCN/W	Y	Fatal (11JAN2021)	NOT RELATED/OTHER: COVID-19	2	72	Y
2	4	TC/TCN	Y	Fatal (11JAN2021)	NOT RELATED/OTHER: COVID-19	2	72	Y

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Monoclonal Antibodies	MONOCLONAL ANTIBODIES	31DEC2020	31DEC2020	

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
MODERNA COVID 19 VACCINE	COVID-19 VACCINE MRNA (MRNA 1273)	23DEC2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30SEP2020	
Completed	VACCINATION	18NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	11JAN2021	DEATH

Narrative Comment
Subject C4591001 1084 10841470, a 65-year-old white male with a pertinent medical history of hyperlipidemia and hypertension (since 2010) and pulmonary fibrosis (since 2014), received Dose 1 on 30 Sep 2020 and Dose 2 on 21 Oct 2020 (Day 22). The subject was diagnosed with COVID-19 infection and multiple organ dysfunction syndrome on 31 Dec 2020, 71 days after receiving Dose 2. On 23 Dec 2020 (Day 85), the subject received a prohibited vaccination (Moderna COVID-19 vaccine [mRNA-1273]) through his employer. The site was first informed of this vaccination by the subject's son on 07 Jan 2021 (Day 100). Concomitant medications included ezetimibe/simvastatin (since 2010) for hyperlipidemia, omeprazole (since 2013) for gastroesophageal reflux disease, nebivolol hydrochloride (since 2015) for hypertension, and trazodone (since 2015) for insomnia. The subject experienced shortness of breath, fever, cough, fatigue, and muscle aches "a day or so after" exposure to COVID-19 on 28 Dec 2020 (Day 90). On 31 Dec 2020 (Day 93), the subject received monoclonal antibodies from his primary care physician. Later the same day (Day 93), the subject presented to the emergency department with weakness, dyspnea, nausea, and diarrhea and was subsequently hospitalized with COVID-19. On the same day (Day 93), the subject's laboratory tests included: a positive SARS-CoV-2 test, sodium of 134 mmol/L (normal range [NR]: 137-145 mmol/L), chloride of 97 mmol/L (NR: 98-107 mmol/L), glucose of 121 mg/dL (NR: 74-99 mg/dL), aspartate aminotransferase of 78 (NR: 17-59, unit not provided), alanine aminotransferase of 51 (normal high: 50, unit not provided), C-reactive protein of 191.2 mg/dL (normal high: 10 mg/dL), total protein of 8.5 g/dL (NR: 6.3-8.2 g/dL), D-dimer quantitative of 1.21 µg/mL fibrinogen equivalent units (normal high: 0.50 µg/mL), red blood cell count of 5.86 M/mm3 (NR: 4.20-5.70 M/mm3), hemoglobin of 17.8 g/dL (NR: 13-17 g/dL), and hematocrit of 53.1% (NR: 40%-50%). The chest x-ray that same day (Day 93) was consistent with bilateral multifocal viral pneumonia. The subject was treated with ondansetron hydrochloride, dexamethasone, sodium phosphate, enoxaparin sodium, nebivolol hydrochloride, magnesium sulfate, trazodone, acetaminophen, magnesium oxide, potassium bicarbonate/citric acid, potassium chloride, pantoprazole, loperamide, melatonin, and vitamin D3. On 02 Jan 2021 (Day 95), the subject was treated at bedside for acute hypoxemic respiratory failure with a left radial arterial line placed, and he was intubated. After being placed on a ventilator, his health status continued to deteriorate, resulting in multiple organ dysfunction syndrome. On 04 Jan 2021 (Day 97), he suffered acute renal failure. Acute hypoxic respiratory failure and acute renal failure were considered because of the COVID-19. On 11 Jan 2021 (Day 104), the subject's family opted for "do-not-resuscitate" status. On 19 Jan 2021 (Day 112), the site learned that the subject had died on 11 Jan 2021 (Day 104), and it was unknown if an autopsy was performed. It was reported that the subject also experienced shock, nose bleeding, pulmonary fibrosis, hypertension, acute kidney injury, dyslipidemia, and gastroesophageal reflux disease. The cause of death was reported as disease progression, multiple organ dysfunction syndrome, and COVID-19 infection. The subject's vaccine status was unblinded on 14 Jan 2021. In the opinion of the investigator, there was no reasonable possibility that the COVID-19 infection and multiple organ dysfunction syndrome were related to the study intervention, concomitant medications, or clinical trial procedures. Multiple organ dysfunction syndrome was considered related to COVID-19. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	65	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.9 cm	143.6 kg	40.7 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Coronary Artery Disease (CAD)	Coronary artery disease	1983	Present
hypercholesterolemia	Hypercholesterolaemia	2010	Present
hypertension	Hypertension	2010	Present
Obesity	Obesity	2010	Present
heart burn - intermittent	Dyspepsia	2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	14:28
2	Placebo	23SEP2020 (24)	08:48

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	COVID-19	COVID-19	29NOV2020 (91)		ONGOING		
2	CARD	Cardiac arrest	cardiac arrest	01DEC2020 (93)		01DEC2020 (93)		1
3	CARD	Coronary artery disease	Coronary Artery Disease	01DEC2020 (93)		01DEC2020 (93)	16:00	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	N	Y	Yes	NOT RELATED/OTHER: COVID-19	2	68	Y
2	4	W	Y	Fatal (01DEC2020)	NOT RELATED/OTHER: unknown	2	70	Y
3	4	N	Y	Resolved (01DEC2020)	NOT RELATED/OTHER: cardiac arrest	2	70	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	26OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	01DEC2020	DEATH

Narrative Comment
Subject C4591001 1088 10881126, a 65-year-old white male with a pertinent medical history of coronary artery disease (since 1983); hypercholesterolemia and hypertension (both since 2010); and dyspepsia (since 2012), received Dose 1 on 31 Aug 2020 and Dose 2 on 23 Sep 2020 (Day 24). The subject was diagnosed with COVID-19 on 29 Nov 2020, and cardiac arrest and coronary artery disease on 01 Dec 2020, 67 days and 69 days after receiving Dose 2. The subject died of cardiac arrest due to coronary artery disease and COVID-19 on 01 Dec 2020, 69 days after receiving Dose 2. Concomitant medications included lisinopril (since 2010) for hypertension, atorvastatin (since 2010) for hypercholesterolemia, omeprazole (since 2010) for heartburn, apixaban (since 2015) for coronary artery disease, and folic acid (since 2015) as a nutritional supplement. The subject attended a COVID-19 illness visit on 30 Nov 2020 (Day 92) for cough first occurring on 29 Nov 2020 (Day 91), and a self-swab was performed, which had a positive result. The local COVID-19 test on 01 Dec 2020 (Day 93) was also positive. The site was trying to contact the subject to unblind him for this study and, after an online search, it was discovered that the subject had died on 01 Dec 2020 (Day 93). On 01 Dec 2020 (Day 93), the subject visited his primary care physician with cough, fatigue, muscle/body aches, diarrhea, nasal congestion, and a runny nose. The subject was advised to self-isolate, increase fluids and rest, take acetaminophen as needed, and consider taking vitamin D and vitamin C to boost his immune system. The subject was reported to have experienced cardiac arrest, and it was unknown if cardiopulmonary resuscitation was attempted. The subject had cardiac arrest due to progression of coronary artery disease, which led to death on the same day (Day 93). The death certificate indicated the cause of death as cardiac arrest due to progression of coronary artery disease, hypertension, and COVID-19. It was also reported that the coronary artery disease and hypertension did not worsen after receiving study intervention. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest due to coronary artery disease and COVID-19 were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1938	82	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
189 cm	104.6 kg	29.3 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Benign prostatic hyperplasia (BPH)	Benign prostatic hyperplasia	2012	Present
hypercholesterolemia	Hypercholesterolaemia	2012	Present
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2015	Present
Coronary Artery Disease (CAD)	Coronary artery disease	2015	Present
sleep apnea	Sleep apnoea syndrome	2015	Present
vitamin D deficiency	Vitamin D deficiency	2017	Present
constipation	Constipation	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02SEP2020 (1)	16:10
2	BNT162b2	15OCT2020 (44)	14:05

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Metastases to lung	Metastases to the lungs	24FEB2021 (176)		06MAR2021 (186)		11	4
2	NEOPL	Pancreatic carcinoma metastatic	Metastatic pancreatic cancer	24FEB2021 (176)		ONGOING			4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (06MAR2021)	NOT RELATED/OTHER: Metastases to the lungs	2	133	Y
2	N	Y	Yes	NOT RELATED/OTHER: Pancreatic Cancer	2	133	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PNEUMONIA VACCINE	PNEUMOCOCCAL VACCINE	16SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	11NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	06MAR2021	DEATH

Narrative Comment
Subject C4591001 1088 10881139, an 82-year-old white male with a pertinent medical history of hypercholesterolemia (since 2012); myocardial infarction with stent placement (in 2015); and coronary artery disease, chronic obstructive pulmonary disease (COPD), and sleep apnea syndrome (all since 2015), received Dose 1 on 02 Sep 2020 and Dose 2 on 15 Oct 2020 (Day 44). The subject was diagnosed with metastatic pancreatic cancer and metastasis to the lungs on 24 Feb 2021, 132 days after receiving Dose 2. The subject died because of metastasis to the lungs on 06 Mar 2021, 142 days after receiving Dose 2. Concomitant medications included simvastatin (since 2012) for hypercholesterolemia; terazosin (since 2012) for benign prostatic hyperplasia; budesonide/formoterol fumarate, tiotropium bromide, and salbutamol (all since 2015) for COPD; nitroglycerin (since 2015) for chest pain; acetylsalicylic acid (since 2015) for cardiovascular prophylaxis; colecalciferol (since 2017) for vitamin deficiency; and docusate and Plantago ovata (both since Jun 2020) for constipation. On 28 Feb 2021 (Day 180), the subject was hospitalized because of pancreatic cancer with metastasis to the lungs. The site was not aware of any preexisting neoplasm. No disease-specific treatment was reported. The subject was discharged from the hospital on 05 Mar 2021 (Day 185). On 06 Mar 2021 (Day 186), the subject died at home because of metastasis to the lungs and disease progression. No autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the metastatic pancreatic cancer and metastasis to the lungs were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	112.91 kg	40.1 kg/m2	06AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
sulfa drug allergy	Drug hypersensitivity	1966	Present
GERD	Gastrooesophageal reflux disease	1983	Present
cervical cancer	Cervix carcinoma	1991	Past
demoral drug allergy	Drug hypersensitivity	1991	Present
hysterectomy	Hysterectomy	1991	Past
COPD	Chronic obstructive pulmonary disease	1999	Present
myocardial infarction	Myocardial infarction	2003	Past
right ankle broken	Ankle fracture	2005	Past
right ankle rods placed	Ankle operation	2005	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
elevated cholesterol	Blood cholesterol increased	2005	Present
hypertension	Hypertension	2005	Present
myocardial infarction	Myocardial infarction	2005	Past
edema bilateral legs	Oedema peripheral	2005	Present
osteoarthritis	Osteoarthritis	2005	Present
insomnia	Insomnia	2008	Present
prilosec drug allergy	Drug hypersensitivity	SEP2008	Present
anxiety	Anxiety	2009	Present
depression	Depression	2009	Present
irritable bowel syndrome diarrhea	Irritable bowel syndrome	2011	Present
seasonal allergies	Seasonal allergy	2012	Present
diabetic neuropathy	Diabetic neuropathy	2013	Present
diabetes type 2	Type 2 diabetes mellitus	2013	Present
chronic back pain	Back pain	2014	Present
penicillin drug allergy	Drug hypersensitivity	2018	Present
clindamycin drug allergy	Drug hypersensitivity	2018	Present
lower lumbar back surgery	Spinal operation	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	06AUG2020 (1)	12:27
2	BNT162b2	04SEP2020 (30)	15:28

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	RESP	Chronic obstructive pulmonary disease	Worsening of COPD	12NOV2020 (99)		12NOV2020 (99)		1

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	W	Y	Fatal (12NOV2020)	NOT RELATED/OTHER: history of COPD	2	70	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	12NOV2020	DEATH

Narrative Comment

Subject C4591001 1089 10891073, a 63-year-old white female with a pertinent medical history of drug hypersensitivity (sulfa allergy; since 1966), tobacco use (since 1975), gastroesophageal reflux disease (GERD; since 1983), cervix carcinoma (in 1991), drug hypersensitivity (Demerol drug allergy; since 1991), chronic obstructive pulmonary disease (COPD; since 1999), myocardial infarction (in 2003 and 2005), ankle fracture (in 2005), hypertension, blood cholesterol increased, osteoarthritis, and peripheral edema (all since 2005), insomnia (since 2008), drug hypersensitivity (Prilosec drug allergy; since Sep 2008), anxiety and depression (both since 2009), irritable bowel syndrome (since 2011), seasonal allergy (since 2012), type 2 diabetes mellitus and diabetic neuropathy (both since 2013), back pain (since 2014), and drug hypersensitivity (clindamycin drug allergy and penicillin drug allergy; since 2018), received Dose 1 on 06 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 30). The subject died of worsening of COPD on 12 Nov 2020, 69 days after receiving Dose 2.

Concomitant medications included acetylsalicylic acid (since 2005) for cardiac prophylaxis, salbutamol (since 2006) for COPD, ranitidine (since 2008) for GERD, furosemide (since 2010) for edema, metformin (since 2010) for type 2 diabetes mellitus, hydralazine hydrochloride (since 2011) for hypertension, spironolactone (since 2019) for edema, paroxetine hydrochloride and lamotrigine (both since 2019) for depression, and aripiprazole (since 2019) for anxiety.

The subject had known but stable chronic lung disease at enrollment. On 01 Dec 2020 (Day 118), the subject's sister-in-law informed the site that the subject had died on 12 Nov 2020 (Day 99) because of worsening of COPD. Relevant tests were unknown. She died under hospice care at home. An autopsy was not performed.

In the opinion of the investigator, there was no reasonable possibility that the worsening of COPD was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1938	82	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	60 kg	22 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	1950	Present
GERD	Gastrooesophageal reflux disease	1970	Present
hysterectomy	Hysterectomy	1980	Past
osteoarthritis	Osteoarthritis	1995	Present
depression	Depression	2000	Present
muscle spasms	Muscle spasms	2000	Present
herpes labialis	Oral herpes	2000	Present
L3 back surgery	Spinal operation	2007	Past
L4 back surgery	Spinal operation	2008	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
chronic diarrhea	Diarrhoea	2010	Present
insomnia	Insomnia	2010	Present
vertigo	Vertigo	2010	Present
chronic cough	Cough	2016	Present
nausea	Nausea	2018	Present
peripheral neuropathy	Neuropathy peripheral	2018	Present
tremors	Tremor	2019	Present
dementia of Alzheimer's	Dementia Alzheimer's type	NOV2019	Present
anemia	Anaemia	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07AUG2020 (1)	16:07
2	Placebo	28AUG2020 (22)	12:34

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Dementia Alzheimer's type	Worsening of Dementia (Alzheimer's).	20DEC2020 (136)		30DEC2020 (146)		11

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (30DEC2020)	NOT RELATED/OTHER: Dementia	2	115	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	28SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	30DEC2020	DEATH

Narrative Comment
Subject C4591001 1089 10891088, an 82-year-old white female with a pertinent medical history of depression and muscle spasms (both since 2000); diarrhea, insomnia, and vertigo (all since 2010); nausea and peripheral neuropathy (both since 2018); tremor (since 2019); dementia Alzheimer's type (since Nov 2019); and anemia (since Jan 2020), received Dose 1 on 07 Aug 2020 and Dose 2 on 28 Aug 2020 (Day 22). The subject was diagnosed with worsening of dementia (Alzheimer's) on 20 Dec 2020, 114 days after receiving Dose 2, and died of the event on 30 Dec 2020, 124 days after receiving Dose 2. According to the subject's spouse, the subject stopped eating and drinking on 20 Dec 2020 (Day 136). All concomitant medications were discontinued from 20 Dec 2020 (Day 136) onward. On 30 Dec 2020 (Day 146), the subject died at home and the cause of death was the worsening of dementia (Alzheimer's). The subject had no symptoms of COVID-19 at the time of the death. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the worsening of dementia (Alzheimer's) was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152.4 cm	79.5 kg	34.2 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cholecystectomy	Cholecystectomy	1990	Past
Hysterectomy	Hysterectomy	1995	Past
Diabetes Type II	Type 2 diabetes mellitus	1995	Present
Asthma	Asthma	2005	Present
Hypothyroid	Hypothyroidism	2005	Present
Hypercholesterolemia	Hypercholesterolaemia	2010	Present
Depression	Depression	26MAY2020	Present
GERD	Gastrooesophageal reflux disease	26MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	14:59
2	Placebo	29SEP2020 (22)	14:25

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Acute respiratory failure	Acute hypoxemic respiratory failure	28NOV2020 (82)		18DEC2020 (102)		21	4
2	INFEC	COVID-19	COVID-19 Infection	26NOV2020 (80)		18DEC2020 (102)		23	4
3	INFEC	Pneumonia	Pneumonia	26NOV2020 (80)		18DEC2020 (102)		23	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN/W	Y	Fatal (18DEC2020)	NOT RELATED/OTHER: COVID-19 Pneumonia	2	61	Y
2	TC	Y	Fatal (18DEC2020)	NOT RELATED/OTHER: COVID-19	2	59	Y
3	TC/TCN	Y	Fatal (18DEC2020)	NOT RELATED/OTHER: COVID-19 Infection	2	59	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	28OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	18DEC2020	DEATH

Narrative Comment
Subject C4591001 1094 10941112, a 57-year-old white female with a pertinent medical history of type 2 diabetes mellitus (since 1995); hypothyroidism and asthma (both since 2005); hypercholesterolemia (since 2010); vitamin D deficiency (since Jan 2020); and insomnia and sleep apnea (both since May 2020), received Dose 1 on 08 Sep 2020 and Dose 2 on 29 Sep 2020 (Day 22). The subject developed COVID-19 infection and pneumonia on 26 Nov 2020, 58 days after receiving Dose 2; and acute hypoxemic respiratory failure on 28 Nov 2020, 60 days after receiving Dose 2. The subject died of the COVID-19 infection, pneumonia, and acute hypoxemic respiratory failure on 18 Dec 2020, 80 days after receiving Dose 2. On 26 Nov 2020 (Day 80), the subject experienced acute shortness of breath, and her family called emergency medical services. On arrival, the subject complained of respiratory symptoms, which she had been experiencing for the past 3 to 4 days. She stated that since the start of her respiratory symptoms, her oxygen levels declined; she had intermittent fevers, diffuse body aches, and left-sided abdominal pain. In the emergency room, her oxygen saturation was 82% on room air, which improved with 4 L of oxygen via nasal cannula. On the same day (Day 80), the subject underwent laboratory tests and procedures, which showed blood urea nitrogen (BUN) at 16 mg/dL (normal range [NR]: 7-22 mg/dL), creatinine at 0.76 mg/dL (NR: 0.50-1.40 mg/dL), white blood cell (WBC) count at 9.2 K/cmm (NR: 3.7-10.4 K/cmm), hemoglobin (Hgb) at 12.5 g/dL (NR: 12.0-16.0 g/dL), hematocrit (Hct) at 36.6% (NR: 36.0%-48.0%), platelet count at 272 K/cmm (NR: 133-450 K/cmm), and troponin less than 0.02 ng/mL (NR: 0.00-0.40 ng/mL); a SARS-CoV-2 nucleic acid amplification test was positive; an electrocardiogram (ECG) showed sinus rhythm but could not rule out anterior infection; chest x-ray showed bilateral pneumonia; computerized tomogram of abdomen with pelvis showed extensive ground-glass pulmonary opacities in the lungs consistent with the given history of COVID-19 infection. On the same day (Day 80), the subject was admitted to the intensive care unit. On 28 Nov 2020 (Day 82), the subject developed acute hypoxemic respiratory failure. On 29 Nov 2020 (Day 83), troponin was less than 0.02 ng/mL, ECG showed sinus bradycardia, and D-dimer was 0.64 µg/mL (NR not provided). On 30 Nov 2020 (Day 84), a chest x-ray showed severe viral pneumonia. On 01 Dec 2020 (Day 85), a chest x-ray showed mildly improved opacities in the lower lobes, with no definite pneumothorax. On 02 Dec 2020 (Day 86), a chest x-ray showed resolution of the right pneumothorax and decrease in size of the trace left apical pneumothorax. On 05 Dec 2020 (Day 89), creatine kinase MB was high at 9.3 ng/mL (NR: 0.5-3.6 ng/mL) and troponin was less than 0.02 ng/mL. On 09 Dec 2020 (Day 93), oxygen saturation was 98.4% (NR: 95.0%-100.0%). On 12 Dec 2020 (Day 96), oxygen saturation was 93.5% and on 13 Dec 2020 (Day 97), the WBC count was 18.0 K/cmm, Hgb was 8.8 g/dL, Hct was 28.7%, and platelet count was 177 K/cmm. On 14 Dec 2020 (Day 98), creatinine was 2.43 mg/dL, BUN was 73 mg/dL, WBC count was 13.6 K/cmm, Hgb was 8.4 g/dL, Hct was 26.7%, and platelet count was 163 K/cmm. On 15 Dec 2020 (Day 99), creatinine was 3.72 mg/dL and BUN was 97 mg/dL. On 16 Dec 2020 (Day 100), oxygen saturation was 83.3%, WBC count was 10.3 K/cmm, Hgb was 7.2 g/dL, Hct was 22.6%, platelet count was 151 K/cmm, creatinine was 4.61 mg/dL, and BUN was 109 mg/dL. SARS-CoV-2 tests were positive on 10 Dec 2020 (Day 94) and 17 Dec 2020 (Day 101) during hospitalization. During the course of hospitalization, the subject was treated with remdesivir, benzonatate, dexamethasone, steroids, convalescent plasma, mechanically assisted ventilation, zinc sulfate, and vitamin C. The subject had a long course with COVID-19; her condition did not improve and she was compassionately extubated. On 21 Dec 2020 (Day 105), the subject's daughter informed the site of her mother's untimely death, which occurred on 18 Dec 2020 (Day 102). An autopsy was not performed, and the cause of death was reported as COVID-19, pneumonia, and acute hypoxemic respiratory failure. In the opinion of the investigator, there was no reasonable possibility that the COVID-19 infection, pneumonia, and acute hypoxemic respiratory failure were related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1933	86	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	72.73 kg	29.3 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Essential Hypertension	Essential hypertension	03JUN2018	Present
GERD	Gastrooesophageal reflux disease	03JUN2018	Present
Osteoarthritis	Osteoarthritis	04JUN2018	Present
Allergic Rhinitis	Rhinitis allergic	04JUN2018	Present
Abnormal Blood Glucose	Blood glucose abnormal	13JAN2020	Present
Hyperlipidemia	Hyperlipidaemia	01JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	10:30
2	BNT162b2	15SEP2020 (23)	11:48

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Septic shock	Septic Shock	16DEC2020 (115)	21:51	21DEC2020 (120)	12:08	6	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN/W	Y	Fatal (21DEC2020)	NOT RELATED/OTHER: Gallbladder Failure	2	93	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	21DEC2020	DEATH

Narrative Comment
Subject C4591001 1097 10971023, an 86-year-old white female with a pertinent medical history of essential hypertension (since 03 Jun 2018), hyperlipidemia (since 01 Jun 2020), and abnormal blood glucose (since 13 Jan 2020), received Dose 1 on 24 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 23). The subject developed septic shock on 16 Dec 2020, 92 days after receiving Dose 2, and died of the septic shock on 21 Dec 2020, 97 days after receiving Dose 2. Concomitant medications included ciclosporin (since 07 Jun 2020) for dry eyes, conjugated estrogens (since 14 Jul 2020) for health maintenance, hydrochlorothiazide/losartan potassium (since 25 Jul 2020) for essential hypertension, meloxicam (since 25 Jul 2020) for osteoarthritis, metoprolol tartrate (since 24 Aug 2020) for essential hypertension, and mirabegron (since 24 Aug 2020) for urinary incontinence. On 16 Dec 2020 (Day 115), the subject had 4 episodes of emesis. On 17 Dec 2020 (Day 116), the subject had 2 episodes of emesis and came to the emergency room, with abdominal pain in the lower quadrant along with nausea. She described the pain as throbbing and aching, which was localized in her lower abdominal area with tenderness in the right upper quadrant. The subject denied fever, chills, bloody emesis, bloody stool, or rectal pain, and she was hospitalized for care. The subject received a nasogastric tube and a dose of magnesium citrate. On 17 Dec 2020 (Day 116), a chest x-ray was unremarkable, computed tomography (CT) of the abdomen showed acute mild small-bowel obstruction due to formed stool, heterogeneously enhanced solid left renal mass, and colonic diverticulitis, and an ultrasound examination of the biliary duct on the same day confirmed cholelithiasis. On the same day (Day 116), laboratory tests showed high levels of lactic acid: 2.4 mmol/L (normal range [NR]: 0.7-1.9 mmol/L) and creatinine: 1.4 mg/dL (NR: 0.52-1.04 mg/dL). Emergency surgery was required because of abdominal pain with acidosis and suspected acute renal failure. During surgery, it was found that the subject had darky bloody fluid in the abdomen and a distended inflamed pregangrenous gallbladder, with a twisted loop of small bowel in the pelvis that could not be released. It was decided to remove the gallbladder after emptying it. On the same day (Day 116), postoperatively, the subject was transferred to the intensive care unit (ICU) and intubated. She was diagnosed with septic shock and was treated with Levophed, vasopressin, Neosynephrine, and intravenous (IV) hydrocortisone sodium succinate. On 19 Dec 2020 (Day 118), the subject's chest x-ray showed bibasilar atelectasis with mild edema and/or infiltrates, and a CT scan of the abdomen showed a small-bowel obstruction and distended gallbladder with gallstones. On the same day (Day 118), the subject's creatinine was high at 3.13 mg/dL. On 20 Dec 2020 (Day 119), the subject's chest x-ray showed development of subcutaneous emphysema, and abdominal x-ray showed paucity of bowel gas. While the subject was in the hospital, her condition continued to decline; she was tachycardic, hypotensive, and in atrial fibrillation with rapid ventricular response and also developed severe metabolic acidosis. During the hospitalization, the subject was treated with acetaminophen rectal suppository 650 mg as needed (PRN); zolpidem tartrate 10 mg (2 tablets) PRN; acetylsalicylic acid 300 mg rectal suppository once per day (QD); diltiazem 20 mg IV once; diltiazem 25 mg IV once; magnesium hydroxide 30 mL orally (PO) PRN; norepinephrine 4 mg + dextrose QD; oxycodone hydrochloride/paracetamol (5/325) 2 tablets PO PRN; omeprazole 40 mg IV QD; paracetamol 650 mg (2 tablets) PRN; piperacillin sodium/tazobactam sodium (dose not provided); fluconazole 200 mg IV QD; diltiazem 100 mg IV + sodium chloride QD; metronidazole 500 mg IV every 8 hours; labetalol 10 mg IV every 6 hours (Q6H); metoprolol 5 mg IV Q6H; morphine 4 mg IV every 4 hours; normal saline flush 10 mL PRN; promethazine 25 mg IV Q6H; ketorolac tromethamine 15 mg IV PRN; and ondansetron 4 mg IV PRN. Even after the treatment, the subject's condition declined and her family decided to withdraw care, and the subject was extubated. On 20 Dec 2020 (Day 119), the subject's creatinine was high at 4.31 mg/dL, blood lactic acid was high at 9.4 mmol/L, and the glomerular filtration rate was 8 mL/min/1.73 m2 (NR not reported). On 21 Dec 2020 (Day 120), at 12:08 am, the subject died of septic shock. An autopsy was not performed. There was no indication in the hospital records that the subject had a COVID-19 test. In the opinion of the investigator, there was no reasonable possibility that the septic shock was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	63	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	74.1 kg	27.2 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Presbyopia	Presbyopia	01JAN1973	Present
Depression	Depression	01JAN1984	Present
Hearing Loss	Deafness	01JAN1991	Present
Postmenopausal	Postmenopause	01JAN2000	Present
Degenerative Disc Disease	Intervertebral disc degeneration	18AUG2005	Present
Hypertension	Hypertension	01JAN2010	Present
Osteoporosis Generalized	Osteoporosis	01JAN2010	Present
Rheumatoid Arthritis-Generalized	Rheumatoid arthritis	01JAN2010	Present
Sleep Apnea	Sleep apnoea syndrome	01JAN2016	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Right Rotator Cuff Tear	Rotator cuff syndrome	01JUL2016	Past
Right Rotator Cuff Repair	Rotator cuff repair	01AUG2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18AUG2020 (1)	15:53
2	BNT162b2	08SEP2020 (22)	15:45

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Sudden cardiac death	Sudden cardiac death	19OCT2020 (63)		19OCT2020 (63)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (19OCT2020)	NOT RELATED/OTHER: unknown	2	42	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	19OCT2020	DEATH

Narrative Comment
Subject C4591001 1114 11141050, a 63-year-old white female with a pertinent medical history of depression (since 01 Jan 1984), intervertebral disc degeneration (since 18 Aug 2005), hypertension (since 01 Jan 2010), generalized rheumatoid arthritis (since 01 Jan 2010), and sleep apnea syndrome (since 01 Jan 2016), received Dose 1 on 18 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 22). The subject experienced sudden cardiac death on 19 Oct 2020, 41 days after receiving Dose 2. Concomitant medications included trazodone (since 01 Jan 2005) for depression, pregabalin (since 01 Jan 2005) for degenerative disc disease, amlodipine (since 01 Jan 2010) for hypertension, baclofen (since 01 Jan 2018) for degenerative disc disease, hydralazine (since 01 Feb 2020) for hypertension, and sertraline (since 01 Jul 2020) for depression. On 19 Oct 2020 (Day 63), the emergency contact confirmed that the subject died. An autopsy determined the cause of death as sudden cardiac death. Of note, the subject had risk factors of hypertension and obesity, which put her at high risk for cardiac/acute myocardial infarction death. In the opinion of the investigator, there was no reasonable possibility that the sudden cardiac death was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.5 cm	105 kg	41.8 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tubal ligation	Female sterilisation	1982	Past
Post Menopausal	Postmenopause	2011	Past
Chronic Back pain	Back pain	2015	Past
cholecystectomy	Cholecystectomy	2015	Past
Cholecystitis	Cholecystitis	2015	Past
Hypertension	Hypertension	2017	Present
Anxiety	Anxiety	2018	Present
Diabetes mellitus Type II	Type 2 diabetes mellitus	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04AUG2020 (1)	17:54
2	BNT162b2	27AUG2020 (24)	17:34

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Cardiac arrest	Cardiac arrest	07NOV2020 (96)		07NOV2020 (96)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (07NOV2020)	NOT RELATED/OTHER: Unknown	2	73	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Completed	VACCINATION	01OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	07NOV2020	DEATH

Narrative Comment
Subject C4591001 1120 11201050, a 58-year-old white female with a pertinent medical history of chronic back pain (since 2015), hypertension (since 2017), anxiety (since 2018), and type 2 diabetes mellitus (since 2018), received Dose 1 on 04 Aug 2020 and Dose 2 on 27 Aug 2020 (Day 24). The subject died of cardiac arrest on 07 Nov 2020, 72 days after receiving Dose 2. Concomitant medications included metformin (since 2017) for type 2 diabetes mellitus; lisinopril (since 2017) and clonidine (since 2018) both for hypertension; and lorazepam (since 2018) for anxiety. On 07 Nov 2020 (Day 96), the subject's husband notified the site that the subject had died in her sleep. The subject's husband reported that the night before her death, she had taken an unspecified muscle relaxant and diazepam (Valium) for her chronic back pain; these medications were previously used by the subject. No symptoms or illnesses leading to the subject's death were reported. The subject was not seen in the hospital. The coroner was called to pronounce death; an autopsy was not performed. On 04 Dec 2020 (Day 123), the subject's husband stated that the cause of death on the death certificate was cardiac arrest (also described as cardiopulmonary arrest). In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	51	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
188 cm	87.6 kg	24.8 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
codeine allergy	Drug hypersensitivity	1988	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10SEP2020 (1)	16:31
2	BNT162b2	29SEP2020 (20)	12:41

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	EYE	Blindness unilateral	LOSS OF VISION LEFT EYE	04DEC2020 (86)		ONGOING		
2	NEOPL	Lung cancer metastatic	Metastatic Lung cancer	04DEC2020 (86)		19JAN2021 (132)		47

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	N	Y	Yes	NOT RELATED/OTHER: UNKNOWN	2	67	Y
2	4	TC/W	Y	Fatal (19JAN2021)	NOT RELATED/OTHER: UNKNOWN	2	67	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	27OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	19JAN2021	DEATH

Narrative Comment
Subject C4591001 1120 11201266, a 51-year-old white male with a pertinent medical history of drug hypersensitivity to codeine (since 1988), received Dose 1 on 10 Sep 2020 and Dose 2 on 29 Sep 2020 (Day 20). On 04 Dec 2020, the subject was diagnosed with metastatic lung cancer and unilateral blindness, 66 days after receiving Dose 2. On 04 Dec 2020 (Day 86), the subject went to an urgent care clinic because of blurred vision and was sent to the emergency room. The subject was treated with levetiracetam 500 mg, dexamethasone 4 mg, and oxycodone hydrochloride/paracetamol 5/325 mg. On an unspecified date in Dec 2020, 2 magnetic resonance imaging scans (1 with dye), 2 computed tomography scans (1 with dye), and a bronchial test (unspecified) were performed and the results were unspecified. The doctors reported a diagnosis of metastatic lung cancer that had spread to the abdomen and brain; the subject also had lost vision in his left eye (unilateral blindness) with the onset date 04 Dec 2020 (Day 86). On 19 Jan 2021 (Day 132), the subject died of the metastatic lung cancer. The unilateral blindness was ongoing at the time of the subject's death. It was not reported if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the metastatic lung cancer and unilateral blindness were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	Multiple	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	71.8 kg	25.4 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to Chlor-Trimeton	Drug hypersensitivity	1978	Present
Hypoglycemia	Hypoglycaemia	1985	Present
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	1990	Present
Tinnitus	Tinnitus	1992	Present
Myocardial Infarction stress related	Myocardial infarction	2008	Past
Myopia	Myopia	2008	Present
Allergy to Tramadol	Drug hypersensitivity	2015	Present
Recurrent seasonal allergies	Seasonal allergy	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	18:55
2	BNT162b2	10SEP2020 (22)	14:57

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Cardio-respiratory arrest	Cardiopulmonary arrest	04DEC2020 (107)	22:00	04DEC2020 (107)		1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (04DEC2020)	NOT RELATED/OTHER: underlying cardiac disease	2	86	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	04DEC2020	DEATH

Narrative Comment
Subject C4591001 1127 11271112, a 53-year-old multiracial male with a pertinent medical history of hypoglycemia (since 1985), chronic obstructive pulmonary disease (since 1990), myocardial infarction (in 2008), and seasonal allergy (since 2018), received Dose 1 on 20 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 22). On 04 Dec 2020, the subject died at 2200 hours, 85 days after receiving Dose 2, and the preliminary cause of death was reported as cardiopulmonary arrest on 18 Dec 2020. On 04 Dec 2020 (Day 107), the subject went downstairs to do laundry, went back upstairs to get shampoo for a shower, and returned downstairs. His mother went down to check on him since it had been a while and found that the subject was sitting cross-legged, leaning forward, and was blue in the face. On 05 Dec 2020 (Day 108) at 1130 hours, the subject's mother called the study site to report the subject's death. An autopsy was performed, and the results were not available at the time of this report. On 18 Dec 2020, cardiopulmonary arrest was considered as the preliminary cause of death. In the opinion of the investigator, there was no reasonable possibility that the cardiopulmonary arrest was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was due to the underlying cardiac disease. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
190.5 cm	128.59 kg	35.4 kg/m2	31JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tobacco Dependency	Nicotine dependence	1970	Present
Vasectomy	Vasectomy	1985	Past
Fluid Retention	Fluid retention	1995	Present
High Blood Pressure	Hypertension	1995	Present
diabetes mellitus type 2	Type 2 diabetes mellitus	1996	Present
Anxiety	Anxiety	2000	Present
Restless Leg Syndrome	Restless legs syndrome	2000	Present
High Cholesterol	Blood cholesterol increased	2001	Present
Drug Allergy Diphendydramine	Drug hypersensitivity	2005	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bilateral Hip Pain	Arthralgia	17NOV2014	Present
Bilateral Hip Replacement	Hip arthroplasty	17NOV2014	Past
intermittent Non-productive Cough	Cough	2016	Present
Angina intermittent	Angina pectoris	2017	Present
MYOCARDIAL INFARCTION	Myocardial infarction	01JAN2017	Past
Coronary Arterial Stent placement	Coronary arterial stent insertion	17JAN2017	Past
Vitamin D Deficiency	Vitamin D deficiency	MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31JUL2020 (1)	16:22
2	Placebo	19AUG2020 (20)	15:02

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Myocardial infarction	Myocardial Infarction	27OCT2020 (89)		28OCT2020 (90)		2	4
2	INFEC	Pneumonia	Pneumonia	28OCT2020 (90)		28NOV2020 (121)	06:00	32	4

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Y	Resolved (28OCT2020)	NOT RELATED/OTHER: failed cardiac stent	2	70	Y
2	TC/W	Y	Fatal (28NOV2020)	NOT RELATED/OTHER: infection	2	71	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31JUL2020	
Completed	VACCINATION	16SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	28NOV2020	DEATH

Narrative Comment
Subject C4591001 1128 11281009, a 66-year-old white male with a pertinent medical history of nicotine dependence (since 1970), fluid retention and hypertension (both since 1995), type 2 diabetes mellitus (since 1996), anxiety (since 2000), increased blood cholesterol (since 2001), cough (since 2016), angina pectoris (since 2017), myocardial infarction (on 01 Jan 2017), coronary arterial stent insertion (on 17 Jan 2017), and vitamin D deficiency (since May 2020), received Dose 1 on 31 Jul 2020 and Dose 2 on 19 Aug 2020 (Day 20). The subject was diagnosed with myocardial infarction on 27 Oct 2020 and pneumonia on 28 Oct 2020, 69 days and 70 days after receiving Dose 2, respectively. He died from progression of pneumonia, on 28 Nov 2020, 101 days after receiving Dose 2. Concomitant medications included vitamin D2 (since May 2000) for vitamin D deficiency, pramipexole (since 2000) for restless legs syndrome, clonazepam (since 2000) for an unknown indication, glimepiride (since 2010) for type 2 diabetes mellitus, clopidogrel (since 2011) for increased blood cholesterol, clonidine hydrochloride (since 2014) for hypertension, gabapentin (since 2014) for bilateral hip pain, benzonatate (since 2016) for cough, nitroglycerin (since 2017) for angina, and furosemide (since 09 Sep 2020) for fluid retention. On 27 Oct 2020 (Day 89), the subject had a myocardial infarction due to failure of a cardiac stent that resulted in hospitalization. The failed stent was removed and replaced. On 28 Oct 2020 (Day 90), the myocardial infarction was considered resolved. After stent replacement procedure, the subject developed pneumonia on 28 Oct 2020 (Day 90) and was discharged against medical advice on 30 Oct 2020 (Day 92). On an unknown date, the site contacted the subject regarding a missed e-diary entry, during which the subject's wife reported that the subject had died at home on 28 Nov 2020 (Day 121) at 0600 hours because of pneumonia. The site requested the subject's death certificate, which was pending at the time of this report. No autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the myocardial infarction and pneumonia were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1942	78	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	59.09 kg	22.3 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
depression	Depression	1950	Present
bilateral astigmatism	Astigmatism	1955	Present
hyperopia	Hypermetropia	1965	Present
myopia	Myopia	1965	Present
Surgical tape allergy	Dermatitis contact	1980	Present
hypercholesterolemia	Hypercholesterolaemia	2009	Present
right cataracts	Cataract	2017	Past
left cataracts	Cataract	2017	Present
hearing loss	Deafness	2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hiatal hernia	Hiatus hernia	2017	Present
osteoporosis	Osteoporosis	2018	Present
diarrhea	Diarrhoea	DEC2019	Past
esophageal stricture	Oesophageal stenosis	MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	08SEP2020 (1)	13:10
2	BNT162b2	28SEP2020 (21)	12:15

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Myocardial infarction	myocardial infarction	03FEB2021 (149)		03FEB2021 (149)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (03FEB2021)	NOT RELATED/OTHER: hyperlipidemia	2	129	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	26OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	03FEB2021	DEATH

Narrative Comment
Subject C4591001 1129 11291166, a 78-year-old white female with a pertinent medical history of hypercholesterolemia (since 2009); peripheral arterial occlusive disease (since 02 Feb 2019); esophageal stenosis (in Mar 2020); diastolic dysfunction (Grade 1; since 14 Aug 2020); and elevated blood pressure, angiopathy, current tobacco use, and gastroesophageal reflux disease (all on unknown dates), received Dose 1 on 08 Sep 2020 and Dose 2 on 28 Sep 2020 (Day 21). The subject died of a myocardial infarction on 03 Feb 2021, 128 days after receiving Dose 2. Concomitant medications included atorvastatin (since 2017) for hypercholesterolemia, omeprazole (since 2017) for hiatal hernia, citalopram hydrobromide (since 2017) for depression, and denosumab (since 2018) for osteoporosis. On 03 Jan 2021 (Day 118), the subject had visited a doctor and it was reported that she was feeling well at this time. It was reported that the subject did not have any side effects after receiving Dose 1 and Dose 2. On 08 Jan 2021 (Day 123), the family spoke to the subject for the last time. The site received a call from the subject's son reporting that his mother had died on 03 Feb 2021 (Day 149); the subject's neighbors found her body in her apartment because of the odor. When the subject's son arrived, he found that there was a large amount of blood and fluids pooled on the floor around her body. Her skin was mottled, bruised, and rigid. The emergency medical technician noted no lacerations that could cause the pool of blood and estimated that she might have died 3 to 5 days before her body was found. The cause of death was reported as myocardial infarction per the medical examiner. No autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the myocardial infarction was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to hyperlipidemia. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1936	84	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.8 cm	91 kg	30.5 kg/m2	22SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tobacco use, past, 6 cigarettes per day	Ex-tobacco user	1945	Past
allergic rhinitis, seasonal	Seasonal allergy	1985	Past
eye glass wearer	Corrective lens user	1995	Present
cataract surgery in both eyes	Cataract operation	2000	Past
osteoarthritis, generalized	Osteoarthritis	2000	Present
hip replacement	Hip arthroplasty	2002	Past
right knee replacement surgery	Knee arthroplasty	2004	Past
erectile dysfunction	Erectile dysfunction	2005	Present
left knee replacement surgery	Knee arthroplasty	2005	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
aortic stenosis	Aortic stenosis	2010	Present
hearing problems	Auditory disorder	2010	Present
dentures	Denture wearer	2013	Present
carpal tunnel syndrome, bilaterally	Carpal tunnel syndrome	2015	Present
memory changes	Memory impairment	2015	Present
atrial fibrillation	Atrial fibrillation	2018	Present
cerebrovascular accident	Cerebrovascular accident	2018	Past
heart murmur	Cardiac murmur	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22SEP2020 (1)	14:28
2	Placebo	15OCT2020 (24)	10:49
3	BNT162b2	21JAN2021 (122)	11:53

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Aortic stenosis	Worsening Aortic Stenosis	05FEB2021 (137)		13FEB2021 (145)		9	3
2	CARD	Cardio-respiratory arrest	Cardiopulmonary Arrest	15FEB2021 (147)	12:35	15FEB2021 (147)	13:35	1	4

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Y	Resolved (13FEB2021)	NOT RELATED/OTHER: atherosclerosis	3	16	Y
2	W	Y	Fatal (15FEB2021)	NOT RELATED/OTHER: Cerebrovascular Event	3	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	22SEP2020	
Completed	VACCINATION	12NOV2020	
Completed	REPEAT SCREENING 1	21JAN2021	
Withdrawn	OPEN LABEL TREATMENT	15FEB2021	DEATH
Withdrawn	FOLLOW-UP	15FEB2021	DEATH

Narrative Comment
Subject C4591001 1131 11311204, an 84-year-old white male with a pertinent medical history of former tobacco use (6 cigarettes per day from 1945 to an unknown date), seasonal allergy (in 1985), aortic stenosis (since 2010), memory impairment (since 2015), cerebrovascular accident (in 2018), atrial fibrillation (since 2018), and cardiac murmur (since 2019), received Dose 1 on 22 Sep 2020 and Dose 2 on 15 Oct 2020 (Day 24). Concomitant medication included apixaban (since Apr 2018) for a cerebrovascular accident. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first dose of BNT162b2 on 21 Jan 2021 (Day 122), and remained in the study until 15 Feb 2021 (Day 147). The subject was diagnosed with worsening aortic stenosis on 05 Feb 2021 and cardiopulmonary arrest on 15 Feb 2021, 15 days and 25 days after receiving the first dose of BNT162b2, respectively. He died of cardiopulmonary arrest on 15 Feb 2021 (Day 147), 25 days after receiving the first dose of BNT162b2. The subject's wife reported that the subject had experienced shortness of breath and was taken to the emergency room on 05 Feb 2021 (Day 137). Subsequently, the subject was hospitalized on the same day (Day 137) because of the worsening of aortic stenosis. The subject underwent an angiogram, and a stent insertion was recommended. On 16 Feb 2021 (Day 148), the subject's wife reported that the worsening of aortic stenosis was considered resolved, and the subject was discharged from the hospital on 13 Feb 2021 (Day 145). She also reported that the subject had lain down for a nap on 15 Feb 2021 (Day 147) and never woke up. The subject's wife was unaware of the cause of death. She also reported that the stent insertion was not completed during the hospitalization, as the cardiologist did not feel it was an urgent need. Later, on 05 Mar 2021, a death certificate received from the subject's primary care physician stated that the immediate cause of death was cardiopulmonary arrest secondary to cerebrovascular event. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the worsening aortic stenosis and cardiopulmonary arrest were related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178 cm	101.9 kg	32.2 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
nearsighted	Myopia	1966	Present
anxiety	Anxiety	1991	Present
cholecystectomy	Cholecystectomy	1991	Past
gallbladder stones	Cholelithiasis	1991	Past
depression	Depression	1998	Present
hearing loss	Deafness	2010	Present
bone spur surgery	Bone lesion excision	2017	Past
cataracts	Cataract	2017	Present
Rt foot bone spur	Exostosis	2017	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
septoplasty	Nasal septal operation	2017	Past
deviated nasal septum	Nasal septum deviation	2017	Past
hypertension	Hypertension	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	05AUG2020 (1)	13:31
2	Placebo	27AUG2020 (23)	11:32
3	BNT162b2	25JAN2021 (174)	10:26

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PSYCH	Completed suicide	Suicide	29JAN2021 (178)	00:00	29JAN2021 (178)	00:00	1
2	NERV	Hypoaesthesia	numbness on the back of the head	04SEP2020 (31)		04SEP2020 (31)		1

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	W	Y	Fatal (29JAN2021)	NOT RELATED/OTHER: unknown	3	5	Y
2	1	N	N	Resolved (04SEP2020)	NOT RELATED/OTHER: muscle strain	2	9	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	24SEP2020	
Completed	REPEAT SCREENING 1	25JAN2021	
Withdrawn	OPEN LABEL TREATMENT	29JAN2021	DEATH
Withdrawn	FOLLOW-UP	29JAN2021	DEATH

Narrative Comment
Subject C4591001 1135 11351033, a 67-year-old white male with a pertinent medical history of anxiety (since 1998) and depression (since 1991), received Dose 1 on 05 Aug 2020 and Dose 2 on 27 Aug 2020 (Day 23). Concomitant medications included diazepam (from 1991 to 29 Jan 2021) for anxiety, paroxetine hydrochloride (from 1998 to 29 Jan 2021) for depression, and losartan (from Jan 2020 to 29 Jan 2021) for hypertension. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first dose of BNT162b2 on 25 Jan 2021 (Day 174) and remained in the study until 29 Jan 2021 (Day 178). The subject committed suicide and died on 29 Jan 2021, 4 days after receiving the first dose of BNT162b2. When the subject missed his Visit 102, the site attempted to contact him, but the site was unsuccessful and called an emergency contact. The emergency contact reported that the subject had committed suicide and died on 29 Jan 2021 (Day 178). An autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the suicide was related to the BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	76	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	60 kg	20.1 kg/m2	29OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
congenital heart defect	Heart disease congenital	1944	Past
patent ductus arteriosus heart surgery	Patent ductus arteriosus repair	1947	Past
patent ductus arteriosus heart surgery	Patent ductus arteriosus repair	1949	Past
appendectomy	Appendicectomy	1954	Past
appendicitis	Appendicitis	1954	Past
bilateral hearing loss	Deafness bilateral	1957	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29OCT2020 (1)	12:21
2	BNT162b2	19NOV2020 (22)	12:13

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Cardiac arrest	cardiac arrest	19DEC2020 (52)	00:00	19DEC2020 (52)	00:00	1
2	GENRL	Injection site pain	injection site pain, right	20NOV2020 (23)	00:00	21NOV2020 (24)	00:00	2
3	GENRL	Injection site pain	sore in injection site, right arm	29OCT2020 (1)	00:00	29OCT2020 (1)	00:00	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/TCN/W	Y	Fatal (19DEC2020)	NOT RELATED/OTHER: cardiac related	2	31	Y
2	1	N	N	Resolved (21NOV2020)	Study Treatment	2	2	N
3	1	N	N	Resolved (29OCT2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29OCT2020	
Withdrawn	VACCINATION	19DEC2020	DEATH
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	19DEC2020	DEATH

Narrative Comment
Subject C4591001 1136 11361102, a 76-year-old white male with a pertinent medical history of congenital heart disease ((b) (6) 1944 to 1949) that was surgically repaired (patent ductus arteriosus repair in 1947 and 1949), appendicitis and appendectomy (both in 1954), and bilateral deafness (since 1957), received Dose 1 on 29 Oct 2020 and Dose 2 on 19 Nov 2020 (Day 22). The subject died of cardiac arrest on 19 Dec 2020, 30 days after receiving Dose 2. Concomitant medication included multivitamins (since an unknown date) for health maintenance. On 22 Jan 2021, after multiple attempts to contact the subject, the site communicated with the subject's emergency contact, who confirmed that the subject had died after experiencing sudden cardiac arrest while on a walk. On 19 Dec 2020 (Day 52), the subject suddenly collapsed while on a walk. The subject was unresponsive and cardiopulmonary resuscitation was performed. An ambulance was called, and the emergency medical services found the subject to have ventricular tachycardia (heart rate not reported) followed by ventricular fibrillation. Two rounds of defibrillation with 3 rounds of epinephrine were done. Chest compressions and epinephrine, calcium, sodium bicarbonate, and amiodarone were administered. An echocardiogram performed at bedside revealed cardiac standstill. Resuscitation efforts were terminated, and the subject died on the same day (Day 52) because of a cardiac arrest. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
190.5 cm	138.73 kg	38.1 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
obesity	Obesity	01JAN1978	Present
bilateral Knee pain	Arthralgia	01AUG2010	Present
Knee Replacement	Knee arthroplasty	01FEB2014	Past
Osteoarthritis	Osteoarthritis	01FEB2014	Present
Coronary Artery Disease	Coronary artery disease	01AUG2015	Present
Depression	Depression	01AUG2018	Present
Hypertension	Hypertension	01AUG2018	Present
Hyperlipidemia	Hyperlipidaemia	01JUN2019	Present
Hyperglycemia	Hyperglycaemia	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14AUG2020 (1)	12:08
2	BNT162b2	04SEP2020 (22)	09:07

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Cardiac arrest	Cardiac Arrest	29DEC2020 (138)		29DEC2020 (138)	13:59	1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (29DEC2020)	NOT RELATED/OTHER: Underlying Comorbidities	2	117	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	29DEC2020	DEATH

Narrative Comment
Subject C4591001 1140 11401117, a 58-year-old white male with a pertinent medical history of obesity (since 01 Jan 1978), coronary artery disease (since 01 Aug 2015), depression and hypertension (both since 01 Aug 2018), hyperlipidemia (since 01 Jun 2019), and hyperglycemia (since Jun 2020; glycosylated hemoglobin of 5.7 in Jun 2020), received Dose 1 on 14 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 22). The subject died of cardiac arrest on 29 Dec 2020, 116 days after receiving Dose 2. Concomitant medications included meloxicam (since 01 Aug 2010) for bilateral knee pain, vitamin D3 (since 01 Aug 2015) for general health, hydrochlorothiazide and losartan (both since 01 Aug 2018) for hypertension, sertraline (since 01 Oct 2018) for depression, acetylsalicylic acid (since 01 Jun 2020) for coronary artery disease, pravastatin (since 01 Jun 2020) for hyperlipidemia, and dulaglutide (since 07 Dec 2020) for hyperglycemia. On 29 Dec 2020 (Day 138), the subject experienced seizure-like activity and collapsed; he was taken to the emergency room (ER) in cardiac arrest with bystander cardiopulmonary resuscitation (CPR) and electrical muscle stimulation (EMS) CPR. The subject was initially found to be in ventricular tachycardic arrest and he received amiodarone and epinephrine along with subsequent CPR attempts. Per emergency medical services, he received 5 rounds of epinephrine, 1 ampoule of sodium bicarbonate, 1 g calcium chloride, 1 mg atropine, and 300 mg amiodarone. The subject's cardiac rhythm was asystole before arrival at the ER, and he was unresponsive upon physical examination. He was defibrillated with 200 J of biphasic electricity but continued to be in pulseless electrical activity and pulseless ventricular fibrillation. Despite appropriate CPR, the subject's carbon dioxide continued to drop and a bedside echocardiogram showed no cardiac activity with complete cardiac standstill. Resuscitative efforts were ceased because of the significantly decreased probability of regaining spontaneous circulation. The subject died of cardiac arrest on 29 Dec 2020 (Day 138) at 1359 hours. No autopsy was performed. Of further note, the subject had reported "sniffles" on 07 Dec 2020 (Day 116), which was not considered to be serious, and had a blood test on an unspecified date that showed COVID-19 antibodies. In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to underlying comorbidities. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	42	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	84.09 kg	28.1 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
chronic sinusitis	Chronic sinusitis	2000	Present
seasonal allergies	Seasonal allergy	2000	Present
breast cancer	Breast cancer	2001	Past
lumpectomy left breast	Breast conserving surgery	2001	Past
breast cancer	Breast cancer	2017	Past
lumpectomy left breast	Breast conserving surgery	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	10:38

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Death	UNDETERMINED CAUSE OF DEATH	26AUG2020 (8)		26AUG2020 (8)		1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	P/W	Y	Fatal (26AUG2020)	NOT RELATED/OTHER: UNDETERMINED CAUSE OF DEATH	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19AUG2020	
Withdrawn	VACCINATION	26AUG2020	DEATH
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	26AUG2020	DEATH

Narrative Comment
Subject C4591001 1152 11521085, a 42-year-old white female with a pertinent medical history of recurrent breast cancer (in 2001 and 2017), treated with lumpectomy and radiation on unknown dates, and implantation of an Essure permanent birth control device (implanted in 2017), received Dose 1 on 19 Aug 2020. The subject was not taking any concomitant medications. The subject died (cause of death was undetermined) on 26 Aug 2020, 7 days after receiving Dose 1. The subject's husband stated that the subject had no adverse events after receiving Dose 1. On 25 Aug 2020 (Day 7), she had a normal evening and went to bed. On 26 Aug 2020 (Day 8), the husband found that the subject had died and the cause of death was undetermined. On 02 Jan 2021, the subject's husband reported that the medical examiner stated that the subject died from sudden cardiac failure brought on by 2 rounds of radiation for recurring breast cancer, which weakened her heart. The subject had no changes in her health and medications. Essure was still in place at the time of death. The investigator felt that the cause of death was sudden cardiac failure from radiation therapy on 2 separate occasions for breast cancer. However, this could not be confirmed. During the follow-up report, it was reported that the medical examiner's office determined the cause of death as "undetermined." An autopsy was performed and the results were still pending at the time of this report. In the opinion of the investigator, there was no reasonable possibility that the death was related to the study intervention. The investigator further stated that although the full autopsy report was pending and determining cause of death at this time was essentially an educated guess, the subject had possible risk factors. She possibly had a thromboembolic event related to a history of breast cancer, or there was a potential toxicity related to the Essure permanent birth control device. The subject had an Essure implant since 2017 for permanent birth control that was taken off the market in the United States by the Food and Drug Administration (FDA) in 2018. A brief review revealed almost 50,000 reports to the FDA regarding the device and approximately 50 deaths. The investigator stated that Essure was a concomitant device that was a cosuspect in the subject's death. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	72	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	78.27 kg	25.1 kg/m2	07OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
lithotripsy	Lithotripsy	1999	Past
nephrolithiasis	Nephrolithiasis	1999	Past
allergy to mango	Food allergy	2000	Present
allergy to celery	Food allergy	2000	Present
hearing loss	Deafness	2010	Present
osteoarthritis	Osteoarthritis	2010	Present
Type II diabetes	Type 2 diabetes mellitus	2010	Present
hypertension	Hypertension	2018	Present
prostatism	Prostatism	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07OCT2020 (1)	12:52

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Shigella sepsis	sepsis related to Shigella infection	26OCT2020 (20)		11NOV2020 (36)		17	4
2	NERV	Syncope	vasovagal syncope	26OCT2020 (20)		26OCT2020 (20)		1	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN/W	Y	Fatal (11NOV2020)	NOT RELATED/OTHER: Shigella infection	1	20	Y
2	N	N	Resolved (26OCT2020)	NOT RELATED/OTHER: sepsis related to shigella infection	1	20	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07OCT2020	
Withdrawn	VACCINATION	11NOV2020	DEATH
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	11NOV2020	DEATH

Narrative Comment
Subject C4591001 1152 11521497, a 72-year-old white male with a pertinent medical history of type 2 diabetes mellitus and osteoarthritis (both since 2010) and hypertension (since 2018), received Dose 1 on 07 Oct 2020. On 26 Oct 2020, the subject was diagnosed with Shigella sepsis, 19 days after receiving Dose 1, and the subject died of the event on 11 Nov 2020, 35 days after receiving Dose 1. Concomitant medications included metformin (since 2013) for diabetes, ibuprofen (since 2015) for osteoarthritis, lisinopril (since 2018) for hypertension, and doxazosin (since 2019) for benign prostatic hypertrophy. On 06 Nov 2020 (Day 31), it was reported that the subject was admitted to the hospital on 26 Oct 2020 (Day 20) after he fainted in the middle of the night. On the same day (Day 20), the syncope resolved. Per medical records from the hospital admission, the subject complained of diarrhea for 2 days, with associated nausea, intermittent vomiting, and increasing lethargy. On arrival, he was febrile (body temperature was not reported) and hypotensive (blood pressure was not reported). The subject was awake, alert, and oriented (AAO × 3-4), but he had mild abdominal pain. The subject was transferred to the intensive care unit. The subject tested negative for COVID-19 at the hospital. Laboratory results showed lactic acidosis (lactic acid was 11.8 mmol/L [normal range: 0.7 - 2.1 mmol/L]); stool test showed fecal leukocytosis; and a computed tomogram of the chest/abdomen showed acute moderate colitis and abundant fluid in the small bowel. On 27 Oct 2020 (Day 21), a gastrointestinal pathogen panel test was positive for Shigella species. The subject was diagnosed with Shigella sepsis with an onset date of 26 Oct 2020 (Day 20) and was treated with ceftriaxone, piperacillin/tazobactam, ciprofloxacin, metronidazole, and meropenem. He also received vasopressors to control hypotensive episodes. Per the investigator, the cause of the syncope was sepsis related to Shigella infection. On 11 Nov 2020 (Day 36), the subject died of Shigella sepsis. No autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the Shigella sepsis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
181.2 cm	98.1 kg	29.9 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
anxiety	Anxiety	NOV2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	12:16
2	Placebo	02OCT2020 (23)	10:39

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Overdose	MULTIPLE DRUG OVERDOSE	02NOV2020 (54)		02NOV2020 (54)		1
2	RESP	Respiratory arrest	RESPIRATORY ARREST	02NOV2020 (54)		02NOV2020 (54)		1

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	W	Y	Fatal (02NOV2020)	NOT RELATED/OTHER: DRUG OVERDOSE	2	32	Y
2	4	W	Y	Fatal (02NOV2020)	NOT RELATED/OTHER: DRUG OVERDOSE	2	32	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Withdrawn	VACCINATION	02NOV2020	DEATH
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	02NOV2020	DEATH

Narrative Comment
Subject C4591001 1156 11561124, a 53-year-old white male with a pertinent medical history of former tobacco use (from an unknown date to 2019), anxiety (since Nov 2018), overweight (since an unknown date), and family history of myocardial infarction, received Dose 1 on 10 Sep 2020 and Dose 2 on 02 Oct 2020 (Day 23). On 02 Nov 2020, the subject died of respiratory arrest following a multiple drug overdose, 31 days after receiving Dose 2. Concomitant medication included alprazolam (since 15 Oct 2018) for anxiety. On 02 Nov 2020 (Day 54), the subject had a multiple drug overdose that resulted in respiratory arrest, and was found deceased at his residence. An autopsy report revealed accidental death due to intoxication with fentanyl, despropionyl fentanyl (4-ANPP), ethanol (all since unknown dates), and alprazolam, which were used as recreational drugs at unknown doses. In the opinion of the investigator, there was no reasonable possibility that the multiple drug overdose and respiratory arrest were related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
143.7 cm	73 kg	35.4 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
cesarean section	Caesarean section	11NOV1974	Past
newborn delivery	Delivery	11NOV1974	Past
cesarean section	Caesarean section	20DEC1983	Past
newborn delivery	Delivery	20DEC1983	Past
cesarean section	Caesarean section	31DEC1987	Past
newborn delivery	Delivery	31DEC1987	Past
cesarean section	Caesarean section	08OCT1991	Past
newborn delivery	Delivery	08OCT1991	Past
human immunodeficiency virus disease	HIV infection	2005	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
anemia	Anaemia	05DEC2015	Present
hyperlipidemia	Hyperlipidaemia	05DEC2015	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	10MAY2017	Present
RHINITIS	Rhinitis	2018	Present
asthma	Asthma	31JAN2018	Present
chronic low back pain	Back pain	08OCT2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21SEP2020 (1)	14:06
2	BNT162b2	12OCT2020 (22)	15:38

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Road traffic accident	MOTOR VEHICLE ACCIDENT	24DEC2020 (95)		24DEC2020 (95)		1

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	W	Y	Fatal (24DEC2020)	NOT RELATED/OTHER: UNKNOWN	2	74	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21SEP2020	
Completed	VACCINATION	10NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	24DEC2020	DEATH

Narrative Comment
Subject C4591001 1156 11561160, a 62-year-old black or African American female with a pertinent medical history of cesarean section and delivery (on 11 Nov 1974, 20 Dec 1983, 31 Dec 1987, and 08 Oct 1991), human immunodeficiency virus (HIV) infection (since 2005), anemia (since 05 Dec 2015), hyperlipidemia (since 05 Dec 2015), rhinitis (since 2018), asthma (since 31 Jan 2018), and back pain (since 08 Oct 2019), received Dose 1 on 21 Sep 2020 and Dose 2 on 12 Oct 2020 (Day 22). On 24 Dec 2020, the subject died after a motor vehicle accident, 73 days after receiving Dose 2. Concomitant medications included abacavir sulfate/dolutegravir sodium/lamivudine (since 24 May 2018) for HIV infection, budesonide/formoterol fumarate aerosol (since 12 May 2020) for asthma, and atorvastatin (since 16 Nov 2020) for hyperlipidemia. On 11 Jan 2021 (Day 113), the emergency contact stated that the subject had a motor vehicle accident on 24 Dec 2020 (Day 95) and was taken to the emergency room. On the same day (Day 95), the subject died because of the motor vehicle accident. The emergency contact declined to provide any additional information. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the motor vehicle accident was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.5 cm	100.4 kg	32.6 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
autoimmune thyroiditis	Autoimmune thyroiditis	2010	Present
overweight/obese	Obesity	2010	Present
traumatic brain injury	Craniocerebral injury	2011	Past
depression	Depression	2011	Present
hip replacement	Hip arthroplasty	2015	Past
reading glasses	Corrective lens user	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10SEP2020 (1)	12:09

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	VASC	Arteriosclerosis	Atherosclerotic Disease	13SEP2020 (4)		13SEP2020 (4)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (13SEP2020)	NOT RELATED/OTHER: underlying disease	1	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Withdrawn	VACCINATION	13SEP2020	DEATH
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	13SEP2020	DEATH

Narrative Comment
Subject C4591001 1162 11621327, a 60-year-old white male with a pertinent medical history of obesity (since 2010), craniocerebral injury (in 2011, recovered), depression (since 2011), and hip arthroplasty (in 2015), received Dose 1 on 10 Sep 2020. On 13 Sep 2020, the subject died of arteriosclerosis, 3 days after receiving Dose 1. Concomitant medications included aripiprazole (from 2011 to an unspecified date) and venlafaxine hydrochloride (from 2015 to an unspecified date), both for depression. On 13 Sep 2020 (Day 4), the study site received a police report indicating that the police had visited the subject's home to perform a welfare check and found him dead. It was reported that the subject's body was cold and had visible lividity. According to the medical examiner, the probable cause of death was progression of atherosclerotic disease. It was unknown if an autopsy was performed (no autopsy results were available at the time of this report). In the opinion of the investigator, there was no reasonable possibility that the arteriosclerosis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	64	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.5 cm	96.8 kg	28.1 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
BILATERAL OSTEOARTHRITIS(KNEE)	Osteoarthritis	2010	Present
SEASONAL ALLERGIES	Seasonal allergy	2010	Present
OSTEOARTHRITIS(NECK)	Spinal osteoarthritis	2010	Present
JOINT PAIN(SPINE)	Spinal pain	2010	Present
CERVICAL SPINAL FUSION	Spinal fusion surgery	2013	Past
BASAL CELL CARCINOMA (FOREHEAD)	Basal cell carcinoma	2015	Past
RINGING IN EARS	Tinnitus	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	12:53
2	Placebo	15SEP2020 (22)	11:42

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	VASC	Aortic rupture	Aortic Rupture	18NOV2020 (86)		18NOV2020 (86)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (18NOV2020)	NOT RELATED/OTHER: Aortic Rupture	2	65	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	16OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	18NOV2020	DEATH

Narrative Comment
Subject C4591001 1168 11681083, a 64-year-old white male with a pertinent medical history of basal cell carcinoma (in 2015), spinal osteoarthritis (since 2010), and spinal fusion surgery (in 2013), received Dose 1 on 25 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 22). On 18 Nov 2020, the subject died of aortic rupture, 64 days after receiving Dose 2. Concomitant medications included ibuprofen (from 2010 to 18 Nov 2020) for general pain, multivitamin (from 2015 to 18 Nov 2020) as a nutritional supplement, gabapentin (from 2019 to 18 Nov 2020) for cervical neck pain, glucosamine (from 2019 to 18 Nov 2020) for full spine joint pain, and hydrocodone bitartrate/paracetamol (from 2020 to 18 Nov 2020) for full spine joint pain. On 16 Nov 2020 (Day 84), the subject had a “head cold” with symptoms of congestion and mild intermittent cough, and he took pseudoephedrine hydrochloride and guaifenesin. The symptoms improved on 17 Nov 2020 (Day 85) but still persisted on 18 Nov 2020 (Day 86). On 18 Nov 2020 (Day 86), the subject was found on the ground and was unresponsive at his workplace. The paramedics arrived and the subject was pronounced dead and taken to the medical examiner. An autopsy was performed. On 20 Nov 2020, the medical examiner verbally confirmed the cause of death as aortic rupture. In the opinion of the investigator, there was no reasonable possibility that the aortic rupture was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator’s causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	84.9 kg	28.4 kg/m2	05NOV2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
heart stent replacement surgery	Coronary arterial stent insertion	2005	Past
type 2 diabetes	Type 2 diabetes mellitus	2010	Present
secong degree liver cirhosis	Hepatic cirrhosis	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	05NOV2020 (1)	10:22
2	Placebo	26NOV2020 (22)	10:54

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Pneumonia bacterial	Bacterial Pneumonia	05FEB2021 (93)		09FEB2021 (97)		5

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (09FEB2021)	NOT RELATED/OTHER: bacterial	2	72	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05NOV2020	
Completed	VACCINATION	14JAN2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	09FEB2021	DEATH

Narrative Comment
Subject C4591001 1207 12071055, a 65-year-old white male with a pertinent medical history of coronary arterial stent insertion (in 2005), type 2 diabetes mellitus (since 2010), and hepatic cirrhosis (since 2015), received Dose 1 on 05 Nov 2020 and Dose 2 on 26 Nov 2020 (Day 22). The subject was diagnosed with bacterial pneumonia on 05 Feb 2021, 72 days after receiving Dose 2, and died of the event on 09 Feb 2021, 75 days after receiving Dose 2. Concomitant medications included metoprolol tartrate (since 2005) as prophylaxis after stent replacement surgery to his heart, insulin (since 2010) for diabetes, and ursodeoxycholic acid (since 2015) for hepatic cirrhosis. On 05 Feb 2021 (Day 93), the subject presented to the emergency room with shortness of breath resulting in hospitalization with a prediagnosis of metabolic acidosis, pneumonia, subarachnoid hemorrhage, and liver cirrhosis. A computed tomography (CT) scan of the head and abdomen performed in the emergency room showed no pathological findings. A pulmonary CT angiography indicated that the pulmonary arteries were open. A CT scan of the thorax revealed parabronchial infiltration in the right lung and pleural effusion in both hemothoraces. A right internal jugular and hemodialysis catheter was inserted with an ultrasound. The subject was admitted to the intensive care unit and was sedated. A SARS-CoV-2 test result was negative. Left radial artery cannulation was performed. The subject was intubated by using midazolam + "vecibloc (as reported)." A total of 2 mg of adrenaline was administrated to the subject, who had cardiac arrest after intubation. The subject was being intubated in the intensive care unit. The subject's condition was rated as third degree. On 06 Feb 2021 (Day 94), the subject's general condition deteriorated, and a blood culture was positive for Escherichia coli; the subject's Acute Physiology and Chronic Health Evaluation (APACHE) II score was 31, his Glasgow coma score was 3, and he had a multiple organ failure score of 7 with an expected death rate of 79.6. During hospitalization, the subject received piperacillin sodium/tazobactam sodium from 05 Feb 2021 to 06 Feb 2021 and meropenem trihydrate from 06 Feb 2021 to 09 Feb 2021 for the pneumonia. On 07 Feb 2021 (Day 95), the subject's general condition further deteriorated, and he continued receiving mechanical ventilator support, being intubated in the intensive care unit (ICU). On 08 Feb 2021 (Day 96), the subject was found to have severe brainstem hypoxia and he was being intubated. On 09 Feb 2021 (Day 97), the subject's general condition further deteriorated and he developed cardiopulmonary asystole followed by hypotension, despite receiving inotropic supportive therapy. Cardiopulmonary resuscitation (CPR) was performed and 1 mg of adrenaline was administrated every 5 minutes. However, the subject was unresponsive to the CPR and he died of bacterial pneumonia that led to cardiac arrest. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the bacterial pneumonia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
155 cm	122.6 kg	51 kg/m2	01OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	1997	Present
Human Immunoviral Infection	HIV infection	2008	Present
hypertension	Hypertension	2010	Present
obesity	Obesity	2010	Present
Menopause	Menopause	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01OCT2020 (1)	14:05
2	Placebo	22OCT2020 (22)	11:42

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	COVID-19 pneumonia	Covid 19 Pneumonia	01JAN2021 (93)		05JAN2021 (97)	03:00	5
2	METAB	Diabetes mellitus	Diabetes Mellitus	28DEC2020 (89)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (05JAN2021)	NOT RELATED/OTHER: Unknown	2	72	Y
2	4	N	Y	Yes	NOT RELATED/OTHER: unknown	2	68	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01OCT2020	
Completed	VACCINATION	20NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	05JAN2021	DEATH

Narrative Comment
Subject C4591001 1229 12291083, a 55-year-old black or African American female with a pertinent medical history of asthma (since 1997), human immunodeficiency virus (HIV) infection (since 2008), and hypertension and obesity (both since 2010), received Dose 1 on 01 Oct 2020 and Dose 2 on 22 Oct 2020 (Day 22). The subject was diagnosed with diabetes mellitus on 28 Dec 2020, 68 days after receiving Dose 2. On 01 Jan 2021, the subject was diagnosed with COVID-19 pneumonia, 72 days after receiving Dose 2. The subject died of COVID-19 pneumonia on 05 Jan 2021, 75 days after receiving Dose 2. Concomitant medications included salbutamol and beclometasone dipropionate (both since 1997) for asthma; efavirenz/emtricitabine/tenofovir disoproxil fumarate (since 2008) for HIV infection; hydrochlorothiazide, amlodipine, and enalapril maleate (all since 2010) for hypertension; and atropine sulfate/chlorpheniramine maleate/ephedrine hydrochloride and amoxicillin trihydrate/clavulanate potassium (both from 17 Dec 2020 to Dec 2020) for sinusitis. On 01 Jan 2021 (Day 93), the subject presented to the emergency room with an elevated blood glucose level (values unavailable) and was subsequently hospitalized for type 2 diabetes mellitus (she had no previous history of the condition). She underwent further laboratory tests on 02 Jan 2021 (Day 94), including a SARS-CoV-2 polymerase chain reaction (PCR) test, which was positive. Other relevant laboratory test reports were unavailable. A SARS-CoV-2 PCR test was positive again on 04 Jan 2021 (Day 96) and the diagnosis of COVID-19 was confirmed. On 05 Jan 2021 (Day 97), the subject died and the cause of death was reported as disease progression and COVID-19 pneumonia. No autopsy was performed. A medical practitioner considered the primary cause of death to be COVID-19 pneumonia, with a secondary cause of type 2 diabetes mellitus. In the opinion of the investigator, there was no reasonable possibility that the diabetes mellitus and COVID-19 pneumonia were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1959	61	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
164 cm	61 kg	22.7 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Arterial hypertension	Hypertension	03MAR2017	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	25AUG2020 (1)	16:20
2	Placebo	13SEP2020 (20)	15:00

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	NERV	Haemorrhagic stroke	Hemorrhagic stroke	27SEP2020 (34)	09:00	28SEP2020 (35)		2

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	TC/W	Y	Fatal (28SEP2020)	NOT RELATED/OTHER: unknown	2	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Withdrawn	VACCINATION	28SEP2020	DEATH
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	28SEP2020	DEATH

Narrative Comment

Subject C4591001 1231 12313972, a 61-year-old white female with a pertinent medical history of hypertension (since 03 Mar 2017), received Dose 1 on 25 Aug 2020 and Dose 2 on 13 Sep 2020 (Day 20). The subject was diagnosed with a hemorrhagic stroke on 27 Sep 2020, 14 days after receiving Dose 2, and died of the event on 28 Sep 2020, 15 days after receiving Dose 2.

Concomitant medication included losartan (since 03 Mar 2017) for arterial hypertension.

On 27 Sep 2020 (Day 34), the subject contacted the medical team complaining of a severe headache and incoercible vomiting, and she was advised to call the emergency system. On 28 Sep 2020 at dawn (Day 35), she arrived at the emergency room unconscious (unknown Glasgow coma score) with nonreactive intermediate pupils. The subject was admitted to the intensive care unit, requiring invasive mechanical ventilation and inotropic support (unknown drugs and doses). A computed tomography scan of the brain showed subarachnoid hemorrhage, intraventricular hemorrhage, and right cerebral hemisphere hematoma (Fisher Scale 4). A brain angiography showed cerebral circulatory arrest, and therefore the location of the aneurysm could not be established. A SARS-CoV-2 swab polymerase chain reaction test was negative. The subject did not respond to life support measures and died of disease progression and hemorrhagic stroke on the same day. It was not reported if an autopsy was performed.

In the opinion of the investigator, there was no reasonable possibility that the hemorrhagic stroke was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	128 kg	42.3 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Smoking	Tobacco user	01JAN1993	Present
obesity	Obesity	2012	Present
Arterial hypertension	Hypertension	14MAR2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	20:30
2	Placebo	16SEP2020 (20)	13:51

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Cardio-respiratory arrest	Non-traumatic cardiorespiratory arrest	05DEC2020 (100)	21:00	06DEC2020 (101)	07:00	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (06DEC2020)	NOT RELATED/OTHER: unknown	2	81	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	06DEC2020	DEATH

Narrative Comment
Subject C4591001 1231 12314987, a 47-year-old white male with a pertinent medical history of tobacco use (since 01 Jan 1993), obesity (since 2012), and hypertension (since 14 Mar 2018), received Dose 1 on 28 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 20). The subject was diagnosed with a cardiorespiratory arrest on 05 Dec 2020, 80 days after receiving Dose 2, and died of the event the next day on 06 Dec 2020, 81 days after receiving Dose 2. Concomitant medications included losartan and amlodipine (both since 01 Mar 2019) for arterial hypertension. According to the subject's brother-in-law, on 05 Dec 2020 (Day 100), the subject had experienced abdominal discomfort, with an episode of vomiting, and also had back pain. On 06 Dec 2020 (Day 101), the subject was taken to a nearby hospital, but he had no vital signs on arrival at the hospital. That same day (Day 101), the subject died of nontraumatic cardiorespiratory arrest (also described as nontraumatic cardiac arrest). An autopsy was performed, but the results were not available at the time of this report. In the opinion of the investigator, there was no reasonable possibility that the cardiorespiratory arrest was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment considering the gap between the event and Dose 2, the pathophysiology of the event, and considering that the cardiorespiratory arrest was most likely related to the subject's underlying contributory factors.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	71.65 kg	29.1 kg/m2	29AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	29AUG2020 (1)	17:53
2	Placebo	18SEP2020 (21)	09:21

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	COVID-19	Severe Covid-19 illness	25DEC2020 (119)	19:00	31JAN2021 (156)	20:30	38	4
2	INFEC	Septic shock	Septic shock	25DEC2020 (119)	19:00	31JAN2021 (156)	20:30	38	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Fatal (31JAN2021)	NOT RELATED/OTHER: COVID-19 infection	2	99	Y
2	TC/TCN/W	Y	Fatal (31JAN2021)	NOT RELATED/OTHER: Severe Covid Disease	2	99	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	22OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	31JAN2021	DEATH

Narrative Comment
Subject C4591001 1231 12315324, a 58-year-old white female with no reported medical history, received Dose 1 on 29 Aug 2020 and Dose 2 on 18 Sep 2020 (Day 21). The subject had severe COVID-19 illness and developed septic shock on 25 Dec 2020, 98 days after receiving Dose 2, and died of the events on 31 Jan 2021, 155 days after study start. On 25 Dec 2020 (Day 119), the subject was febrile (maximum temperature of 38.4°C), and complained of cough, chills, and fatigue. Two local COVID-19 tests were performed, on 26 Dec 2020 (Day 120) and on 02 Jan 2021 (Day 127), with negative results. As part of the C4591001 study, a potential COVID-19 illness visit was also performed on 26 Dec 2020 and a nasal swab was collected at the site; the swab result was later reported as positive. On 05 Jan 2021 (Day 130) the subject was hospitalized because of bilateral pneumonia. A chest computed tomography (CT) scan on the same day showed extensive bilateral patchy foci of ground-glass interstitial infiltrates, dense tracts, and bronchiectatic-like images in both lower lobes. On 13 Jan 2021 (Day 138), a chest CT scan showed mediastinum slightly retracted to the left, without evidence of adenomegaly, and extensive, mixed (predominantly consolidated), bilateral parenchymal infiltrates were observed. On 14 Jan 2021 (Day 139), the subject was moved to the intensive care unit (ICU) and required a mechanical ventilator from 16 Jan 2021 (Day 141) because of respiratory failure. On 15 Jan 2021 (Day 140), a third local COVID-19 test was positive. On 31 Jan 2021 (Day 156), the subject died of septic shock in the context of the severe COVID-19 illness. The subject developed metabolic acidosis, acute renal failure with dialysis criteria, and marked cytopenias (anemia and thrombocytopenia). Laboratory results on an unknown date showed hemoglobin of 8.4 g/dL, hematocrit of 25%, leukocytes of 6000/mm3, neutrophils of 79%, platelets of 16,000/mm3, urea of 132 g/L, creatinine of 3.49 mg/dL, prothrombin time of 14.5 seconds, kaolin partial thromboplastin time (KPTT) of greater than 1 minute, Quick test result of 66%, lactate dehydrogenase of 4367 IU/L, direct bilirubin of 2.9 mg/dL, total bilirubin of 3.8 mg/dL, aspartate aminotransferase of 329 IU/L, alanine aminotransferase of 222 IU/L, alkaline phosphatase of 545 IU/L, albumin of 2.8 g/dL, pH of 7.06, partial pressure of carbon dioxide of 72 mmHg, partial pressure of oxygen of 37 mmHg, and bicarbonates of 20 mmol/L (unknown normal ranges). The subject required vasopressor support with norepinephrine (dose unknown) from 19 Jan 2021 (Day 144) onward. On 31 Jan 2021 (Day 156), the subject presented with severe bradycardia, followed by cardiac arrest. She received advanced resuscitation maneuvers (according to American Heart Association [AHA] protocol) for 30 minutes, without response. The causes of death reported on the death certificate were acute respiratory failure, multiorgan failure, and multilobar pneumonia. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the septic shock and severe COVID-19 illness were related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1939	80	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	75 kg	29.2 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2018	Present
Seasonal Allergies	Seasonal allergy	18APR2018	Present
Vertigo	Vertigo	02OCT2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	15:44
2	BNT162b2	08SEP2020 (23)	10:50

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RENAL	Acute kidney injury	Acute Renal failure	25DEC2020 (131)	22:03	26DEC2020 (132)	09:55	2
2	INFEC	COVID-19 pneumonia	Pneumonia due to COVID-19	25DEC2020 (131)	22:03	26DEC2020 (132)	09:55	2
3	INJ&P	Skin laceration	Scalp Laceration	08DEC2020 (114)	19:05	08DEC2020 (114)	20:30	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Resolved (26DEC2020)	NOT RELATED/OTHER: Kidney damage	2	109	N
2	4	TC/W	Y	Fatal (26DEC2020)	NOT RELATED/OTHER: Pneumonia	2	109	Y
3	1	TC	N	Resolved (08DEC2020)	NOT RELATED/OTHER: Accident	2	92	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	05OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	26DEC2020	DEATH

Narrative Comment
Subject C4591001 1252 12521010, an 80-year-old white male with a pertinent medical history of systolic congestive heart failure (since 2016); hypertension, hyperlipidemia, gastroesophageal reflux disease (GERD), and atrial fibrillation (all since Apr 2018); seasonal allergy (since 18 Apr 2018); hypokalemia (since Jul 2018); neuropathy and chronic back pain (both since Aug 2019); insomnia (since Sep 2019); and cerebrovascular accident (on 05 Aug 2020), received Dose 1 on 17 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 23). The subject was diagnosed with COVID-19 pneumonia on 25 Dec 2020, 108 days after receiving Dose 2. The subject died of COVID-19 pneumonia on 26 Dec 2020, 109 days after receiving Dose 2. Concomitant medications included tramadol (since 2018) for chronic back pain, amiodarone (since Apr 2018) for atrial fibrillation, bumetanide (since Apr 2018) for fluid retention, carvedilol (since Apr 2018) for hypertension, ropinirole (since 2019) for restless legs syndrome, ondansetron (since 2019) for nausea, amlodipine (since Jun 2019) for hypertension, trazodone (since Sep 2019) for insomnia, simvastatin (since 2020) for hyperlipidemia, benazepril/hydrochlorothiazide (since 17 Mar 2020) for hypertension, chlorthalidone (since 29 Jun 2020) for congestive heart failure, apixaban (since Jul 2020) for cerebrovascular accident, omeprazole (since Jul 2020) for GERD, potassium chloride (since 03 Aug 2020) as a supplement, sacubitril valsartan sodium hydrate (since 05 Aug 2020) for chronic heart failure, and sulfamethoxazole/trimethoprim (from 07 Dec 2020 to 17 Dec 2020) for lower leg wound. On 25 Dec 2020 (Day 131), the subject complained of garbled speech and increased confusion, and he was taken to the emergency room (ER). The subject's family reported that he was in rehabilitation care from 15 Dec 2020 (Day 121) to 23 Dec 2020 (Day 129) for a scalp laceration (on Day 114) due to a fall from a chair. The subject had experienced difficulty with ambulation and, hence, physical and occupational therapy was provided. He also had shortness of breath and chest congestion, but denied having fever, chills, nausea, vomiting, or diarrhea. A COVID-19 test on 14 Dec 2020 was negative. On arrival at the ER on 25 Dec 2020 (Day 131), the subject's blood pressure (BP) was 124/68 mmHg, body temperature was 36.8°C, heart rate was 79 beats/min, respiratory rate was 20 breaths/min, and oxygen saturation was 98%. On the same day (Day 131), a SARS-CoV-2 test was positive; laboratory test results showed elevated aspartate aminotransferase of 819 IU/L, estimated glomerular filtration rate of 13 mL/min, low hemoglobin of 9.2 g/dL, elevated international normalized ratio of 2.26, low lymphocytes of 8.8 (units not reported), and low platelets of 125 µL (normal ranges were not reported); a chest x-ray showed bilateral airspace disease (cardiomegaly with congestive heart failure); and a computed tomography scan of the brain was normal. The subject was diagnosed with COVID-19 pneumonia, which was considered life-threatening by the investigator. On an unspecified date in Dec 2020, the laboratory results showed blood urea nitrogen (BUN) of 91, creatinine of 4.1, BUN/creatinine ratio of 21.9 (normal ranges and units were not reported), and C-reactive protein of 24.7 mg/dL (normal range was not reported). The subject was not in any cardiopulmonary distress, but had acute kidney injury (on Day 131) secondary to acute tubular necrosis from the underlying COVID-19 infection. It was reported that there was no need for any dialysis at that time. Treatment with benazepril/hydrochlorothiazide and bumetanide was withheld because of the acute kidney injury and because the subject's baseline renal function results were unknown. On an unspecified date in Dec 2020, the subject was kept in isolation, during which his oxygen saturation was 96% on room air. The subject was on telemetry and continued to do poorly. The family stated that the subject had a do-not-resuscitate status. Over the short stay in the telemetry unit, his oxygen saturation dropped to 83% and the subject was given 6 liters of oxygen via nasal cannula. He continued to have dyspnea and became unresponsive. He was treated in the ER with dexamethasone and ipratropium/albuterol (both from 25 Dec 2020 to 26 Dec 2020) for COVID-19 pneumonia. On 26 Dec 2020 (Day 132), the subject died of COVID-19 pneumonia. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the COVID-19 pneumonia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	25	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	81.82 kg	25.1 kg/m2	30JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Migraines	Migraine	2005	Past
Seasonal Allergies	Seasonal allergy	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30JUL2020 (1)	10:23

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	20AUG2020 (22)	09:56
3	BNT162b2	02FEB2021 (188)	13:18
4	BNT162b2	22FEB2021 (208)	13:29

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	MUSC	Psoriatic arthropathy	psoriatic arthritis	26SEP2020 (59)	06:00	ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			2	TC	Y	Yes	Study Treatment	2	38	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30JUL2020	
Completed	VACCINATION	23SEP2020	
Completed	REPEAT SCREENING 1	02FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1003 10031111, a 25-year-old white male with a pertinent medical history of seasonal allergy (since 2010), received Dose 1 on 30 Jul 2020 (Day 1) and Dose 2 on 20 Aug 2020 (Day 22), both in the left deltoid. The subject was diagnosed with psoriatic arthropathy on 26 Sep 2020, 37 days after receiving Dose 2. Concomitant medication included loratadine (since 2010) for seasonal allergies. On an unspecified date, the subject was asymptomatic and came to the site for the 1-month post–Dose 2 visit and had his blood drawn for the immunogenicity assessment. After a few days, the subject developed swelling and pain in the left elbow that made it painful to externally rotate the elbow joint. About a week later, the subject experienced pain and swelling in his right foot, primarily the dorsum of the foot and the second and third toes. He also developed pain and swelling of the left index finger in the shaft area of the proximal interphalangeal (PIP) joints. The swelling was present in the morning and abated at night. The subject had no fever, chills, or night sweats, and no other joints were involved. He also had no prior history of arthritis or tenosynovitis and no recent history of urethral pain on urination, but he had a family history of rheumatoid arthritis (grandmother). On physical examination (date not specified), the subject's left elbow was not warm or swollen, the index finger of the left hand was not swollen or tender to motion, the right foot was not warm but was swollen in the dorsal area, the second and third toes were diffusely swollen (sausage toes) without pain, and there was no joint pain. There

was no sign of a tick bite or rash, and there was no adenopathy in the epitrochlear or axillary area. The site's clinical impression was tenosynovitis of the second and third right toes, resolving tenosynovitis of the left index finger, and possible tenosynovitis of the left elbow. Laboratory results showed an erythrocyte sedimentation rate (ESR) of 2, C-reactive protein (CRP) of 0.168, white blood cell (WBC) count of 5.7, hemoglobin (Hgb) of 16.6, platelet count of 1.61, and lymphocyte count of 1.0 (units and normal ranges were not reported for all); and rheumatoid factor and Lyme serology tests were both negative.

The subject saw his primary care physician, who referred him to a rheumatologist for evaluation (date not specified). The subject was diagnosed with reactive arthritis. On 13 Nov 2020 (Day 107), laboratory investigations showed a CRP of 0.777 and ESR of 14 (normal range: 0-20); cyclic citrullinated peptide, rheumatoid factor, and human leukocyte antigen B27 assay tests were all negative; and urinalysis was normal. On the same day (Day 107), the subject was prescribed prednisone 30 mg for 5 days, followed by tapering doses of 20 mg for 5 days and 10 mg for the next 5 days. On 24 Nov 2020 (Day 118), following treatment with prednisone, the subject reported improvement in the foot swelling but continued to have swelling in the second and third digits of his right foot, in his left index finger, and in his left elbow. The subject continued to have significant joint pain in the left elbow and in the index finger, resulting in limited sports activities, but he continued to work. On 25 Nov 2020 (Day 119), x-ray results of both hands and the right foot were normal. Since his last visit to the site, the subject had several appointments with a rheumatology/immunology consultant and had undergone several laboratory tests; the most notable was the slight rise in ESR to 14 from a prior value of 2, as well as an increase in CRP to 1.53 from 0.168, with unremarkable complete blood count and basic metabolic panels.

On 11 Dec 2020 (Day 135), the subject had an unscheduled visit to the site. At this visit, the swelling in his right foot and the second and third toes had resolved; his right index finger remained tender with movement of the PIP and distal interphalangeal joints; and his left elbow was more symptomatic with increased pain, swelling, and limited range of motion. On this day (Day 135), the WBC count was 5.50, platelet count was 23,3000, and Hgb was 16.3 (units not reported for all); neutrophils were 70.6%, lymphocytes were 18.6%, and eosinophils were 2.2%; aspartate aminotransferase, alanine aminotransferase, blood electrolytes, blood urea nitrogen, and blood creatinine were all normal. A left elbow x-ray result was normal. The subject had also developed several new patchy, scaly cutaneous lesions above his right eyebrow, hairline, and scalp; and there were no cutaneous lesions on his trunk or extremities. The rheumatologist's tentative clinical diagnosis was psoriatic arthropathy. As the subject had limited ability to carry out prior activities, the investigator assessed the psoriatic arthropathy as a serious adverse event of special interest. The subject was treated with leflunomide 10 mg orally (PO) (from 11 Dec 2020 to 21 Jan 2021), sulfasalazine 1000 mg PO twice a day (since 21 Jan 2021), and ibuprofen 400 mg PO 2 to 3 times a day as needed (since 13 Nov 2020). The psoriatic arthropathy was ongoing at the time of the last available report.

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 02 Feb 2021 (Day 188) and 22 Feb 2021 (Day 208), respectively, and remains in the study.

In the opinion of the investigator, there was a reasonable possibility that the psoriatic arthropathy was related to the study intervention and clinical trial procedure (blood draw) but was not related to the concomitant medication. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	Asian	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	65.91 kg	26.5 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Migraines	Migraine	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	17:01
2	BNT162b2	09SEP2020 (24)	15:20

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	EYE	Corneal irritation	Right corneal irritation	17AUG2020 (1)	22:54	20AUG2020 (4)		4
2	GENRL	Shoulder injury related to vaccine administration	SIRVA - shoulder injury related to vaccine administration	09SEP2020 (24)	18:00	08FEB2021 (176)		153

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	N	N	Resolved (20AUG2020)	NOT RELATED/OTHER: Contact lens wear	1	1	N
2	3	N	Y	Resolved (08FEB2021)	Study Treatment	2	1	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1015 10151047, a 30-year-old Asian female with no pertinent medical history, received Dose 1 on 17 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 24), both in her left deltoid. The subject experienced a shoulder injury related to vaccine administration (SIRVA) on 09 Sep 2020 (Day 24), on the same day as Dose 2. Concomitant medication included cetirizine hydrochloride for allergies (since an unknown date). On 09 Sep 2020 (Day 24), after Dose 2 administration and late in the evening, the subject experienced pain in the left arm. She noted that the adhesive bandage from Dose 2 was very high on her arm and experienced some soreness of her upper arm with very limited range of motion for the first few days and burning pain down her arm. Initially, she also had a tingling sensation down her arm; however, this resolved. On 15 Sep 2020 (Day 30), the subject had a sensation of numbness, which affected her arm and hand, with a sensation of loss of dexterity, notable when typing. The subject reported that her condition was improving gradually, especially in terms of pain, but she still had a significant limitation in range of motion and daily activities. On examination, she had no obvious swelling, color change, bruising, or tenderness over the left deltoid. She could raise her left arm slightly higher than 90 degrees and with assistance could lift higher, but this caused significant discomfort; she could not extend her left arm behind her back well. The strength was noted to be 5/5. When moving her arm against resistance, she experienced pain down her arm and increased sensation of numbness. The investigator reported a possible diagnosis of SIRVA that was considered an important medical event. The subject was aware that the shoulder injury could be self-limited but could last for some time and was considering physical therapy as an option. The investigator suggested a neurology consultation and also discussed arrangements for physical therapy. The subject was seen by a neurologist, who noted the following findings: motor function had normal muscle bulk and tone. No apparent fasciculation or scapular winging was noted. Shoulder abduction was limited to 70 degrees, shoulder internal rotation was limited as well, but she was able to extend her left hand behind her back. The neurologist considered 2 diagnoses: SIRVA and immune-mediated brachial plexus neuropathy (Parsonage-Turner syndrome), noting that the clinical picture demonstrated components of both. An electromyography (EMG) was recommended to determine if there was nerve involvement and, if so, to what degree. At the time of the neurological evaluation, the subject had started physical therapy. On 02 Oct 2020 (Day 47), a needle EMG of the left upper extremity for all muscles was performed and was reported to be unremarkable. The deltoid sample was not collected because of the suspected prior injury to the area. It was reported that since onset, both the pain and limitation in range of motion had improved at this time; additionally, there was great improvement in the shoulder and upper arm, but less so in the hand or fingers. The EMG results did not reveal any neurophysiological evidence of a left brachial plexopathy, median dysfunction at the left wrist, ulnar dysfunction across the left elbow, or left cervical radiculopathy. On 07 Oct 2020 (Day 52), the neurologist considered SIRVA as the diagnosis, most likely based on the clinical improvement and the EMG result that did not reveal nerve involvement. The subject reported continued improvement, especially of the upper arm, with increased range of motion, but continued to experience decreased dexterity of the left hand. The subject was attending physical therapy twice weekly and reported satisfaction with the gradual and continued improvement. On 03 Nov 2020 (Day 79), the subject reported that 5 weeks of physical therapy had been completed and that the improvement was significant, but that she was not back to her usual state of health. Later, after completing physical therapy, she felt much better and had returned to baseline state of health, and the SIRVA was considered resolved on 08 Feb 2021 (Day 176). In the opinion of the investigator, there was a reasonable possibility that the SIRVA was related to the study intervention and to a clinical trial procedure (vaccine administration), but not related to concomitant medications. Pfizer concurred with the investigator's causality assessment. Additionally, it appears that the vaccine was erroneously administered into or near the shoulder joint capsule. As postulated in the medical literature, unintentional injection of vaccines into the shoulder joint synovial tissues may result in an immune-mediated inflammatory reaction causing SIRVA.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	62.27 kg	19.9 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obstructive breathing due to deviated septum	Nasal septum deviation	(b) (6) 1967	Past
benign cyst removed	Cyst removal	1993	Past
Fibrocystic Breast Disease	Fibrocystic breast disease	1993	Past
Migraines once or twice a month	Migraine	2008	Present
Chronic Neck Pain	Neck pain	2008	Present
Rhinoplasty	Rhinoplasty	2008	Past
Breast augmentation	Mammoplasty	2010	Past
Vitamin D deficiency	Vitamin D deficiency	2013	Past
right shoulder dislocation	Joint dislocation	2014	Past
Occipital Neuralgia R>L	Occipital neuralgia	2014	Present
Right Shoulder Repair	Shoulder operation	2014	Past
Rhinoplasty	Rhinoplasty	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14AUG2020 (1)	11:33
2	BNT162b2	04SEP2020 (22)	16:07

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	NERV	Paraesthesia	Right Leg Paresthesia	20OCT2020 (68)		ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			2	TC	Y	Yes	Study Treatment	2	47	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1018 10181159, a 53-year-old white female with a pertinent medical history of osteopenia and vitamin B_{12} deficiency (dates unknown), vitamin D deficiency (from 2013 to 2014), migraine and neck pain (both since 2008), joint dislocation (right shoulder) and shoulder operation (both in 2014), and occipital neuralgia (since 2014), received Dose 1 on 14 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 22). The subject experienced right leg paresthesia on 20 Oct 2020, 46 days after receiving Dose 2. Concomitant medications included zolmitriptan (since 2008) for migraines and vitamin D (since 2013) as a supplement. On 20 Oct 2020 (Day 68), the subject began experiencing right leg paresthesia. On 28 Oct 2020 (Day 76), she had a nasal/sinus operation and received codeine phosphate/paracetamol for 3 days. On 02 Nov 2020 (Day 81), she had lower back pain and bilateral lower extremity pain that was described as shooting pain, worse on the right side. Her legs and parietal area of the scalp were sensitive to touch, with an associated burning pain. She also reported tenderness in the bilateral inguinal area. The symptoms had gradually developed over approximately the past 3 weeks. The subject's spine magnetic resonance imaging (MRI) was unremarkable; and the subject did not

Narrative Comment
consult her primary care physician or a neurologist at that time. The subject denied any neurological or lower back problems. She stated that when she began experiencing the symptoms, her pain score was assessed as 8-9 on a scale of 10 for a couple of weeks and she used analgesics. She also reported that there had been a significant decrease in her level of activity. On 10 Nov 2020 (Day 89), during a follow-up visit with the investigator, the subject reported that the paresthesia and skin sensitivity over the parietal area had improved. The subject reported that she used paracetamol, ibuprofen, and codeine phosphate/paracetamol initially, and later received celecoxib. After treatment with analgesics, her pain score at its worst was 6-7 on a scale of 10. She continued to use analgesics daily and was able to function adequately despite persistence of mild (1-2/10 in severity) constant pain in her lower back and legs. The subject also reported that she had not noticed any exacerbating factors and denied any recent injury, travel, infection, or change in diet. On 10 Nov 2020 (Day 89), the subject reported that she walked approximately 1 mile without any problem. Despite still not having an official diagnosis, the investigator opted to report this as an important medical event since symptoms had persisted and the subject believed the symptoms started closer to 5 weeks after vaccination, which was close to the 4-week postvaccination observation period. The site obtained the medical records from the neurologist and the subject was seen on 06 Nov 2020 (Day 85). As per the neurologist's note, an MRI of the cervical spine performed several years before showed mild degenerative changes and spondylosis. The MRI of the lumbar spine performed recently showed "degenerative discopathy with small left central disc protrusion at T5-T6 with minimal indentation thecal sac. No spinal cord compression, spinal canal stenosis, or neural foramina narrowing was observed. Multilevel hypertrophic changes of the facets within the lumbar spine with no neural foramina stenosis was noted. An incidental finding revealed multilevel small hemangiomas in the cervical and thoracic vertebral bodies." A neurological examination on the same day (Day 85) was normal, including gait and tandem walk. Tenderness was noted throughout the lower extremity musculature bilaterally and large mobile inguinal lymph nodes were palpable bilaterally. The laboratory tests ordered by the neurologist were normal, including vitamin B_{12}: 635 pg/mL (normal range [NR]: 200-960 pg/mL), folate: 19.6 µg/L (NR: ≥6.0 µg/L), vitamin D 25-hydroxy: 33 ng/mL (NR: 30-100 ng/mL), total creatine phosphokinase: 45 U/L (NR: 28-176 U/L), erythrocyte sedimentation rate: 15 mm/hour (NR: 0-20 mm/hour), C-reactive protein: 0.3 mg/dL (NR: <0.5 mg/dL), serum aldolase: 3.9 U/L (NR: 1.5-7.2 U/L), thyroid-stimulating hormone: 1.130 µIU/mL (NR: 0.400-4.100 µIU/mL), free thyroxine: 1.42 ng/dL (NR: 0.80-1.90 ng/dL), Lyme antibody: 0.25 (negative less than 0.9; units not reported); antinuclear antibody was negative, serum protein electrophoresis was normal, and no monoclonal protein was seen. Imaging study reports were not available; the neurologist's impression included possible postviral syndrome or an autoimmune process. There was no mention of concern for myelitis or any plan for further workup. The neurologist's recommendation was to continue celecoxib, as needed, and follow up with the primary care physician if laboratory results were unrevealing. It was planned to have the subject return to the clinic to obtain more in-depth history and possibly some laboratory tests as well as request reports of MRIs. The right leg paresthesia was ongoing at the time of the last available report. In the opinion of the investigator, there was a reasonable possibility that the right leg paresthesia was related to the study intervention, but not related to concomitant medications or clinical trial procedures. Pfizer did not assess the right leg paresthesia as related to the study intervention and considered that there is not enough evidence to establish a causal relationship with the study vaccine apart from a chronological association at the time of the report. Based on the information currently available, it was more likely that the right leg paresthesia was associated with the subject's underlying known neurological conditions.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2003	17	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.83 cm	59.45 kg	22.1 kg/m2	20NOV2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
asthma	Asthma	2003	Present
eczema	Eczema	2003	Present
tree nuts allergy	Food allergy	2004	Present
peanuts allergy	Food allergy	2004	Present
legumes allergy	Food allergy	2004	Present
flaxseed allergy	Food allergy	2004	Present
chickpeas allergy	Food allergy	2004	Present
seasonal allergies oak	Seasonal allergy	2004	Present
pollen allergy	Seasonal allergy	2007	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin allergy	Drug hypersensitivity	2010	Present
bronchoscopy	Bronchoscopy	2016	Past
right hand neuropathy	Neuropathy peripheral	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20NOV2020 (1)	17:04
2	Placebo	15DEC2020 (26)	15:16
3	BNT162b2	25JAN2021 (67)	16:50

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	IMMUN	Anaphylactoid reaction	Anaphylactoid Reaction	27JAN2021 (69)	10:30	27JAN2021 (69)	11:24

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	4	TC/P	Y	Resolved (27JAN2021)	Study Treatment	3	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20NOV2020	
Completed	VACCINATION	12JAN2021	
Completed	REPEAT SCREENING 1	25JAN2021	
Withdrawn	OPEN LABEL TREATMENT	27JAN2021	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1129 11291260, a 17-year-old white female with a pertinent medical history of asthma and eczema (both since 2003), food allergy (allergies to flaxseed, chickpeas, legumes, peanuts, and tree nuts, all since 2004; chocolate allergy since 2012), seasonal allergy (allergy to oak since 2004 and pollen allergy since 2007), and drug hypersensitivity (penicillin allergy since 2010), received Dose 1 on 20 Nov 2020 and Dose 2 on 15 Dec 2020 (Day 26), both in the left deltoid. Concomitant medications included epinephrine (since 2005) for penicillin and food allergies, cetirizine hydrochloride and loratadine (both since 2007) for pollen allergy, triamcinolone acetonide (since 2007) for eczema, and salbutamol sulfate (since 2010) for asthma. In accordance with the protocol allowance, this subject was unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 25 Jan 2021 (Day 67), administered in the left deltoid. The subject experienced anaphylactoid reaction on 27 Jan 2021, 2 days after receiving the first dose of BNT162b2. On 27 Jan 2021 (Day 69), at 1030 hours, the subject developed hives on the left arm and self-administered her epinephrine pen at 1054 hours. Shortly after that, at 1100 hours, she developed shortness of breath. She denied any other symptoms and confirmed no exposure to allergens prior to these events. She was not evaluated by the school nurse nor did she seek further medical attention. The investigator considered the anaphylactoid reaction as life-threatening given the history of experiencing similar symptoms and anaphylaxis reaction with tree nuts. On the same day (Day 69), the hives resolved at 1104 hours and the shortness of breath resolved around 1124 hours, and the anaphylactoid reaction was considered resolved. The subject was discontinued from the study intervention on 27 Jan 2021 because of the anaphylactoid reaction and remains in the study. In the opinion of the investigator, there was a reasonable possibility that the anaphylactoid reaction was related to BNT162b2, but not related to Doses 1 and 2 of study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	71	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	60.09 kg	22 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergy to penicillin	Drug hypersensitivity	1970	Present
breast cancer	Breast cancer	1992	Past
(R) breast reconstruction	Breast reconstruction	1992	Past
(R) mastectomy	Mastectomy	1992	Past
Atrioventricular block, complete	Atrioventricular block complete	1996	Present
Cardiac pacemaker in situ	Cardiac pacemaker insertion	1996	Present
Sinoatrial Node Dysfunction	Sinus node dysfunction	27JUN2012	Present
Paroxysmal Atrial Fibrillation	Atrial fibrillation	08APR2015	Present
Paroxysmal supraventricular tachycardia	Supraventricular tachycardia	11MAY2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21SEP2020 (1)	10:03
2	BNT162b2	14OCT2020 (24)	15:16

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	CARD	Ventricular arrhythmia	Ventricular arrhythmias	14OCT2020 (24)		21OCT2020 (31)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	8	3	TC	Y	Resolved (21OCT2020)	Study Treatment	2	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Completed	VACCINATION	16NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1142 11421247, a 71-year-old white female with a pertinent medical history of complete atrioventricular block and cardiac pacemaker insertion (both since 1996), sinus node dysfunction (since 27 Jun 2012), atrial fibrillation (since 08 Apr 2015), and supraventricular tachycardia (since 11 May 2015), received Dose 1 on 21 Sep 2020 and Dose 2 on 14 Oct 2020 (Day 24). The subject experienced ventricular arrhythmia on 14 Oct 2020, on the same day as Dose 2. Concomitant medications included fluticasone propionate (since 30 Jun 2010) for allergic rhinitis, cetirizine hydrochloride (since 03 Nov 2010) for allergic rhinitis, atorvastatin (since 22 Feb 2013) for hyperlipidemia, duloxetine hydrochloride (since 17 Sep 2014) for an unknown indication, metoprolol succinate (since 08 Apr 2015) for paroxysmal supraventricular tachycardia, apixaban (since 28 Dec 2015) for atrial fibrillation, and alendronate sodium (since 03 Sep 2019) for osteoporosis. In the evening of 14 Oct 2020 (Day 24) at 2308 hours, the subject's pacemaker recorded nonsustained ventricular tachycardia (NSVT) with an average heart rate of 134 beats per minute (bpm), lasting 8 seconds. On 15 Oct 2020 (Day 25) at 0956 hours, the pacemaker recorded NSVT with an average heart rate of 199 bpm, lasting 15 seconds. On 16 Oct 2020 (Day 26) at 1854 hours, the pacemaker recorded NSVT with an average heart rate of 164 bpm, lasting 9 seconds. On 17 Oct 2020 (Day 27) at 1308 and 1322 hours, the subject had 2 episodes of NSVT with average heart rates of 185 bpm and 194 bpm, lasting 9 seconds and 8 seconds, respectively. On 18 Oct 2020 (Day 28) at 1308 hours, the subject had an episode of NSVT with an average heart rate of 174 bpm, lasting 9 seconds. The subject reported fatigue and general malaise during the NSVT episodes. On 20 Oct 2020 (Day 30), the subject reported to the site that she experienced subsequent episodes of ventricular tachycardia as noted above and that her cardiologist recommended placement of a defibrillator. Relevant laboratory test results on 21 Oct 2020 (Day 31) included troponin I of 0.016 ng/mL (normal range [NR]: 0-0.034 ng/mL), creatine kinase (CK) of 98 U/L (NR: 33-194 U/L), CK-MB of 2.76 ng/mL (NR: 0-3.50 ng/mL), CK-MB index of 2.8% (NR: 0%-2.5%), sodium of 140 mmol/L (NR: 135-145 mmol/L), potassium of 4.5 mmol/L (NR: 3.5-5.0 mmol/L), chloride of 104 mmol/L (NR: 98-108 mmol/L), carbon dioxide of 26 mmol/L (NR: 23-31 mmol/L), and anion gap of 10 (NR: 2-16; units not reported). According to her cardiologist, the CK-MB index result was within acceptable limits and the other test results were also normal. The ventricular arrhythmia was considered resolved on 21 Oct 2020 (Day 31). On 27 Oct 2020 (Day 37), the COVID-19 polymerase chain reaction molecular test and SARS-CoV-2 immunoglobulin G (IgG) antibody test results were negative. An electrophysiology study on 29 Oct 2020 (Day 39) showed no evidence of sustained VT/pmVT/VF (ventricular tachycardia/polymorphic ventricular tachycardia/ventricular fibrillation); however, brief paroxysms of pmVT were seen "with aggressive phase of electrical stimulation protocol at 400/260/200/200," which was nonspecific. No indication for an implantable cardioverter-defibrillator was observed. In the opinion of the investigator, there was a reasonable possibility that the ventricular arrhythmia was related to the study intervention based on the temporal relationship since the arrhythmias began within 24 hours of Dose 2, but not related to concomitant medications or clinical trial procedures. Pfizer did not assess the ventricular arrhythmia as related to the study intervention. Additionally, Pfizer commented that there was not enough evidence to establish a causal relationship with the study intervention apart from a chronological association at the time of this report. In the absence of evidence for an inflammatory response to study intervention, it was more likely that the ventricular arrhythmia was associated with the subject's underlying known cardiac conditions.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	113.64 kg	36.9 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	1977	Present
sinus headache	Sinus headache	1977	Present
pitocin allergy	Drug hypersensitivity	1998	Present
benign paroxysmal vertigo	Vertigo positional	1998	Present
menorrhagia	Menorrhagia	2003	Past
uterine fibroids	Uterine leiomyoma	2003	Past
hysterctomy	Hysterectomy	2005	Past
osteoarthritis, bilateral knees and feet	Osteoarthritis	2015	Present
eczema	Eczema	2017	Present

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	13:38

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	chills	05SEP2020 (2)	18:00	05SEP2020 (2)	20:00
2	GENRL	Injection site erythema	injection site redness	04SEP2020 (1)	19:00	05SEP2020 (2)	19:00
3	GENRL	Injection site pain	injection site muscle soreness	04SEP2020 (1)	19:00	06SEP2020 (3)	
4	GENRL	Injection site warmth	injection site warmth	04SEP2020 (1)	19:00	05SEP2020 (2)	19:00
5	BLOOD	Lymphadenopathy	right axilla lymphadenopathy	16SEP2020 (13)		20NOV2020 (78)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	TC	N	Resolved (05SEP2020)	Study Treatment	1	2	N
2	2	1	N	N	Resolved (05SEP2020)	Study Treatment	1	1	N
3	3	2	N	N	Resolved (06SEP2020)	Study Treatment	1	1	N
4	2	1	N	N	Resolved (05SEP2020)	Study Treatment	1	1	N
5	66	2	TC/P	Y	Resolved (20NOV2020)	Study Treatment	1	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Withdrawn	VACCINATION	25SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1178 11781107, a 48-year-old white female with a pertinent medical history of drug hypersensitivity to Pitocin, received Dose 1 on 04 Sep 2020 in her left deltoid. The subject was diagnosed with lymphadenopathy on 16 Sep 2020, 12 days after receiving Dose 1. Concomitant medications included ibuprofen (since 2000) for headache and osteoarthritis, cetirizine hydrochloride (since 2015) for seasonal allergies, and crisaborole (since 2017) for eczema. On 04 Sep 2020 (Day 1), approximately 6 hours after Dose 1 administration, the subject reported mild injection site erythema and warmth and moderate injection site pain. On 05 Sep 2020 (Day 2), she reported mild chills. That same day (Day 2), the injection site erythema, warmth, and chills were considered resolved, and on 06 Sep 2020 (Day 3), the injection site pain resolved. On 16 Sep 2020 (Day 13), the subject reported discomfort in her right arm, shoulder, and chest region, which she described as feeling like a pulled muscle, even at rest. Additionally, the subject reported that her physician referred her to the regional hospital emergency room (ER) for further evaluation. On 20 Sep 2020 (Day 17), the subject visited the ER, at which time her right axilla was examined, and a subsequent ultrasound examination of the right axilla on the same day revealed at least 4 enlarged lymph nodes; the largest was 2.5 × 1.1 × 2.4 cm. The laboratory results on the same day showed a white blood cell count of 7.0 k/µL (normal range [NR]: 4.0-10.0 k/µL) with 35.2% lymphocytes (NR: 20%-40%), and an absolute lymphocyte count of 2.4 k/µL (NR: 1.0-4.0 k/µL). The subject denied any injuries, cuts, or puncture wounds to the right arm or having had a similar problem previously. It was reported that no other areas other than the right axilla were assessed for lymphadenopathy. The subject received ketorolac 10 mg intravenously once (on 20 Sep 2020) while in the ER for lymphadenopathy. The lymphadenopathy was considered medically significant by the investigator. A biopsy was completed on 05 Oct 2020 (Day 32) without issue. On 12 Oct 2020 (Day 39), the subject communicated via telephone the results of her workup, stating that her blood tests returned to normal and the biopsy showed no markers for lymphoma or other cancer. Per subject report, the oncologist considered the vaccine as the most likely etiology for her lymphadenopathy. The lymphadenopathy was considered resolved on 20 Nov 2020 (Day 78). A follow-up oncological visit was planned in 3 months with a possible repeat of the axillary ultrasonography. The subject was scheduled to have a follow-up visit and ultrasound examination on 29 Dec 2020 (Day 117). The subject was discontinued from the study intervention on 25 Sep 2020 because of the lymphadenopathy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the lymphadenopathy was related to the study intervention, but not related to concomitant medications or clinical trial procedures. Pfizer did not assess the lymphadenopathy as related to the study intervention and considered that there was not enough evidence to establish a causal relationship with the study intervention apart from a chronological association at the time of this report. It was also noted that the subject received the study intervention in the left deltoid and the lymphadenopathy was in the right axillary area.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1979	41	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
174 cm	83.4 kg	27.5 kg/m2	04NOV2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	04NOV2020 (1)	10:35
2	BNT162b2	25NOV2020 (22)	11:07

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	MUSC	Myalgia	mild muscle pain	15JAN2021 (73)	02:00	19JAN2021 (77)	16:08	5
2	CARD	Myocardial infarction	Heart Attack	03FEB2021 (92)	02:00	03FEB2021 (92)	08:00	1

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (19JAN2021)	NOT RELATED/OTHER: workout	2	52	N
2	4	TC/TCN	Y	Resolved (03FEB2021)	Study Treatment	2	71	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04NOV2020	
Completed	VACCINATION	23DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1212 12121024, a 41-year-old white male with no reported medical history, received Dose 1 on 04 Nov 2020 and Dose 2 on 25 Nov 2020 (Day 22). The subject was diagnosed with a myocardial infarction on 03 Feb 2021, 70 days after receiving Dose 2.

On 02 Feb 2021 (Day 91), the subject presented to the emergency room (ER) with chest pain, numbness in the left arm, and anxiety. The laboratory tests showed normal values of high-sensitivity troponin of 10.01 ng/L (normal range [NR]: 0-34.2 ng/L) and creatine phosphokinase MB of 14 IU/L (NR: 0-24 IU/L) at that time. An electrocardiogram was normal; however, the high-sensitivity troponin values approximately after 4 and 6 hours were elevated at 139 ng/L and 282.2 ng/L, respectively.

On 03 Feb 2021 (Day 92), the subject was hospitalized because of a non-ST myocardial infarction, diagnosed by a cardiologist. A coronary angiography showed slow flow, and a plaque was detected in the left descending artery. On the same day (Day 92), the subject was started on treatment with enoxaparin sodium 0.6 (units not reported), aspirin 100 mg daily, atorvastatin 20 mg daily, metoprolol 50 mg daily, and ramipril twice a day. On 03 Feb 2021 (Day 92), the myocardial infarction was considered resolved. The myocardial infarction was considered as life-threatening by the investigator. Discharge information was not reported at the time of this report.

In the opinion of the investigator, there was a reasonable possibility that the myocardial infarction was related to the study intervention, but not related to clinical trial procedures. The investigator additionally stated that it was difficult to state if the myocardial infarction was related or unrelated to the study intervention, as the subject described himself as healthy, with no cardiac disease, cardiac complaint, or coronary obstruction before study intervention, and no family history of heart disease. Pfizer did not concur with the investigator's causality assessment and considered the event not related to study intervention, concomitant medications, or clinical trial procedures based on the finding of slow flow and plaque in the left descending coronary artery and the temporal latency of 2 months 8 days.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	110.82 kg	37.1 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
MENOPAUSE	Menopause	1994	Present
HIGH CHOLESTEROL	Blood cholesterol increased	2000	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2000	Present
HIGH BLOOD PRESSURE	Hypertension	2000	Present
SWELLING OF FEET	Peripheral swelling	2000	Present
DEPRESSION	Depression	2015	Present
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2018	Present
TYPE II DIABETES	Type 2 diabetes mellitus	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03SEP2020 (1)	15:14

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GENRL	Facial pain	FACIAL TENDERNESS	06SEP2020 (4)		16SEP2020 (14)		11	2	TC/P	N
2	GENRL	Injection site pain	INJECTION SITE PAIN	04SEP2020 (2)		07SEP2020 (5)		4	2	N	N
3	GENRL	Swelling face	FACIAL SWELLING	06SEP2020 (4)		16SEP2020 (14)		11	2	TC/P	N
4	INFEC	Upper respiratory tract infection	UPPER RESPIRATORY INFECTION	06SEP2020 (4)		16SEP2020 (14)		11	2	TC	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (16SEP2020)	NOT RELATED/OTHER: ALLERGIC REACTION TO UNKNOWN AGENT	1	4	Y
2	Resolved (07SEP2020)	Study Treatment	1	2	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	Resolved (16SEP2020)	NOT RELATED/OTHER: ALLERGIC REACTION TO UNKNOWN AGENT	1	4	Y
4	Resolved (16SEP2020)	NOT RELATED/OTHER: CONCURRENT ILLNESS	1	4	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	03SEP2020	
Withdrawn	VACCINATION	13SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1005 10051214, a 71-year-old white female with a pertinent medical history of hypertension (since 2000), chronic obstructive pulmonary disease (since 2018), and type 2 diabetes mellitus (since Feb 2020), received Dose 1 on 03 Sep 2020. The subject experienced facial pain and swelling on 06 Sep 2020, 3 days after receiving Dose 1. On 04 Sep 2020 (Day 2), the subject experienced moderate injection site pain that resolved on 07 Sep 2020 (Day 5). She also experienced facial pain and facial swelling that began on 06 Sep 2020 (Day 4), 3 days after receiving Dose 1, and resolved on 16 Sep 2020 (Day 14). On 06 Sep 2020 (Day 4), the subject experienced upper respiratory infection, which also resolved on 16 Sep 2020 (Day 14). The subject was discontinued from the study intervention on 13 Sep 2020 because of the facial pain and facial swelling and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the facial pain and facial swelling were related to the study intervention, but rather they were related to an allergic reaction to an unknown agent. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	75	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	80.45 kg	24 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
FACTOR 5 LIDEN	Coagulation factor V level	(b) (6) 1944	Present
RECURRENT PEPTIC ULCER	Peptic ulcer	1980	Present
DEEP VEIN THROMBOPHLEBITIS RIGHT LEG	Deep vein thrombosis	1983	Present
CORONARY ARTERY DISEASE	Coronary artery disease	1989	Present
MITRAL VALVE PROLAPSE	Mitral valve prolapse	1989	Past
CORONARY ATHEROSCLEROSIS	Arteriosclerosis coronary artery	DEC1989	Present
HEART ATTACK	Myocardial infarction	DEC1989	Past
LEFT BACK PAIN	Back pain	1990	Present
DIABETES TYPE 2	Type 2 diabetes mellitus	21AUG1995	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2000	Present
RECURRENT BILATERAL LOWER EXTREMITIES EDEMA	Oedema peripheral	2000	Present
CARDIAC STENT PLACEMENT	Coronary arterial stent insertion	25MAR2004	Past
HEART ATTACK	Myocardial infarction	25MAR2004	Past
FLATULENCE	Flatulence	2008	Present
CAUTERIZED ULCERS ON DUODENUM	Duodenal ulcer repair	09FEB2008	Past
BOWEL BLOCKAGE	Intestinal obstruction	01APR2008	Past
BOWEL BLOCKAGE REMOVAL	Intestinal operation	01APR2008	Past
BASAL CELL CARCINOMA, RECURRENT, MULTIPLE LOCATIONS	Basal cell carcinoma	2010	Present
CATARACT SURGERY	Cataract operation	AUG2010	Past
XEROSIS CUTIS	Dry skin	2015	Present
POLYNEUROPATHY, DIABETIC BILATERAL FEET	Diabetic neuropathy	2016	Present
PLANTAR FACIITIS OF RIGHT FOOT	Plantar fasciitis	2016	Present
TRANSIENT ISCHEMIC ATTACK	Transient ischaemic attack	JAN2016	Past
RIGHT BUNDLE BRANCH BLOCK	Bundle branch block right	2017	Present
CARDIAC STENT PLACEMENT	Coronary arterial stent insertion	MAR2017	Past
HEART ATTACK	Myocardial infarction	MAR2017	Past
ANAL FISSURE	Anal fissure	2018	Present
HYPERTENSION	Hypertension	2018	Present
TRANSIENT ISCHEMIC ATTACK	Transient ischaemic attack	JUL2018	Past
CARDIOVASCULAR ACCIDENT	Cardiovascular disorder	06MAR2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	11:32

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	CARD	Acute myocardial infarction	NON-ST ELEVATED MYOCARDIAL INFARCTION	25AUG2020 (14)		27AUG2020 (16)		3	3	TC/TCN
2	CARD	Angina pectoris	ANGINA	21AUG2020 (10)		27AUG2020 (16)		7	2	TCN
3	CARD	Coronary artery occlusion	CORONARY ARTERY OCCLUSION	25AUG2020 (14)		27AUG2020 (16)		3	4	TC/TCN/P/W
4	RESP	Dyspnoea exertional	DYSPNEA ON EXERTION	25AUG2020 (14)		27AUG2020 (16)		3	2	TCN
5	CARD	Mitral valve incompetence	MITRAL VALVE REGURGITATION	25AUG2020 (14)		27AUG2020 (16)		3	3	TCN

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Resolved (27AUG2020)	NOT RELATED/OTHER: CORONARY ARTHEROSCLEROSIS	1	14	N
2	N	Resolved (27AUG2020)	NOT RELATED/OTHER: CORONARY ATHEROSCLEROSIS	1	10	N
3	Y	Resolved (27AUG2020)	NOT RELATED/OTHER: CORONARY ATHEROSCLEROSIS	1	14	Y

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	N	Resolved (27AUG2020)	NOT RELATED/OTHER: CORONARY ATHEROSCLEROSIS	1	14	N
5	N	Resolved (27AUG2020)	NOT RELATED/OTHER: PROGRESSION OF MYXOMATOUS MITRAL VALVE	1	14	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Withdrawn	VACCINATION	16SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	16SEP2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1006 10061020, a 75-year-old white male with a pertinent medical history of factor V Leiden (since (b) (6) 1944), deep vein thrombosis (since 1983), coronary artery disease (since 1989), arteriosclerosis coronary artery (since Dec 1989), mitral valve prolapse (in 1989), myocardial infarction (in Dec 1989, on 25 Mar 2004, and in Mar 2017), type 2 diabetes (since 21 Aug 1995), hypercholesterolemia (since 2000), coronary arterial stent insertion (on 25 Mar 2004 and in Mar 2017), transient ischemic attack (in Jan 2016 and in Jul 2018), right bundle branch block (since 2017), hypertension (since 2018), and cardiovascular accident (on 06 Mar 2019), received Dose 1 on 12 Aug 2020. The subject was diagnosed with coronary artery occlusion on 25 Aug 2020, 13 days after receiving Dose 1. Concomitant medications included warfarin (since 2005) for factor V Leiden; metformin (since 2010), insulin aspart (since 2019), and insulin glargine (since Feb 2019), all for type 2 diabetes; probiotics and magnesium (since 2015) as supplements; atorvastatin calcium (since 2018) for hypercholesterolemia; and lisinopril (since 2018) for hypertension. On 21 Aug 2020 (Day 10), the subject reported angina pectoris. On 25 Aug 2020 (Day 14), the subject presented to the emergency room (ER) reporting shortness of breath, for which he was admitted to the hospital with chief complaints of exertional dyspnea and angina with little exertion that did not abate as usual. In the ER, the subject received enoxaparin 80 mg subcutaneously once and atorvastatin 40 mg orally once daily. A chest x-ray showed no evidence of acute cardiopulmonary disease. An electrocardiogram (ECG) showed previously diagnosed right bundle branch block with ST depression in lead II and T-wave inversion in leads I, Vl, and aVF and inferior infarct of undetermined age with no ST elevation; the subject had an elevated troponin level of 0.84 ng/mL (normal range [NR]: 0-0.15 ng/mL). He was diagnosed with an acute non–ST-elevation myocardial infarction. Additional laboratory values included an elevated glucose level (value not reported) and a prothrombin time of 20.6 seconds (NR: 12.2-15.5 seconds). Other laboratory results included brain natriuretic peptide, fibrin D-dimer, complete blood count, and lipase, which were within normal limits (values not provided). No COVID-19 testing was performed. That same day (Day 14), the subject was also diagnosed with mitral valve incompetence. On 26 Aug 2020 (Day 15), an angiogram was performed, which showed worsening of coronary artery disease and severe multivessel coronary artery disease with significant multivessel coronary artery occlusion. The coronary artery occlusion was considered life-threatening. The subject was given vitamin K and on 27 Aug 2020 (Day 16), he underwent 2-vessel coronary artery bypass graft surgery, during which it was recognized that mitral regurgitation was severe, and the mitral valve was repaired. The subject was treated with Cardene, albumin 250 mg, and epinephrine 0.03 µg/kg/min, but was quickly weaned off. On 27 Aug 2020 (Day 16), the exertional dyspnea, angina pectoris, coronary artery occlusion, acute myocardial infarction, and mitral valve incompetence were considered resolved. The subject was discharged from the hospital on an unknown date. The subject was withdrawn from the study on 16 Sep 2020 because of the coronary artery occlusion. In the opinion of the investigator, there was no reasonable possibility that the coronary artery occlusion was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to coronary atherosclerosis. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	92 kg	28.4 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to food - shellfish	Food allergy	1952	Present
drug allergy Penicillin	Drug hypersensitivity	1958	Present
drug allergy sulfa	Drug hypersensitivity	1958	Present
Hepatitis B	Hepatitis B	1970	Past
Tobacco use disorder, continuous use	Tobacco abuse	1975	Present
Hypertension	Hypertension	1980	Present
Reflux esophagitis	Gastrooesophageal reflux disease	1989	Present
Fundoplication	Oesophagogastric fundoplasty	1989	Past
Asthma	Asthma	1990	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hepatitis C	Hepatitis C	1999	Past
COPD	Chronic obstructive pulmonary disease	2000	Present
Cardiac surgery	Cardiac operation	2006	Past
Coronary artery disease	Coronary artery disease	2006	Present
Iodine allergy	Iodine allergy	2006	Present
Enlarged prostate (benign)	Benign prostatic hyperplasia	25APR2011	Present
Hypercholesterolemia	Hypercholesterolaemia	25NOV2011	Present
Depression	Depression	2016	Present
Post-traumatic stress disorder	Post-traumatic stress disorder	2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15OCT2020 (1)	14:40
3	BNT162b2	01FEB2021 (110)	13:18
4	BNT162b2	23FEB2021 (132)	10:04

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Atrial fibrillation	atrial fibrillation	25OCT2020 (11)	11:30	26OCT2020 (12)		2	3

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/P	Y	Resolved (26OCT2020)	NOT RELATED/OTHER: history of coronary artery disease	1	11	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15OCT2020	
Withdrawn	VACCINATION	05NOV2020	ADVERSE EVENT
Completed	REPEAT SCREENING 1	01FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1007 10071347, a 68-year-old white male with a pertinent medical history of tobacco abuse (since 1975), hypertension (since 1980), esophagogastric fundoplication (1989), asthma (from 1990 to 2000), chronic obstructive pulmonary disease (COPD) (since 2000), cardiac operation (placing 2 stents, in 2006), coronary artery disease (since 2006), hypercholesterolemia (since 25 Nov 2011), and depression (since 2016), received Dose 1 on 15 Oct 2020. The subject was diagnosed with atrial fibrillation on 25 Oct 2020, 10 days after receiving Dose 1. Concomitant medications included atorvastatin (since 16 Oct 2019) for hypercholesterolemia; sildenafil (since 17 Feb 2020) for erectile dysfunction; tiotropium bromide for COPD; hydrochlorothiazide/lisinopril and metoprolol tartrate for hypertension; trazodone for depression; and acetylsalicylic acid as prophylaxis for coronary artery disease (all since unknown dates). On 25 Oct 2020 (Day 11), the subject experienced palpitations and presented to the emergency room. He denied having had palpitations previously and had no history of atrial fibrillation. He also denied recent illness, dizziness, shortness of breath, chest pain, syncope, nausea, vomiting, or diarrhea. He was hospitalized and an electrocardiogram (ECG) showed atrial fibrillation. On the same day (Day 11), the SARS-CoV-2 RNA nasopharyngeal swab test was negative and a chest x-ray was normal. The subject was treated with diltiazem 125 mg/125 mL intravenous (IV) infusion at 2.5-15 mg/hour and heparin 25,000 units/250 mL IV infusion at 18 units/kg/hour. The diltiazem and heparin infusions were discontinued on 26 Oct 2020 (Day 12) after the subject achieved cardiac sinus rhythm, and he was placed on oral apixaban. The subject's troponin I was less than 0.015 ng/mL (normal range: 0-0.045 ng/mL) on 25 Oct 2020 (Day 11) and less than 0.015 ng/mL on 26 Oct 2020 (Day 12). On 26 Oct 2020 (Day 12), an echocardiogram was normal and an ECG showed incomplete right bundle branch block, old inferior infarct, and sinus rhythm (abnormalities consistent with previous history). On the same day (Day 12), the atrial fibrillation resolved and the subject was discharged from the hospital on 27 Oct 2020 (Day 13). The subject was discontinued from the study intervention on 05 Nov 2020 because of the atrial fibrillation. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; he therefore received the first and second doses of BNT162b2 on 01 Feb 2021 (Day 110) and 23 Feb 2021 (Day 132), respectively, and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the atrial fibrillation was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to the history of coronary artery disease. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1941	79	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	80.73 kg	26.2 kg/m2	22OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Non allergic rhinitis	Rhinitis	1945	Present
Penicillin allergy	Drug hypersensitivity	1957	Present
Asthma	Asthma	1976	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2005	Present
Hypertension	Hypertension	2005	Present
Levaquin allergy	Drug hypersensitivity	2014	Present
Diabetes type II	Type 2 diabetes mellitus	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22OCT2020 (1)	11:33
2	Placebo	12NOV2020 (22)	09:29
3	BNT162b2	13JAN2021 (84)	10:46
4	BNT162b2	03FEB2021 (105)	10:32

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Hepatic cancer	liver cancer	25FEB2021 (127)		ONGOING		
2	GENRL	Injection site pain	injection site are soreness	12NOV2020 (22)	19:30	13NOV2020 (23)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	W	Y	Yes	NOT RELATED/OTHER: unknown	4	23	Y
2	1	N	N	Resolved (13NOV2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22OCT2020	
Completed	VACCINATION	10DEC2020	
Completed	REPEAT SCREENING 1	13JAN2021	
Completed	OPEN LABEL TREATMENT	04MAR2021	
Withdrawn	FOLLOW-UP	10MAR2021	ADVERSE EVENT

Narrative Comment
Subject C4591001 1008 10081667, a 79-year-old white male with a pertinent medical history of type 2 diabetes mellitus (since 2017), received Dose 1 on 22 Oct 2020 and Dose 2 on 12 Nov 2020 (Day 22). Concomitant medications included omeprazole (since 2005) for gastroesophageal reflux disease, fexofenadine hydrochloride and loratadine (both since 2005) for seasonal allergies, montelukast sodium (since 2010) for seasonal allergies/asthma, atorvastatin (since 2015) for hypercholesterolemia, losartan (since 2016) for hypertension, metformin (since 2017) for type 2 diabetes mellitus, acetylsalicylic acid (since 2019) for cardiac prophylaxis, and azelastine (since 30 Dec 2020) for nonallergic rhinitis. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; he therefore received the first and second doses of BNT162b2 on 13 Jan 2021 (Day 84) and 03 Feb 2021 (Day 105), respectively. He was diagnosed with hepatic cancer on 25 Feb 2021, 22 days after receiving the second dose of BNT162b2. On 04 Mar 2021 (Day 134), during Visit 103, the subject informed the site that he had been diagnosed with hepatic cancer on 25 Feb 2021. The hepatic cancer was considered an important medical event by the investigator. The subject refused any further follow-up in the study, contact by the site or sponsor, and to provide any medical records or testing and treatment details. No further attempts were made by the site for any additional information. The subject was withdrawn from the study on 10 Mar 2021 because of the hepatic cancer that was ongoing at the time of withdrawal. In the opinion of the investigator, there was no reasonable possibility that the hepatic cancer was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1963	57	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
162.56 cm	85.45 kg	32.3 kg/m2	08OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	08OCT2020 (1)	14:40

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	NERV	Paraesthesia	Tingling at finger tips	08OCT2020 (1)	15:15	08OCT2020 (1)	16:15	1
2	GASTR	Paraesthesia oral	Tingling around the mouth	08OCT2020 (1)	15:15	08OCT2020 (1)	16:14	1
3	GASTR	Toothache	Toothache	30OCT2020 (23)	09:00	17NOV2020 (41)	09:00	19

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (08OCT2020)	Study Treatment	1	1	N
2	1	P	N	Resolved (08OCT2020)	Study Treatment	1	1	Y
3	1	TC	N	Resolved (17NOV2020)	NOT RELATED/OTHER: tooth ache	1	23	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08OCT2020	
Withdrawn	VACCINATION	08OCT2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1011 10111181, a 57-year-old white female with no reported medical history, received Dose 1 on 08 Oct 2020 at 1440 hours. The subject experienced oral paresthesia starting at 1515 hours on 08 Oct 2020, the same day as Dose 1. On 08 Oct 2020 (Day 1), the subject also experienced paresthesia of fingertips starting at 1515 hours. On the same day (Day 1), the oral paresthesia and paresthesia of fingertips resolved by 1614 hours and 1615 hours, respectively. The subject was discontinued from the study intervention on 08 Oct 2020 because of the oral paresthesia and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the oral paresthesia was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	63.18 kg	20.5 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cat Scratch Disease	Cat scratch disease	1982	Present
Penicillin Allergy (Anaphylactic Shock)	Anaphylactic shock	1984	Present
Codeine Allergy	Drug hypersensitivity	1984	Present
Allergic Atopic Dermatitis	Dermatitis atopic	2016	Present
Iodine Allergy	Iodine allergy	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	09SEP2020 (1)	16:58

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site dermatitis	LEFT UPPER ARM DERMATITIS AT INJECTION SITE	11SEP2020 (3)		ONGOING	
2	PSYCH	Insomnia	INSOMNIA	12SEP2020 (4)		ONGOING	
3	INV	Weight decreased	WEIGHT LOSS	14SEP2020 (6)		04OCT2020 (26)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	P/W	N	Yes	Study Treatment	1	3	Y
2		2	TC	N	Yes	Study Treatment	1	4	N
3	21	3	N	N	Resolved (04OCT2020)	Study Treatment	1	6	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Withdrawn	VACCINATION	24SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	17OCT2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1012 10121163, a 41-year-old white female with a pertinent medical history of atopic dermatitis (since 2016), received Dose 1 on 09 Sep 2020. The subject experienced injection site dermatitis (left upper arm) on 11 Sep 2020, 2 days after receiving Dose 1. The subject was discontinued from the study intervention on 24 Sep 2020, and was subsequently withdrawn from the study on 17 Oct 2020 because of injection site dermatitis. The injection site dermatitis was ongoing at the time of withdrawal. In the opinion of the investigator, there was a reasonable possibility that the injection site dermatitis was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	75 kg	22.4 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Childhood asthma	Childhood asthma	1975	Present
Acid reflux	Gastrooesophageal reflux disease	2000	Present
Vertigo	Vertigo	2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	14:39
3	BNT162b2	21DEC2020 (117)	13:20
4	BNT162b2	13JAN2021 (140)	12:45

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Chills	13JAN2021 (140)	20:00	15JAN2021 (142)	
2	GASTR	Diarrhoea	Diarrhea	28AUG2020 (2)		28AUG2020 (2)	
3	NERV	Headache	Headache	28AUG2020 (2)		01SEP2020 (6)	
4	NERV	Headache	Headache	14JAN2021 (141)	03:00	15JAN2021 (142)	
5	GENRL	Injection site pain	Injection site pain	21DEC2020 (117)		22DEC2020 (118)	
6	GENRL	Injection site pain	Injection site pain	13JAN2021 (140)	20:00	15JAN2021 (142)	
7	GASTR	Nausea	Nausea	28AUG2020 (2)		01SEP2020 (6)	
8	EAR	Vertigo	Worsening and continuing episode of Veritgo	28AUG2020 (2)		21DEC2020 (117)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	1	N	N	Resolved (15JAN2021)	Study Treatment	4	1	N
2	1	1	N	N	Resolved (28AUG2020)	Study Treatment	1	2	N
3	5	1	N	N	Resolved (01SEP2020)	Study Treatment	1	2	N

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	2	2	TC	N	Resolved (15JAN2021)	Study Treatment	4	2	N
5	2	1	N	N	Resolved (22DEC2020)	Study Treatment	3	1	N
6	3	1	N	N	Resolved (15JAN2021)	Study Treatment	4	1	N
7	5	1	N	N	Resolved (01SEP2020)	Study Treatment	1	2	N
8	116	2	P	N	Resolved (21DEC2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
Fluzone Quadrivalent	INFLUENZA VACCINE INACT SPLIT 4V	28SEP2020

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27AUG2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	VACCINATION	06NOV2020	ADVERSE EVENT
Completed	REPEAT SCREENING 1	21DEC2020	
Completed	OPEN LABEL TREATMENT	10FEB2021	
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1015 10151134, a 55-year-old white male with a pertinent medical history of vertigo (since 2012), received Dose 1 on 27 Aug 2020. The subject experienced a worsening and continuing episode of vertigo on 28 Aug 2020, 1 day after receiving Dose 1.

On 28 Aug 2020 (Day 2), the subject also experienced diarrhea, headache, and nausea. The diarrhea resolved on the same day (Day 2) and the headache and nausea resolved on 01 Sep 2020 (Day 6). The subject received the influenza vaccine inact split 4V on 28 Sep 2020 (Day 33).

The subject was discontinued from the study intervention on 06 Nov 2020 because of the worsening and continuing episode of vertigo. On 21 Dec 2020 (Day 117), the worsening and continuing episode of vertigo resolved.

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 21 Dec 2020 (Day 117) and 13 Jan 2021 (Day 140), respectively, and remains in the study.

In the opinion of the investigator, there was a reasonable possibility that the worsening and continuing episode of vertigo was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	43	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	77.32 kg	24.4 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	APR1994	Present
allergy to flagyl	Drug hypersensitivity	APR2002	Present
meniscus repair	Meniscus operation	JUL2009	Past
migraines	Migraine	APR2010	Present
ovarian fibroid	Ovarian fibroma	JAN2015	Past
hysterectomy	Hysterectomy	JUN2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10AUG2020 (1)	10:35

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site swelling	injection site swelling	10AUG2020 (1)		19AUG2020 (10)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	10	3	TC/P	N	Resolved (19AUG2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
pfizer bnt162b2 vaccine	BNT162B2	14JAN2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10AUG2020	
Withdrawn	VACCINATION	31AUG2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1016 10161087, a 43-year-old white female with no pertinent medical history, received Dose 1 on 10 Aug 2020. On the same day (Day 1), the subject reported severe injection site swelling after receiving Dose 1. The injection site swelling resolved on 19 Aug 2020 (Day 10). The subject was discontinued from the study intervention on 31 Aug 2020 because of the injection site swelling and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the injection site swelling was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	64	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166.37 cm	83 kg	29.9 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	17JUL2007	Present
Osteoarthrosis right lower leg	Osteoarthritis	16NOV2007	Present
Menopausal	Menopause	04DEC2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	11:09
2	Placebo	14SEP2020 (22)	13:02
3	BNT162b2	01FEB2021 (162)	11:25

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Moderate Chills	01FEB2021 (162)	19:00	03FEB2021 (164)	19:00
2	GASTR	Diarrhoea	Moderate Diarrhea	04FEB2021 (165)	08:00	07FEB2021 (168)	08:00
3	NERV	Headache	Moderate Headache	01FEB2021 (162)	19:00	03FEB2021 (164)	19:00
4	GENRL	Injection site pain	Injection Site Pain	01FEB2021 (162)	19:00	04FEB2021 (165)	19:00
5	MUSC	Myalgia	Generalized Myalgias	01FEB2021 (162)	19:00	03FEB2021 (164)	19:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	2	P	N	Resolved (03FEB2021)	Study Treatment	3	1	Y
2	4	2	P	N	Resolved (07FEB2021)	Study Treatment	3	4	Y
3	3	2	P	N	Resolved (03FEB2021)	Study Treatment	3	1	Y
4	4	3	P	N	Resolved (04FEB2021)	Study Treatment	3	1	Y
5	3	2	P	N	Resolved (03FEB2021)	Study Treatment	3	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	16OCT2020	
Completed	REPEAT SCREENING 1	01FEB2021	
Withdrawn	OPEN LABEL TREATMENT	19FEB2021	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1022 10221053, a 64-year-old white female with a pertinent medical history of osteoarthritis (since 16 Nov 2007), received Dose 1 on 24 Aug 2020 and Dose 2 on 14 Sep 2020 (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 01 Feb 2021 (Day 162). She experienced moderate chills, moderate headache, moderate myalgia, and severe injection site pain, approximately 7.5 hours after receiving the first dose of BNT162b2. On 04 Feb 2021, 3 days after receiving the first dose of BNT162b2, she experienced diarrhea. On 03 Feb 2021 (Day 164), the chills, headache, and myalgia resolved. On 04 Feb 2021 (Day 165), the injection site pain resolved. On 07 Feb 2021 (Day 168), the diarrhea resolved. The subject was discontinued from the study intervention on 19 Feb 2021 because of the chills, headache, myalgia, injection site pain, and diarrhea and remains in the study. In the opinion of the investigator, there was a reasonable possibility that the chills, headache, myalgia, injection site pain, and diarrhea were related to BNT162b2.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.47 cm	65.45 kg	24.1 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Migraine Headaches	Migraine	1995	Present
Allergy to Shellfish	Food allergy	1996	Present
Allergy to Iodine	Iodine allergy	1996	Present
Mitral Valve Prolapse	Mitral valve prolapse	2007	Present
Hypertension	Hypertension	2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	15:00

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Back pain	Lower back pain	08SEP2020 (12)		11SEP2020 (15)		4
2	MUSC	Back pain	Mid back pain	11SEP2020 (15)		14SEP2020 (18)		4
3	GENRL	Chest pain	Left-sided chest pain	08SEP2020 (12)		08SEP2020 (12)		1
4	IMMUN	Drug hypersensitivity	Allergic Reaction to investigational product	29AUG2020 (2)		11SEP2020 (15)		14
5	GASTR	Gastrooesophageal reflux disease	GERD	08SEP2020 (12)		ONGOING		
6	NERV	Hypoaesthesia	Right arm numbness	11SEP2020 (15)		11SEP2020 (15)		1
7	MUSC	Muscular weakness	Right leg weakness	10SEP2020 (14)		10SEP2020 (14)		1
8	RESP	Pharyngeal swelling	Throat Swelling	29AUG2020 (2)		08SEP2020 (12)		11

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (11SEP2020)	NOT RELATED/OTHER: GERD	1	12	N
2	1	N	N	Resolved (14SEP2020)	NOT RELATED/OTHER: GERD	1	15	N
3	1	TC	N	Resolved (08SEP2020)	NOT RELATED/OTHER: Gerd	1	12	N
4	2	TC/P	N	Resolved (11SEP2020)	Study Treatment	1	2	Y
5	1	TC	N	Yes	NOT RELATED/OTHER: acid reflux	1	12	N

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
6	1	N	N	Resolved (11SEP2020)	NOT RELATED/OTHER: Unknown	1	15	N
7	2	TCN	N	Resolved (10SEP2020)	NOT RELATED/OTHER: Unknown	1	14	N
8	2	TC	N	Resolved (08SEP2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28AUG2020	
Withdrawn	VACCINATION	11SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1027 10271105, a 46-year-old black or African American female with a pertinent medical history of allergy to shellfish and iodine (since 1996), received Dose 1 on 28 Aug 2020. The subject developed pharyngeal swelling considered to be an allergic reaction to the investigational product on 29 Aug 2020, 1 day after receiving Dose 1. The subject experienced throat swelling and difficulty swallowing and was treated with systemic and oral corticosteroids. Her symptoms persisted and she was seen by a gastroenterologist. An endoscopy was normal. The pharyngeal swelling resolved on 08 Sep 2020 (Day 12) and the allergic reaction to the investigational product resolved on 11 Sep 2020 (Day 15). The subject was discontinued from the study intervention on 11 Sep 2020 because of the allergic reaction to the investigational product and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the allergic reaction to the investigational product was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	Asian	Not reported	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.99 cm	49.8 kg	19.9 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Myopia	Myopia	1994	Present
Anus Surgery (Hemorrhoids)	Haemorrhoid operation	2009	Past
Hemorrhoids	Haemorrhoids	2009	Past
Environmental allergy	Hypersensitivity	2013	Present
Induced Abortion	Abortion induced	JUL2013	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	10:03
2	Placebo	04SEP2020 (22)	11:04

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	INJ&P	Exposure during pregnancy	exposure during pregnancy	29NOV2020 (108)		ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1				W	N	Yes	Study Treatment	2	87	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	05OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	21DEC2020	PREGNANCY

Narrative Comment
Subject C4591001 1028 10281003, a 41-year-old Asian female with pertinent obstetrical history of 5 previous pregnancies resulting in 3 live births, 1 induced abortion (in Jul 2013), and 1 spontaneous abortion, received Dose 1 on 14 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 22). The subject had an exposure during pregnancy on 29 Nov 2020, 86 days after receiving Dose 2. Concomitant medication included multivitamin (since 2019) as a health supplement. On 21 Dec 2020 (Day 130), the subject called to inform the investigator of her pregnancy, which the subject had found out on 19 Dec 2020 (Day 128). Her first day of the last menstrual period was on 15 Nov 2020 (Day 94), the estimated date of conception was 29 Nov 2020 (Day 108), and the estimated delivery date is 22 Aug 2021. The gestational age at the time of initial exposure was first trimester. It was reported that the subject's 48-year-old male partner was also part of the study and he received his first dose on 20 Aug 2020 and second dose on 11 Sep 2020. The subject and her partner did not smoke, drink alcohol, or use illicit drugs during this pregnancy. The subject was withdrawn from the study on 21 Dec 2020 because of the exposure during pregnancy. She was unblinded on 21 Dec 2020 (Day 130), after withdrawing from the trial. Her partner decided to stay in the study and continue per protocol. On 28 Dec 2020 (Day 137), the subject informed the site that she had started bleeding and had a miscarriage on 22 Dec 2020 (Day 131). The blood work done by her doctor confirmed that she was no longer pregnant.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	37	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.9 cm	83.7 kg	25 kg/m2	05OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	01JAN2008	Present
Temporomandibular joint dysfunction	Temporomandibular joint syndrome	2010	Past
Gerd	Gastrooesophageal reflux disease	2015	Present
Tricyclic Drug Intolerance	Drug intolerance	01SEP2019	Present
Herniated disc	Intervertebral disc protrusion	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	05OCT2020 (1)	15:55
2	Placebo	26OCT2020 (22)	13:47
3	BNT162b2	04MAR2021 (151)	10:30

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Chills	chills	27OCT2020 (23)		28OCT2020 (24)		2
2	GENRL	Fatigue	fatigue	27OCT2020 (23)		28OCT2020 (24)		2
3	NERV	Headache	headache	27OCT2020 (23)		28OCT2020 (24)		2
4	GENRL	Injection site pain	Injection site pain	04MAR2021 (151)		04MAR2021 (151)		1
5	MUSC	Intervertebral disc protrusion	Worsening of herniated disc	05JAN2021 (93)		ONGOING		
6	MUSC	Myalgia	generalized myalgia	27OCT2020 (23)		28OCT2020 (24)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (28OCT2020)	Study Treatment	2	2	N
2	1	N	N	Resolved (28OCT2020)	Study Treatment	2	2	N
3	1	N	N	Resolved (28OCT2020)	Study Treatment	2	2	N
4	1	TC/W	N	Resolved (04MAR2021)	Study Treatment	3	1	Y

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	2	TC	N	Yes	NOT RELATED/OTHER: unk	2	72	N
6	1	N	N	Resolved (28OCT2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	05OCT2020	
Completed	VACCINATION	23NOV2020	
Completed	REPEAT SCREENING 1	03FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
After the data cutoff date of 13 Mar 2021 (with snapshot taken on 25 Mar 2021), it was determined that Subject C4591001 1044 10441163 did not withdraw from the study because of the injection site pain and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	84.35 kg	28.3 kg/m2	23SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
lactose intolerance	Lactose intolerance	2016	Present
appendectomy	Appendicectomy	14FEB2017	Past
appendicitis	Appendicitis	14FEB2017	Past
cyst, R axilla	Cyst	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23SEP2020 (1)	12:32

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Dizziness	lightheadedness	23SEP2020 (1)	12:40	23SEP2020 (1)	14:40
2	GASTR	Nausea	nausea	23SEP2020 (1)	12:40	23SEP2020 (1)	14:40

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	P	N	Resolved (23SEP2020)	Study Treatment	1	1	Y
2	1	1	P	N	Resolved (23SEP2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23SEP2020	
Withdrawn	VACCINATION	23SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1054 10541186, a 71-year-old black or African American female with no pertinent medical history, received Dose 1 on 23 Sep 2020 at 1232 hours. The subject experienced dizziness and nausea on 23 Sep 2020 at 1240 hours, the same day as receiving Dose 1, which resolved on the same day at 1440 hours. The subject was discontinued from the study intervention on 23 Sep 2020 because of the dizziness and nausea and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the dizziness and nausea were related to the study intervention.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1985	35	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
166 cm	89 kg	32.3 kg/m2	28AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	28AUG2020 (1)	14:35

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Cerebral capillary telangiectasia	Cerebral Capillary telangiectasia	26SEP2020 (30)		ONGOING			1
2	GENRL	Chronic fatigue syndrome	Chronic Fatigue Syndrome	05JAN2021 (131)		ONGOING			2
3	GASTR	Dysphagia	Dysphagia	AUG2020 ()		ONGOING			1
4	MUSC	Fibromyalgia	Fibromyalgia	05JAN2021 (131)		ONGOING			2
5	MUSC	Pain in extremity	Bilateral upper extremity pain	10OCT2020 (44)		ONGOING			1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: anatomical abnormality	1	30	N
2	N	N	Yes	NOT RELATED/OTHER: Unknown etiology	1	131	N
3	P	N	Yes	NOT RELATED/OTHER: unknown, GI or neurological abnormality			Y
4	TC	N	Yes	NOT RELATED/OTHER: Unknown etiology	1	131	N
5	TC	N	Yes	NOT RELATED/OTHER: Cause is being evaluated	1	44	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Pfizer BNT162b2	BNT162B2	26FEB2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Withdrawn	VACCINATION	14OCT2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1055 10551145, a 35-year-old white female with no reported medical history, received Dose 1 on 28 Aug 2020. The subject experienced dysphagia in late Aug 2020. The subject was discontinued from the study intervention on 14 Oct 2020 because of the dysphagia that was ongoing at the time of the last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the dysphagia was related to the study intervention, but rather it was related to an unknown gastrointestinal or neurological abnormality.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.7 cm	100.7 kg	33.8 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PARTIAL HYSTERECTOMY	Hysterectomy	2012	Past
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2013	Present
HYPERTENSION	Hypertension	2015	Present
TYPE II DIABETES	Type 2 diabetes mellitus	2016	Present
CONGESTIVVE HEART FAILURE	Cardiac failure congestive	2017	Present
ALLERGIC RHINITIS	Rhinitis allergic	2017	Present
STROKE	Cerebrovascular accident	2019	Past
CORONARY ARTERY DISEASE	Coronary artery disease	2019	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	JAN2019	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
BILATERAL LEG EDEMA	Oedema peripheral	JAN2019	Present
BILATERAL ANKLE EDEMA	Oedema peripheral	JUN2019	Present
VISION LOSS	Blindness	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12AUG2020 (1)	12:15

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Coronary artery disease	WORSENING coronary artery disease	23AUG2020 (12)		31AUG2020 (20)		9	2	TCN/P/W	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (31AUG2020)	NOT RELATED/OTHER: Hypertensive cardiovascular disease or arteriosclerotic heart disease	1	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Withdrawn	VACCINATION	23AUG2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	28AUG2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1071 10711023, a 56-year-old black or African American female with a pertinent medical history of hypertension (since 2015), congestive cardiac failure (since 2017), arteriosclerosis (since 2017), cerebrovascular accident (in 2019), hypercholesterolemia (since Jan 2019), coronary artery disease (since 2019, with 6 coronary stents placed in Sep 2019), and arteriosclerotic heart disease (since an unspecified date), received Dose 1 on 12 Aug 2020. The subject was diagnosed with worsening coronary artery disease on 23 Aug 2020, 11 days after receiving Dose 1. Concomitant medications included omeprazole (since 2010) for gastroesophageal reflux disease, sacubitril/valsartan sodium hydrate (since Jan 2018) and isosorbide dinitrate and clopidogrel (both since 2018) for congestive heart failure, acetylsalicylic acid (since 2018) for cardiovascular prophylaxis, cyanocobalamin (since 2018) as a nutritional supplement, metformin (since 2018) and empagliflozin (since Jan 2020) for type 2 diabetes, fexofenadine (since 2018) for allergic rhinitis, atorvastatin (since Jan 2019) for hypercholesterolemia, metoprolol (since Jan 2019) for hypertension, and spironolactone (since Jan 2019) and furosemide (since Jun 2019), both for edema. On 18 Aug 2020 (Day 7), the subject underwent a coronary angiogram and her doctor called her back that week and stated that she needed surgery. On 21 Aug 2020 (Day 10), the subject stated that she was never in the hospital overnight and was at the hospital only for a stress test. The site staff requested the medical records to verify the stress test. On 23 Aug 2020 (Day 12), the subject was hospitalized and underwent quadruple coronary artery bypass surgery on 24 Aug 2020 (Day 13). According to the medical records, her postoperative course was unremarkable. On 31 Aug 2020 (Day 20), she recovered from the worsening coronary artery disease and was discharged from the hospital. The subject was discontinued from the study intervention on 23 Aug 2020 and was withdrawn from the study on 28 Aug 2020 because of the worsening coronary artery disease. In the opinion of the investigator, there was no reasonable possibility that the worsening coronary artery disease was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was due to arteriosclerotic heart disease. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	77.1 kg	24.4 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ECZEMA	Eczema	1970	Present
ALCOHOL ABUSE	Alcohol abuse	1982	Present
DEPRESSION	Depression	1982	Present
DRUG ABUSE	Drug abuse	1982	Present
SEIZURE DISORDER	Seizure	1986	Present
ALLERGIC RHINITIS	Rhinitis allergic	2013	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2015	Present
ATAXIA	Ataxia	2018	Present
CHOLELITHIASIS	Cholelithiasis	2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HEPATOSTEATOSIS	Hepatic steatosis	2018	Present
PERIPHERAL NEUROPATHY BILATERAL FEET	Neuropathy peripheral	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15SEP2020 (1)	16:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Alcohol poisoning	ACUTE ALCOHOL INTOXICATION	02OCT2020 (18)		15OCT2020 (31)		14	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	P/W	Y	Resolved (15OCT2020)	NOT RELATED/OTHER: ALCOHOL DEPENDENCE	1	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15SEP2020	
Withdrawn	VACCINATION	15OCT2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	15OCT2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1071 10711169, a 56-year-old white male with a pertinent medical history of alcohol abuse, drug abuse, and depression (all since 1982), seizures (since 1986), grand mal seizure (in 2015), and ataxia, hepatic steatosis, and peripheral neuropathy (all since 2018), received Dose 1 on 15 Sep 2020. The subject was diagnosed with alcohol poisoning on 02 Oct 2020, 17 days after receiving Dose 1. Concomitant medications included loratadine (since 2013) for allergic rhinitis and levetiracetam (since Mar 2019) for a seizure disorder. On 02 Oct 2020 (Day 18), the subject went to the emergency room because of acute alcohol intoxication and was hospitalized. On 15 Oct 2020 (Day 31), the alcohol poisoning resolved, and the subject was discharged from the hospital to a rehabilitation facility. The subject was withdrawn from the study on 15 Oct 2020 because of the alcohol poisoning. In the opinion of the investigator, there was no reasonable possibility that the alcohol poisoning was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to alcohol dependence. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.2 cm	61.05 kg	25.7 kg/m2	29JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	1986	Present
IBS-M	Irritable bowel syndrome	1998	Present
Insomnia	Insomnia	1999	Present
Allergic Rhinitis - Seasonal	Seasonal allergy	2010	Present
GERD	Gastrooesophageal reflux disease	2012	Present
Hypothyroidism	Hypothyroidism	2012	Present
Fibromyalgia	Fibromyalgia	2017	Present
Cholelithiasis - Gallstones	Cholelithiasis	28JUL2020	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hydronephrosis	Hydronephrosis	28JUL2020	Present
Ovarian cyst	Ovarian cyst	28JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29JUL2020 (1)	14:35

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Adenocarcinoma gastric	INFILTRATING, POORLY DIFFERENTIATED ADENOCARCINOMA - STOMACH	20AUG2020 (23)	12:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	P/W	Y	Yes	NOT RELATED/OTHER: n/a	1	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	29JUL2020	
Withdrawn	VACCINATION	20AUG2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	27AUG2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1079 10791004, a 48-year-old white female with a pertinent medical history of irritable bowel syndrome (since 1998), gastroesophageal reflux disease (since 2012), and cholelithiasis (since 28 Jul 2020), received Dose 1 on 29 Jul 2020. The subject was diagnosed with poorly differentiated gastric adenocarcinoma on 20 Aug 2020, 22 days after receiving Dose 1. On 20 Aug 2020 (Day 23), the subject visited her physician's office and an upper gastrointestinal endoscopic biopsy revealed infiltrating poorly differentiated adenocarcinoma. No information was available about gastrointestinal symptoms beyond ongoing reflux disease; staging and chemotherapy were planned but no details are available at this time. The subject was discontinued from the study intervention on 20 Aug 2020 and was withdrawn from the study on 27 Aug 2020 because of the poorly differentiated gastric adenocarcinoma that was ongoing at the time of withdrawal. In the opinion of the investigator, there was no reasonable possibility that the poorly differentiated gastric adenocarcinoma was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
155 cm	62.9 kg	26.2 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Nicotine abuse	Tobacco abuse	1985	Present
tonsillectomy	Tonsillectomy	1999	Past
tonsillitis	Tonsillitis	1999	Past
mild depression	Depression	2000	Present
hysterectomy	Hysterectomy	2005	Past
migraine headaches	Migraine	2005	Present
kidney stones	Nephrolithiasis	2007	Past
percutaneous nephrolithotomy	Renal stone removal	2007	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
c5-c7 spinal fusion	Spinal fusion surgery	2019	Past
Presbyopia	Presbyopia	2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	13:27
2	Placebo	23SEP2020 (21)	12:14

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Malignant melanoma	Malignant Melanoma (etiology unknown)	24NOV2020 (83)		ONGOING		
2	MUSC	Neck pain	neck pain	21SEP2020 (19)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	W	Y	Yes	NOT RELATED/OTHER: etiology unknown	2	63	Y
2	1	TC	N	Yes	NOT RELATED/OTHER: previous neck injury	1	19	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	24NOV2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1082 10821149, a 53-year-old white female with no pertinent medical history, received Dose 1 on 03 Sep 2020 and Dose 2 on 23 Sep 2020 (Day 21). The subject was diagnosed with malignant melanoma on 24 Nov 2020, 62 days after receiving Dose 2. Concomitant medications included fluoxetine hydrochloride, lamotrigine, quetiapine fumarate, and lurasidone hydrochloride (all since 2000) for depression, topiramate (since 2005) for migraine headaches, and tizanidine (since 21 Sep 2020) for neck pain. The subject contacted the site and reported the new diagnosis of malignant melanoma. The subject was withdrawn from the study on 24 Nov 2020 because the malignant melanoma required surgical procedures. The malignant melanoma was ongoing at the time of withdrawal. In the opinion of the investigator, there was no reasonable possibility that the malignant melanoma was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	132.18 kg	40.6 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
chronic sinus infection	Chronic sinusitis	1990	Past
Intermittent Headache	Headache	1990	Present
tonsillitis	Tonsillitis	1993	Past
bilateral carpal tunnel syndrome	Carpal tunnel syndrome	2002	Past
bilateral carpal tunnel repair	Carpal tunnel decompression	2003	Past
obesity	Obesity	2004	Present
balloon sinuplasty	Sinuplasty	2011	Past
allergy to oak	Allergy to plants	2013	Present
allergy to cedar	Allergy to plants	2013	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis	Rhinitis allergic	2013	Present
heartburn	Dyspepsia	2018	Present
gastroesophageal reflux disease	Gastrooesophageal reflux disease	2018	Present
anxiety	Anxiety	NOV2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04AUG2020 (1)	12:21

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Atrial fibrillation	Paroxysmal Atrial fibrillation with rapid ventricular response	23AUG2020 (20)		08SEP2020 (36)	00:00	17	3
2	CARD	Atrial flutter	Atrial Flutter	02SEP2020 (30)	00:00	08SEP2020 (36)	00:00	7	3
3	EAR	Ear pain	Ear Pain	04DEC2020 (123)	00:00	ONGOING			1
4	VASC	Hypertension	Hypertension	24AUG2020 (21)	00:00	ONGOING			1
5	CARD	Left atrial enlargement	Left Atrial Enlargement	09SEP2020 (37)	00:00	ONGOING			1
6	CARD	Left ventricular hypertrophy	Left Ventricular Hypertrophy	24AUG2020 (21)	00:00	ONGOING			1
7	CARD	Mitral valve incompetence	Mitral Regurgitation	09SEP2020 (37)	00:00	ONGOING			1

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
8	CARD	Mitral valve prolapse	Bileaflet mitral valve prolapse	09SEP2020 (37)	00:00	ONGOING			1
9	CARD	Myocardial infarction	Prior Septual Myocardinal Infarction	08SEP2020 (36)	00:00	08SEP2020 (36)	00:00	1	1
10	INJ&P	Skin laceration	Laceration-Left Index Finger	01SEP2020 (29)	00:00	15SEP2020 (43)	00:00	15	2

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN/P	Y	Resolved (08SEP2020)	NOT RELATED/OTHER: Heart Disease	1	20	Y
2	TC/TCN	N	Resolved (08SEP2020)	NOT RELATED/OTHER: Cardiac Disease	1	30	N
3	TC	N	Yes	NOT RELATED/OTHER: Strep Prevention	1	123	N
4	TC	N	Yes	NOT RELATED/OTHER: Medical Illness	1	21	N
5	N	N	Yes	NOT RELATED/OTHER: Heart Disease	1	37	N
6	TC	N	Yes	NOT RELATED/OTHER: Medical Illness	1	21	N
7	N	N	Yes	NOT RELATED/OTHER: Heart Disease	1	37	N
8	N	N	Yes	NOT RELATED/OTHER: Heart Disease	1	37	N
9	N	N	Resolved (08SEP2020)	NOT RELATED/OTHER: Heart Disease	1	36	N
10	TCN	N	Resolved (15SEP2020)	NOT RELATED/OTHER: Hobby Injury	1	29	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	04AUG2020	
Withdrawn	VACCINATION	23AUG2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1083 10831029, a 50-year-old white male with a pertinent medical history of obesity (since 2004), received Dose 1 on 04 Aug 2020. The subject was diagnosed with atrial fibrillation on 23 Aug 2020, 19 days after receiving Dose 1. Concomitant medications included naproxen sodium and acetylsalicylic acid (since 1990) for headache; fluticasone propionate (since 2013) for seasonal allergies; omeprazole (since 2018) for gastroesophageal reflux disease; and pregabalin, desvenlafaxine succinate, and lorazepam (all since 2019) for anxiety. On 23 Aug 2020 (Day 20), the subject presented to the emergency room (ER) with palpitations associated with a "funny" sensation in his head and was hospitalized on 24 Aug 2020 (Day 21). An electrocardiogram (ECG) showed atrial fibrillation with rapid ventricular response of 141 beats per minute (bpm), no PR interval, normal QRS, and normal-appearing ST and T waves. The ventricular rate was controlled by treatment with diltiazem and a beta blocker. Cardiac telemetry showed a heart rate ranging from 80 to 90s (bpm). The subject's echocardiography revealed mild left ventricular hypertrophy. The estimated ejection fraction was 55% to 60%. Additional laboratory results on 23 Aug 2020 (Day 20) showed an elevated nonfasting blood glucose level of 195 mg/dL (normal range [NR]: 70-110 mg/dL) (and it was reported that the subject had eaten high-sugar food prior to the ER visit), high blood urea nitrogen of 25 mg/dL (NR: 7-18 mg/dL), and low blood potassium of 3.4 mmol/L (NR: 3.5-5.1 mmol/L). On 24 Aug 2020 (Day 21), the subject's blood pressure was noted to be 136/89 mmHg, and a diagnosis of hypertension was made. Additionally, the subject was treated with ketorolac tromethamine 10 mg orally (PO) as needed since 25 Aug 2020 for atrial fibrillation, metoprolol tartrate 50 mg PO from 25 Aug 2020 to 02 Sep 2020 and then at 50 mg PO twice a day (BID) since 02 Sep 2020 for hypertension, and apixaban 5 mg PO BID from 25 Aug 2020 to 08 Oct 2020 for atrial fibrillation. The subject was monitored for his response on the beta blocker and calcium channel blocker. On 25 Aug 2020 (Day 22), the subject's laboratory results showed elevated alanine aminotransferase of 107 IU/L (NR: 30-65 IU/L), aspartate aminotransferase of 57 IU/L (NR: 15-37 IU/L), chloride of 108 mmol/L (NR: 98-107 mmol/L), and magnesium of 2.5 mg/dL (NR: 1.8-2.4 mg/dL); as well as low anion gap of 5 (NR: 7-16; units not reported). On the same day (Day 22), the subject was discharged from the hospital and was scheduled for an outpatient cardioversion with a transesophageal echocardiogram. On 02 Sep 2020 (Day 30), the subject followed up with his cardiologist, who performed a stress test and cardiac catheterization (results pending). An ECG performed on the same day was abnormal and showed atrial fibrillation with a nonspecific T-wave abnormality, and the subject was diagnosed with atrial flutter with an onset date of 02 Sep 2020 (Day 30). On 08 Sep 2020 (Day 36), the transesophageal ECG results revealed new cardiac findings of septal myocardial infarction that was considered probably old, mitral valve incompetence, bileaflet mitral valve prolapse, and left atrial enlargement. On the same day (Day 36), the myocardial infarction, atrial fibrillation, and atrial flutter were considered resolved. On 08 Sep 2020 (Day 36), a transesophageal echocardiography with cardioversion was performed with no complications. The cardiac rhythm was successfully converted from atrial fibrillation to normal sinus rhythm with a ventricular rate of 69 bpm. On 09 Sep 2020 (Day 37), the subject was diagnosed with bileaflet mitral valve prolapse, left atrial enlargement, and mitral valve incompetence. The subject was treated with acetylsalicylic acid 81 mg PO once daily (since 30 Sep 2020) as prophylaxis. The subject was discontinued from the study intervention on 23 Aug 2020 because of the atrial fibrillation and remains in the study to be evaluated for safety, immunogenicity, and efficacy. The hypertension, mitral valve incompetence, left atrial enlargement, left ventricular hypertrophy, and mitral valve prolapse were ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the paroxysmal atrial fibrillation with rapid ventricular response was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment and considered the event to be more likely a coincidental condition associated with the underlying cardiovascular conditions and arrhythmias and might be indicative of COVID-19.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	81.91 kg	27.4 kg/m2	06AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic Rhinitis-Seasonal	Seasonal allergy	1976	Present
Hair Loss	Alopecia	2000	Present
Umbilical hernia	Umbilical hernia	2010	Present
Pectoralis Tendon Tear-Right	Tendon rupture	2013	Past
Pectoralis tendon Tear Repair-Right	Tenoplasty	2013	Past
Partial Achilles Tendon Tear-Right Foot	Tendon rupture	MAR2018	Past
Right Foot Achilles Tendon Repair	Tenoplasty	MAR2018	Past
Stomach Cramps	Abdominal pain upper	03AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	06AUG2020 (1)	11:30
3	BNT162b2	06MAR2021 (213)	11:00

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain	Worsening of Abdominal Pain	14AUG2020 (9)	00:00	24AUG2020 (19)	11:32	11	4
2	INFEC	Cellulitis	Phlegmon Formation	20AUG2020 (15)	00:00	20AUG2020 (15)	00:00	1	3
3	GASTR	Diverticular perforation	Ruptured diverticulum	14AUG2020 (9)	00:00	24AUG2020 (19)	00:00	11	4
4	INFEC	Diverticulitis	Diverticulitis	20AUG2020 (15)	00:00	25AUG2020 (20)		6	4
5	INFEC	Diverticulitis	Diverticulitis	26AUG2020 (21)		ONGOING			3
6	GENRL	Fatigue	Fatigue	07MAR2021 (214)	00:00	08MAR2021 (215)	00:00	2	1
7	NERV	Headache	Slight Headache	07MAR2021 (214)	00:00	08MAR2021 (215)	00:00	2	1
8	GENRL	Injection site pain	Injection Site Pain-Left	07MAR2021 (214)	00:00	08MAR2021 (215)	00:00	2	1
9	MUSC	Myalgia	Muscle Aches	07MAR2021 (214)	00:00	08MAR2021 (215)	00:00	2	1
10	INJ&P	Postoperative ileus	Post Operative Ileus	18AUG2020 (13)	00:00	23AUG2020 (18)	00:00	6	2
11	GASTR	Small intestinal obstruction	Small Bowel Obstruction	20AUG2020 (15)	00:00	20AUG2020 (15)	00:00	1	3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (24AUG2020)	NOT RELATED/OTHER: Ruptured Diverticulum	1	9	N
2	TC/TCN	N	Resolved (20AUG2020)	NOT RELATED/OTHER: Diverticulitis	1	15	N
3	TC/TCN/P	Y	Resolved (24AUG2020)	NOT RELATED/OTHER: Infection	1	9	Y
4	TC/TCN	N	Resolved (25AUG2020)	NOT RELATED/OTHER: Infection	1	15	N
5	TC	N	Yes	NOT RELATED/OTHER: Medical event	1	21	N
6	N	N	Resolved (08MAR2021)	Study Treatment	3	2	N
7	N	N	Resolved (08MAR2021)	Study Treatment	3	2	N
8	N	N	Resolved (08MAR2021)	Study Treatment	3	2	N
9	N	N	Resolved (08MAR2021)	Study Treatment	3	2	N
10	TC	N	Resolved (23AUG2020)	NOT RELATED/OTHER: Surgical Side Effect	1	13	N
11	TC/TCN	N	Resolved (20AUG2020)	NOT RELATED/OTHER: Ruptured Diverticulum	1	15	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Influenza Vaccine	INFLUENZA VACCINE	02FEB2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06AUG2020	
Withdrawn	VACCINATION	14AUG2020	ADVERSE EVENT
Completed	REPEAT SCREENING 1	06MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1083 10831060, a 45-year-old white male with a pertinent medical history of upper abdominal pain (since 03 Aug 2020), received Dose 1 on 06 Aug 2020. The subject was diagnosed with a diverticular perforation on 14 Aug 2020, 8 days after receiving Dose 1. Concomitant medications included finasteride (since Apr 2020) for hair loss, dicyclomine and omeprazole magnesium (since 11 Aug 2020) for stomach cramps, and acetaminophen (since 11 Aug 2020) for fever. On 06 Aug 2020 (Day 1), the subject did not report any symptoms related to the diverticular perforation. On 08 Aug 2020 (Day 3), the subject had a fever, and on 11 Aug 2020 (Day 6), he experienced abdominal pain and reported both to the site. The subject was prescribed dicyclomine and omeprazole for possible gastritis by (b) (6) (b) (6), who was a family physician; additionally, the subject was also taking acetaminophen before the onset of the abdominal pain for fever. The subject stated that he had abdominal cramps since 03 Aug 2020 (Day -3); however, he did not report this to the clinical research coordinator at the time of screening. On 13 Aug 2020 (Day 8), the subject visited a primary care physician for a Helicobacter pylori test; the result was unknown. On 14 Aug 2020 (Day 9), the subject presented to the emergency department with worsening right-sided abdominal pain and was hospitalized ultimately for a small-bowel obstruction. He was diagnosed with a heterogeneous cecal mass via a computed tomogram of the abdomen/pelvis with contrast performed on the same day. On 15 Aug 2020 (Day 10), a SARS-CoV-2 test result was negative. On 16 Aug 2020 (Day 11), 4 benign lymph nodes, ruptured diverticulum, sessile serrated polyps/adenoma, focal serosal colon adhesions, and benign liver cyst were observed via an exploratory laparotomy. On the same day (Day 11), the subject underwent bowel resection with a right hemicolectomy and allograft tissue reinforcement of anastomosis and abdominal wall excision; the right colon and appendix were removed. The pathology result was negative for malignancy. On 17 Aug 2020 (Day 12), a magnetic resonance imaging scan with and without contrast confirmed the benign liver cyst. On 18 Aug 2020 (Day 13), the subject experienced postoperative ileus. On 20 Aug 2020 (Day 15), he was diagnosed with phlegmon formation, small-intestinal obstruction, and diverticulitis. The small-intestinal obstruction and phlegmon formation resolved on the same day (Day 15), and the subject was able to tolerate an oral diet without difficulties. On 23 Aug 2020 (Day 18), the postoperative ileus was considered resolved. On 24 Aug 2020 (Day 19), the subject's laboratory tests showed an elevated alanine aminotransferase of 114 IU/L (normal range [NR]: 16-61 IU/L) and elevated aspartate aminotransferase of 82 IU/L (NR: 15-37 IU/L). A culture was performed (date not provided), which was negative. The subject recovered from the diverticular perforation and worsening of abdominal pain on 24 Aug 2020 (Day 19). He was discharged from the hospital on the same day (Day 19) with the following medications: gabapentin 300 mg orally (PO) 3 times a day, docusate sodium 100 mg PO once daily, pantoprazole 40 mg PO every morning, sucralfate 1 g PO 4 times a day as needed, and tramadol 50 mg PO every 8 hours. The investigator considered the diverticular perforation as life-threatening. On 18 Sep 2020 (Day 44), the subject reported that he was not stable enough to travel or attend the safety visit. The subject was discontinued from the study intervention on 14 Aug 2020 because of the diverticular perforation and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received a first dose of BNT162b2 on 06 Mar 2021 (Day 213) and remains in the study. The diverticulitis was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the diverticular perforation was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to infection. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1985	34	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
178.05 cm	70.59 kg	22.2 kg/m2	18AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	18AUG2020 (1)	17:19
2	Placebo	10SEP2020 (24)	17:06

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure During Pregnancy	23DEC2020 (128)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			W	N	Yes	NOT RELATED/OTHER: Unknown	2	105	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	08OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	24FEB2021	ADVERSE EVENT

Narrative Comment
Subject C4591001 1085 10851129, a 34-year-old white female with a pertinent obstetrical history of 1 previous pregnancy with a live birth, received Dose 1 on 18 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 24). The subject had an exposure during pregnancy on 23 Dec 2020, 104 days after receiving Dose 2. On 16 Jan 2021 (Day 152), the subject's vaccine status was unblinded and she was notified that she had originally received placebo and was eligible for the crossover, but she reported COVID-19 symptoms. During a convalescent visit, she reported to the site that she was 7 weeks pregnant, with a positive pregnancy test on 10 Feb 2021 (Day 177). The gestational period at the time of initial exposure was first trimester. The subject and her partner did not smoke, drink alcohol, or use illicit drugs during the pregnancy. The subject was withdrawn from the study on 24 Feb 2021 because of the exposure during pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	73.75 kg	23.3 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
INSOMNIA	Insomnia	1990	Present
GERD	Gastrooesophageal reflux disease	2010	Present
Alcoholic Cirrhosis	Cirrhosis alcoholic	2019	Present
Esophageal Ulcers	Oesophageal ulcer	2019	Present
Esophageal varices	Varices oesophageal	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	14:43

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	BLOOD	Blood loss anaemia	Acute blood loss anemia	07SEP2020 (20)		09SEP2020 (22)		3	3
2	HEPAT	Cirrhosis alcoholic	Worsening of alcoholic cirrhosis	07SEP2020 (20)		ONGOING			3
3	GASTR	Gastrointestinal haemorrhage	GI Bleed	07SEP2020 (20)		09SEP2020 (22)		3	3
4	GASTR	Haematochezia	Hematochezia	07SEP2020 (20)		09SEP2020 (22)		3	3
5	METAB	Hypernatraemia	Hypernatremia	07SEP2020 (20)		09SEP2020 (22)		3	2
6	GASTR	Oesophageal ulcer	Worsening of esophageal ulcers	07SEP2020 (20)		09SEP2020 (22)		3	3
7	BLOOD	Thrombocytopenia	Thrombocytopenia	07SEP2020 (20)		ONGOING			3
8	GASTR	Varices oesophageal	Worsening of esophageal varices	07SEP2020 (20)		09SEP2020 (22)		3	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (09SEP2020)	NOT RELATED/OTHER: due to varices	1	20	N
2	N	N	Yes	NOT RELATED/OTHER: Worsening of previous condition	1	20	N
3	TC/TCN/P/W	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: Due to Ulcers	1	20	Y
4	TC	N	Resolved (09SEP2020)	NOT RELATED/OTHER: Due to ulcers	1	20	N
5	N	N	Resolved (09SEP2020)	NOT RELATED/OTHER: Spontaneous event	1	20	N

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
6	TC/TCN	N	Resolved (09SEP2020)	NOT RELATED/OTHER: Worsening of previous condition	1	20	N
7	N	N	Yes	NOT RELATED/OTHER: Due to cirrhosis	1	20	N
8	TC/TCN	N	Resolved (09SEP2020)	NOT RELATED/OTHER: Worsening of previous condition	1	20	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19AUG2020	
Withdrawn	VACCINATION	09SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	09SEP2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1087 10871121, a 67-year-old white male with a pertinent medical history of gastroesophageal reflux disease (since 2010) and alcoholic cirrhosis, esophageal ulcers, and esophageal varices (all since 2019), received Dose 1 on 19 Aug 2020. The subject was diagnosed with a gastrointestinal hemorrhage on 07 Sep 2020, 19 days after receiving Dose 1. Concomitant medication included tramadol (since 01 Jun 2020) for insomnia. On 07 Sep 2020 (Day 20), the subject was hospitalized for gastrointestinal hemorrhage. The clinical chemistry laboratory results on 07 Sep 2020 (Day 20) showed sodium of 147, potassium of 3.7, chloride of 116, carbon dioxide (CO2) of 16.6, blood urea nitrogen (BUN) of 22, creatinine of 1.07, international normalized ratio of 1.18, albumin of 3.0, total protein of 6.5, direct bilirubin of 0.61, alanine aminotransferase (ALT) of 24, aspartate aminotransferase (AST) of 28, and alkaline phosphatase (ALP) of 96 (normal ranges and units were not reported). On 07 Sep 2020 (Day 20), the subject was diagnosed with anemia due to blood loss, alcoholic cirrhosis, hematochezia, esophageal ulcer, thrombocytopenia, esophageal varices, and hypernatremia. An esophagogastroduodenoscopy performed the next day (Day 21) revealed postbanding ulcers and residual esophageal varices. The esophageal varices were rebanded, and the subject was observed overnight. It was reported that the subject failed to report a past history of esophageal varices and alcoholic cirrhosis. Laboratory results on 08 Sep 2020 (Day 21) revealed a hematocrit (Hct) of 22.9, hemoglobin (Hb) of 7.1, sodium of 147, potassium of 3.7, chloride of 119, CO2 of 19.8, BUN of 18, creatinine of 0.86, white blood cell count of 2.9, platelet count of 70, albumin of 2.7, total protein of 5.3, ALT of 15, AST of 31, and ALP of 82 (normal ranges and units were not reported). On 09 Sep 2020 (Day 22), the laboratory results showed Hct of 21.4, Hb of 7.0, sodium of 143, potassium of 3.6, chloride of 115, CO2 of 21.0, BUN of 14, and creatinine of 0.73 (normal ranges and units were not reported). A COVID-19 test was not performed during the hospitalization. The blood-loss anemia, gastrointestinal hemorrhage, hematochezia, hypernatremia, esophageal ulcer, and esophageal varices were considered resolved on 09 Sep 2020 (Day 22). It was noted that the bleeding did not reoccur, and the subject was discharged on the same day (Day 22). The subject notified the site that he was feeling well and had recovered from the event. The subject was withdrawn from the study on 09 Sep 2020 because of the gastrointestinal hemorrhage. The alcoholic cirrhosis and thrombocytopenia were ongoing at the time of withdrawal. In the opinion of the investigator, there was no reasonable possibility that the gastrointestinal hemorrhage was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to ulcers. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	72	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.9 cm	92.5 kg	27.7 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERTENSION	Hypertension	2005	Present
GROUT	Gout	2017	Present
BILATERAL FOOT PAIN	Pain in extremity	2018	Present
BENIGN PROSTATIC HYPERPLASIA	Benign prostatic hyperplasia	JAN2020	Present
CONGESTIVE HEART FAILURE	Cardiac failure congestive	FEB2020	Present
CHRONIC KIDNEY DISEASE	Chronic kidney disease	FEB2020	Present
Triple Bypass	Coronary artery bypass	FEB2020	Past
CORONARY ARTERY DISEASE	Coronary artery disease	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	13:02

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	VASC	Accelerated hypertension	Accelerated Hypertension	03SEP2020 (9)		06SEP2020 (12)		4	3	N	N
2	RENAL	Acute kidney injury	Acute Kidney Injury	03SEP2020 (9)		07SEP2020 (13)		5	2	N	N
3	RESP	Acute respiratory failure	Acute Respiratory Failure	03SEP2020 (9)		04SEP2020 (10)		2	3	TC	N
4	CARD	Atrial fibrillation	PAROXYSMAL ATRIAL Fibrillation	03SEP2020 (9)		08SEP2020 (14)		6	2	N	N
5	CARD	Cardiac failure congestive	Worsening of Chronic Congestive Heart Failure	03SEP2020 (9)		08SEP2020 (14)		6	3	TC/P/W	Y
6	METAB	Dehydration	DEHYDRATION	03SEP2020 (9)		04SEP2020 (10)		2	2	TCN	N
7	NERV	Dizziness	Dizziness	05SEP2020 (11)		08SEP2020 (14)		4	2	TCN	N
8	RESP	Dyspnoea	SHORTNESS OF BREATH	03SEP2020 (9)		04SEP2020 (10)		2	3	N	N
9	METAB	Hypokalaemia	HYPOKALEMIA	04SEP2020 (10)		06SEP2020 (12)		3	2	TC	N
10	VASC	Hypotension	Hypotension	05SEP2020 (11)		07SEP2020 (13)		3	2	N	N
11	MUSC	Pain in extremity	WORSENING OF BILATERAL FOOT PAIN	05SEP2020 (11)		06SEP2020 (12)		2	2	TC	N
12	RESP	Pulmonary oedema	BILATERAL PULMONARY EDEMA	03SEP2020 (9)		05SEP2020 (11)		3	2	N	N

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Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
13	GENRL	Pyrexia	LOW-GRADE FEVER	05SEP2020 (11)		06SEP2020 (12)		2	2	N	N
14	INFEC	Urinary tract infection	Urinary Tract Infection	03SEP2020 (9)		08SEP2020 (14)	08:08	6	2	TC	N

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (06SEP2020)	NOT RELATED/OTHER: worsening of pre-existing condition	1	9	N
2	Resolved (07SEP2020)	NOT RELATED/OTHER: Dehydration	1	9	N
3	Resolved (04SEP2020)	NOT RELATED/OTHER: due to congestive heart failure	1	9	N
4	Resolved (08SEP2020)	NOT RELATED/OTHER: URINARY TRACT INFECTION	1	9	N
5	Resolved (08SEP2020)	NOT RELATED/OTHER: worsening of pre-existing condition	1	9	Y
6	Resolved (04SEP2020)	NOT RELATED/OTHER: DUE TO DIURETICS	1	9	N
7	Resolved (08SEP2020)	NOT RELATED/OTHER: due to UTI	1	11	N
8	Resolved (04SEP2020)	NOT RELATED/OTHER: CONGESTIVE HEART FAILURE	1	9	N
9	Resolved (06SEP2020)	NOT RELATED/OTHER: DUE TO DIURESIS	1	10	N
10	Resolved (07SEP2020)	NOT RELATED/OTHER: due to diuresis	1	11	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
11	Resolved (06SEP2020)	NOT RELATED/OTHER: WORSENING OF PRE-EXISTING CONDITION	1	11	N
12	Resolved (05SEP2020)	NOT RELATED/OTHER: CONGESTIVE HEART FAILURE	1	9	N
13	Resolved (06SEP2020)	NOT RELATED/OTHER: URINARY TRACT INFECTION	1	11	N
14	Resolved (08SEP2020)	NOT RELATED/OTHER: spontaneous	1	9	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Withdrawn	VACCINATION	16SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	16SEP2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1087 10871228, a 72-year-old white male with a pertinent medical history of hypertension (since 2005), benign prostatic hyperplasia (since Jan 2020), and congestive cardiac failure, chronic kidney disease, and coronary artery disease including coronary artery bypass (all since Feb 2020), received Dose 1 on 26 Aug 2020. The subject experienced worsening of chronic congestive heart failure on 03 Sep 2020, 8 days after receiving Dose 1. Concomitant medications included metoprolol (from 2005 to 03 Sep 2020) for hypertension, rivaroxaban (since Feb 2020) for coronary artery disease, colchicine (since Feb 2020) for gout, tamsulosin (since Mar 2020) for benign prostatic hyperplasia, and nifedipine (since Jul 2020) for hypertension. On 03 Sep 2020 (Day 9), the subject went to an emergency room with dyspnea (shortness of breath), accelerated hypertension, and an acute kidney injury and was subsequently admitted to the hospital with exacerbation of chronic congestive heart failure resulting in acute respiratory failure. On 03 Sep 2020 (Day 9), the subject's blood pressure (BP) was 217/113 mmHg and laboratory results were as follows: cardiac troponin I: 0.095 (units not reported), carbon dioxide (CO2): 21.8 mmol/L, blood urea nitrogen (BUN): 35 mg/dL, creatinine: 2.61 mg/dL, N-terminal prohormone brain natriuretic peptide (NT-proBNP): 19,381 pg/mL, and hemoglobin A1C: 5.40 mg/dL (normal ranges not reported for all). A chest x-ray showed previous cardiac surgery with sternotomy wires in place and mild to moderate pulmonary opacities that were suspicious for inflammation/infection or edema; no significant pleural effusions were noted. A second chest x-ray performed on the same day (Day 9) revealed bilateral pulmonary edema, for which the subject was treated with furosemide intravenously, then transitioned to oral (PO) administration. A urinalysis was positive for nitrites and leukocytes and a urine culture showed Citrobacter freundii complex. On 03 Sep 2020 (Day 9), the subject was also diagnosed with a urinary tract infection, paroxysmal atrial fibrillation, and dehydration. He was treated with sulfamethoxazole/trimethoprim for 3 days for the urinary tract infection. While he was in the hospital, his SARS-CoV-2 (COVID-19) test was negative. On 04 Sep 2020 (Day 10), laboratory tests showed white blood cell (WBC) count: 6.3 K/µL, hematocrit (HCT): 32.8%, hemoglobin (Hb): 96 g/dL, platelet count (PLT): 157 K/µL, sodium (Na): 140 mmol/L, potassium (K): 3.3 mmol/L, chloride (Cl): 110 mmol/L, CO2: 23.7 mmol/L, BUN: 36 mg/dL, creatinine: 2.55 mg/dL, proBNP: 20,860 pg/mL, and albumin (ALB): 3.2 g/dL (normal ranges not reported for all). On the same day (Day 10), the dyspnea, acute respiratory failure, and dehydration were considered resolved, and the subject was noted to have hypokalemia. On 05 Sep 2020 (Day 11), the subject experienced dizziness, hypotension, worsening of bilateral foot pain, and pyrexia (low-grade fever). His BP was 118/69 mmHg (lower than his typical BP) because of treatment with furosemide and isosorbide mononitrate. Laboratory tests showed Na: 140 mmol/L, K: 3.3 mmol/L, Cl: 110 mmol/L, CO2: 26.2 mmol/L, BUN: 38 mg/dL, creatinine: 2.61 mg/dL, and ALB: 3.5 g/dL. On the same day (Day 11), the pulmonary edema resolved. Laboratory tests on 06 Sep 2020 (Day 12) showed Na: 136 mmol/L, K: 3.7 mmol/L, Cl: 104 mmol/L, CO2: 24.2 mmol/L, BUN: 38 mg/dL, creatinine: 2.45 mg/dL, NT-proBNP: 3465 pg/mL, and ALB: 3.2 g/dL. On 06 Sep 2020 (Day 12), the accelerated hypertension, hypokalemia, worsening of bilateral foot pain, and pyrexia resolved. On 07 Sep 2020 (Day 13), the laboratory tests showed a WBC count of 5.6 K/µL, HCT of 36.4%, Hb of 10.6 g/dL, PLT of 176 K/µL, Na of 137 mmol/L, K of 3.9 mmol/L, Cl of 107 mmol/L, CO2 of 23.7 mmol/L, BUN of 38 mg/dL, creatinine of 2.49 mg/dL, and ALB of 3.1 g/dL; on 08 Sep 2020 (Day 14), the results were WBC count of 4.3 K/µL, HCT of 37%, Hb of 10.8 g/dL, and PLT of 186 K/µL. On 07 Sep 2020 (Day 13), the acute kidney injury and hypotension resolved. On 08 Sep 2020 (Day 14), the atrial fibrillation, worsening of chronic congestive heart failure, dizziness, and urinary tract infection resolved, and the subject was discharged on furosemide PO and supplemental oxygen. The subject was withdrawn from the study on 16 Sep 2020 because of the worsening of chronic congestive heart failure. In the opinion of the investigator, there was no reasonable possibility that the worsening of chronic congestive heart failure was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1997	23	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
182.88 cm	83.5 kg	25 kg/m2	08SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	08SEP2020 (1)	12:36

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	GENRL	Fatigue	Fatigue	11SEP2020 (4)		ONGOING
2	MUSC	Myalgia	Myalgia	11SEP2020 (4)		ONGOING
3	GENRL	Vaccination site pain	Soreness in Vaccine Arm	08SEP2020 (1)		ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			1	N	N	Yes	Study Treatment	1	4	N
2			1	P/W	N	Yes	Study Treatment	1	4	Y
3			1	N	N	Yes	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Withdrawn	VACCINATION	17SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	17SEP2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1087 10871354, a 23-year-old white male with no reported medical history, received Dose 1 on 08 Sep 2020. The subject experienced myalgia on 11 Sep 2020, 3 days after receiving Dose 1. The subject experienced vaccination site pain on 08 Sep 2020 (Day 1) and developed fatigue and myalgia on 11 Sep 2020 (Day 4). The subject was withdrawn from the study on 17 Sep 2020 because of the myalgia. The fatigue, myalgia, and vaccination site pain were all ongoing at the time of withdrawal. In the opinion of the investigator, there was a reasonable possibility that the myalgia was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	Asian	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	55.92 kg	23.3 kg/m2	14OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to under cooked shrimp	Food allergy	2005	Present
POLYCYSTIC OVARIAN SYNDROME	Polycystic ovaries	2005	Present
Vitamin D Deficiency	Vitamin D deficiency	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14OCT2020 (1)	13:08

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	24OCT2020 (11)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		P	N	Yes	NOT RELATED/OTHER: Sexual Intercourse	1	11	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14OCT2020	
Withdrawn	VACCINATION	05NOV2020	PREGNANCY
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1087 10871557, a 34-year-old Asian female with no previous pregnancies and a pertinent medical history of polycystic ovaries (since 2005), received Dose 1 on 14 Oct 2020. The subject had a positive urine pregnancy test on 05 Nov 2020 (Day 23) and had an exposure during pregnancy on 24 Oct 2020, 10 days after receiving Dose 1. Concomitant medications included cyanocobalamin (since 2018) as a dietary supplement and cholecalciferol (since 2018) for vitamin deficiency. A repeat pregnancy test was also positive. The subject confirmed that she used contraceptives (condom with spermicide), was unaware that she was pregnant, and planned to follow up with her obstetrician/gynecologist. The first date of her last menstrual period was 17 Sep 2020 and the estimated date of conception was 24 Oct 2020 (Day 11). She did not smoke, drink alcohol, or use illicit drugs during her pregnancy. Her husband did not have any potential environmental or occupational exposures or family history of consanguinity. The subject and her husband did not have any family history of congenital abnormalities or genetic diseases. Her husband smoked, drank alcohol, and used recreational drugs during her pregnancy. The subject was discontinued from the study intervention on 05 Nov 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
182.88 cm	131.64 kg	39.3 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
inguinal hernia	Inguinal hernia	1990	Past
inguinal hernia repair	Inguinal hernia repair	1990	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11SEP2020 (1)	10:39
2	BNT162b2	02OCT2020 (22)	11:12

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	HEPAT	Acute hepatic failure	Acute Liver Failure	19DEC2020 (100)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		4	W	Y	Yes	NOT RELATED/OTHER: unknown	2	79	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	30OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	19DEC2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1089 10891289, a 48-year-old white male with no pertinent medical history, received Dose 1 on 11 Sep 2020 and Dose 2 on 02 Oct 2020 (Day 22). The subject was diagnosed with acute hepatic failure on 19 Dec 2020, 78 days after receiving Dose 2. On 19 Dec 2020 (Day 100), the subject visited the emergency room because of the acute hepatic failure, which was considered as life-threatening, requiring hospitalization. It was unknown if a COVID-19 test was done. The subject was withdrawn from the study on 19 Dec 2020 because of the acute hepatic failure that was ongoing at the time of withdrawal. In the opinion of the investigator, there was no reasonable possibility that the acute hepatic failure was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	124 kg	45.5 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	1980	Present
Allergic Rhinitis	Rhinitis allergic	1980	Present
Asthmatic Bronchitis	Asthma	1985	Present
Eczema	Eczema	1985	Present
Allergy to Dust	Dust allergy	1990	Present
Allergy to Tomatoes	Food allergy	1990	Present
Latex Allergy	Rubber sensitivity	1990	Present
Kidney Stones	Nephrolithiasis	1996	Present
Endometriosis	Endometriosis	2003	Present

Medical History

Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
ACL surgery	Ligament operation	2003	Past
torn ACL	Ligament rupture	2003	Past
polycystic ovarian syndrome	Polycystic ovaries	2003	Present
Meniscus Repair Surgery due to meniscus tear	Meniscus operation	2016	Past
Type II Diabetes	Type 2 diabetes mellitus	JUN2020	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	11AUG2020 (1)	16:20
2	Placebo	31AUG2020 (21)	16:10
3	BNT162b2	27JAN2021 (170)	13:32
4	BNT162b2	18FEB2021 (192)	14:34

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INFEC	Appendicitis perforated	acute appendicitis with perforation	04FEB2021 (178)		11FEB2021 (185)		8
2	INFEC	Focal peritonitis	localized peritonitis	04FEB2021 (178)		11FEB2021 (185)		8
3	NERV	Headache	Headache	18FEB2021 (192)	18:30	20FEB2021 (194)		3
4	GENRL	Injection site pain	Injection site pain-right arm	18FEB2021 (192)	18:30	20FEB2021 (194)		3

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
5	MUSC	Myalgia	Myalgia	18FEB2021 (192)	18:30	20FEB2021 (194)		3
6	INFEC	Pelvic abscess	pelvic abscess	04FEB2021 (178)		11FEB2021 (185)		8

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	TC/TCN	Y	Resolved (11FEB2021)	NOT RELATED/OTHER: unknown	3	9	Y
2	4	TC/TCN	Y	Resolved (11FEB2021)	NOT RELATED/OTHER: appendicitis	3	9	Y
3	2	TC	N	Resolved (20FEB2021)	Study Treatment	4	1	N
4	2	TC/W	N	Resolved (20FEB2021)	Study Treatment	4	1	Y
5	2	TC	N	Resolved (20FEB2021)	Study Treatment	4	1	N
6	4	TC/TCN	Y	Resolved (11FEB2021)	NOT RELATED/OTHER: appendicitis	3	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	02OCT2020	
Completed	REPEAT SCREENING 1	27JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1090 10901140, a 44-year-old white female with a pertinent medical history of nephrolithiasis (since 1996), endometriosis (since 2003), polycystic ovary disease (since 2003), and type 2 diabetes mellitus (since Jun 2020), received Dose 1 on 11 Aug 2020 and Dose 2 on 31 Aug 2020 (Day 21). Concomitant medications included cetirizine hydrochloride (since 2016) for allergies, fluticasone furoate/vilanterol trifenatate (since Feb 2019) for asthma, and phentermine hydrochloride/topiramate (since Jun 2020) for weight loss. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 27 Jan 2021 (Day 170). The subject experienced perforated appendicitis, focal peritonitis, and pelvic abscess starting on 04 Feb 2021, 8 days after receiving the first dose of BNT162b2. On 15 Feb 2021 (Day 189), the subject informed the site that she was hospitalized on 08 Feb 2021 (Day 182) because of the acute appendicitis with perforation and localized peritonitis with pelvic abscess. On 08 Feb 2021 (Day 182), the subject presented to the emergency room (ER) with right lower quadrant abdominal pain (since 04 Feb 2021). The subject had nausea, but no fever. A computed tomography scan showed acute appendicitis with perforation. In the ER, the subject received intravenous fluids and antibiotics (unspecified). A SARS-CoV-2 test performed on 08 Feb 2021 (Day 182) was negative. On the same day (Day 182), the subject underwent a laparoscopic appendectomy and a drainage of the pelvic abscess was also performed. On 11 Feb 2021 (Day 185), the perforated appendicitis, focal peritonitis, and pelvic abscess resolved and the subject was discharged from the hospital on antibiotics (amoxicillin/clavulanic acid 875/125 mg twice a day for 7 days) and pain medications (hydroxyzine and oxycodone as needed). In the opinion of the investigator, there was no reasonable possibility that the perforated appendicitis, focal peritonitis, and pelvic abscess were related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. The subject received the second dose of BNT162b2 on 18 Feb 2021 (Day 192). On 18 Feb 2021, the subject reported injection site pain, headache, and myalgia. After the data cutoff date of 13 Mar 2021 (with snapshot taken on 25 Mar 2021), it was determined that the subject did not withdraw from the study because of the injection site pain and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
150 cm	57.6 kg	25.6 kg/m2	17SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Insect Allergy	Allergy to arthropod sting	1973	Present
Mushroom Allergy	Food allergy	1973	Present
Allergic Rhinitis	Rhinitis allergic	1973	Present
Grass Allergy	Seasonal allergy	1973	Present
Allergy to Pollen	Seasonal allergy	1973	Present
Osteopenia	Osteopenia	1996	Present
Chronic Back Pain	Back pain	2000	Present
Post-Menopausal	Postmenopause	2000	Present
Chronic Urinary Tract Infections	Urinary tract infection	2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vaginal Dryness	Vulvovaginal dryness	2000	Present
Insomnia	Insomnia	2015	Present
Osteoarthritis of Neck	Spinal osteoarthritis	2015	Present
Recurrent GERD	Gastrooesophageal reflux disease	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17SEP2020 (1)	13:08
3	BNT162b2	21JAN2021 (127)	12:28
4	BNT162b2	10FEB2021 (147)	13:21

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	VASC	Hypertension	hypertension	09OCT2020 (23)		ONGOING		
2	INFEC	Sinusitis	sinus infection, possible	30SEP2020 (14)		11NOV2020 (56)		43

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC/P	N	Yes	NOT RELATED/OTHER: unknown	1	23	Y
2	2	TC	N	Resolved (11NOV2020)	NOT RELATED/OTHER: unk	1	14	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
Flu vaccine	INFLUENZA VACCINE	03OCT2020

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17SEP2020	
Withdrawn	VACCINATION	13NOV2020	ADVERSE EVENT
Completed	REPEAT SCREENING 1	21JAN2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	10MAR2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1090 10901415, a 68-year-old white female with a pertinent medical history of back pain and postmenopause (both since 2000), spinal osteoarthritis and insomnia (both since 2015), and gastroesophageal reflux disease (since 2018), received Dose 1 on 17 Sep 2020. The subject was diagnosed with hypertension on 09 Oct 2020 (Day 23), 22 days after receiving Dose 1. The subject was withdrawn from the study intervention on 13 Nov 2020 because of the hypertension that was ongoing at the time of withdrawal. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 21 Jan 2021 (Day 127) and 10 Feb 2021 (Day 147), respectively, and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the hypertension was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.5 cm	75.9 kg	28 kg/m2	09OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic Rhinitis	Rhinitis allergic	1986	Present
Basal Cell Carcinoma Leg (L)	Basal cell carcinoma	2000	Past
Gastrointestinal Polyps	Intestinal polyp	2003	Present
Basal Cell Carcinoma Chest	Basal cell carcinoma	2004	Past
Basal Cell Carcinoma Arm (L)	Basal cell carcinoma	2005	Past
Post-Menopausal	Postmenopause	2010	Present
Recurrent GERD	Gastrooesophageal reflux disease	OCT2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09OCT2020 (1)	14:30
2	Placebo	02NOV2020 (25)	16:20
3	BNT162b2	01FEB2021 (116)	09:56
4	BNT162b2	22FEB2021 (137)	11:31

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Fatigue	Fatigue	23FEB2021 (138)		24FEB2021 (139)	
2	MUSC	Myalgia	Myalgia	23FEB2021 (138)		24FEB2021 (139)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	W	N	Resolved (24FEB2021)	Study Treatment	4	2	Y
2	2	1	TC	N	Resolved (24FEB2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09OCT2020	
Completed	VACCINATION	30NOV2020	
Completed	REPEAT SCREENING 1	01FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
After the data cutoff date of 13 Mar 2021 (with snapshot taken on 25 Mar 2021), it was determined that Subject C4591001 1090 10901492 did not withdraw from the study because of the fatigue and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.6 cm	80.6 kg	29.7 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	2007	Present
Recurrent Constipation	Constipation	2007	Present
Depression	Depression	2007	Present
Irritable Bowel Syndrome	Irritable bowel syndrome	2007	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	11:18
3	BNT162b2	11MAR2021 (147)	13:07

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	SKIN	Urticaria	Hives, upper chest	19OCT2020 (4)		22OCT2020 (7)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	2	TC/P	N	Resolved (22OCT2020)	Study Treatment	1	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
Withdrawn	VACCINATION	04NOV2020	ADVERSE EVENT
Completed	REPEAT SCREENING 1	11MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1090 10901507, a 31-year-old black or African American female with a pertinent medical history of anxiety (since 2007), received Dose 1 on 16 Oct 2020. The subject experienced urticaria (hives, upper chest) on 19 Oct 2020, 3 days after receiving Dose 1. On 22 Oct 2020 (Day 7), the urticaria resolved. The subject was discontinued from the study intervention on 04 Nov 2020 because of the urticaria and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 11 Mar 2021 (Day 147) and remains in the study. In the opinion of the investigator, there was a reasonable possibility that the urticaria was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1939	81	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186 cm	97.5 kg	28.2 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Penicillin Allergy	Drug hypersensitivity	1970	Present
hypertension	Hypertension	2005	Present
Anxiety	Anxiety	2008	Present
Actinic Keratosis	Actinic keratosis	2010	Present
BLE Edema	Oedema peripheral	2010	Present
Arrythmia	Arrhythmia	2015	Past
Cardiac Ablation	Cardiac ablation	2015	Past
Basal Cell Carcinoma	Basal cell carcinoma	2018	Past
B/L Cataracts	Cataract	2018	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
B/L Cataract Surgery	Cataract operation	2018	Past
Sulfa Drug Allergy	Drug hypersensitivity	2018	Present
Parkinson's Disease	Parkinson's disease	AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03SEP2020 (1)	12:42
2	BNT162b2	22SEP2020 (20)	14:10

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Arthropod sting	Itching due to Beestings	17SEP2020 (15)		21SEP2020 (19)		5	2
2	INJ&P	Arthropod sting	Swelling due to Beestings	17SEP2020 (15)		21SEP2020 (19)		5	1
3	GASTR	Dental caries	dental cavity	17SEP2020 (15)		17SEP2020 (15)		1	1
4	SKIN	Dermatitis	Dermatitis of unknown origin on chest and bilateral arms	JAN2021 ()		ONGOING			1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (21SEP2020)	NOT RELATED/OTHER: insect sting	1	15	N
2	TC	N	Resolved (21SEP2020)	NOT RELATED/OTHER: insect sting	1	15	N
3	N	N	Resolved (17SEP2020)	NOT RELATED/OTHER: dental issue	1	15	N
4	TC/W	N	Yes	NOT RELATED/OTHER: Unknown irritant to skin	2		Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
After the data cutoff date of 13 Mar 2021 (with snapshot taken on 25 Mar 2021), it was determined that Subject C4591001 1091 10911247 did not withdraw from the study because of the dermatitis and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2002	18	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168.5 cm	51 kg	18 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
headaches (intermittent)	Headache	2015	Present
seasonal allergies	Seasonal allergy	2017	Present
exercise induced asthma	Asthma exercise induced	2018	Present
anxiety	Anxiety	DEC2019	Present
depression	Depression	DEC2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14SEP2020 (1)	15:40
2	Placebo	05OCT2020 (22)	16:55
3	BNT162b2	22FEB2021 (162)	15:52

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Fatigue	fatigue	22FEB2021 (162)	21:00	26FEB2021 (166)		5	2
2	INFEC	Fungal infection	yeast infection	13FEB2021 (153)		19FEB2021 (159)		7	1
3	GENRL	Injection site pain	injection site pain	22FEB2021 (162)	21:00	24FEB2021 (164)		3	1
4	INFEC	Vulvovaginal mycotic infection	vaginal yeast infection	02OCT2020 (19)		05OCT2020 (22)		4	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	N	Resolved (26FEB2021)	Study Treatment	3	1	Y
2	TC	N	Resolved (19FEB2021)	NOT RELATED/OTHER: imbalance of vaginal pH	2	132	N
3	TC	N	Resolved (24FEB2021)	Study Treatment	3	1	N
4	TC	N	Resolved (05OCT2020)	NOT RELATED/OTHER: fungal infection	1	19	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine	INFLUENZA VACCINE	02NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	02NOV2020	
Completed	REPEAT SCREENING 1	22FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
After the data cutoff date of 13 Mar 2021 (with snapshot taken on 25 Mar 2021), it was determined that Subject C4591001 1091 10911297 did not withdraw from the study because of the fatigue and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	69.45 kg	26.2 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
dyslipidemia	Dyslipidaemia	2000	Present
dry eye syndrome	Dry eye	2005	Present
thyroid goiter	Goitre	2005	Present
hypertension	Hypertension	AUG2008	Present
postmenopausal	Postmenopause	2010	Present
seasonal allergies	Seasonal allergy	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	09:30
2	Placebo	10SEP2020 (22)	08:48
3	BNT162b2	02FEB2021 (167)	11:57
4	BNT162b2	23FEB2021 (188)	10:40

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Chills	02FEB2021 (167)	23:00	03FEB2021 (168)	
2	GENRL	Fatigue	Fatigue	23FEB2021 (188)	18:30	24FEB2021 (189)	11:00
3	GENRL	Pain	Body Aches	02FEB2021 (167)	23:00	03FEB2021 (168)	
4	GENRL	Pain	Body aches	23FEB2021 (188)	18:30	24FEB2021 (189)	11:00
5	GENRL	Pyrexia	Fever	23FEB2021 (188)	21:00	24FEB2021 (189)	11:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (03FEB2021)	Study Treatment	3	1	N
2	2	1	N	N	Resolved (24FEB2021)	Study Treatment	4	1	N
3	2	2	TC	N	Resolved (03FEB2021)	Study Treatment	3	1	N
4	2	2	TC/W	N	Resolved (24FEB2021)	Study Treatment	4	1	Y
5	2	1	N	N	Resolved (24FEB2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	08OCT2020	
Completed	REPEAT SCREENING 1	02FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
After the data cutoff date of 13 Mar 2021 (with snapshot taken on 25 Mar 2021), it was determined that Subject C4591001 1092 10921021 did not withdraw from the study because of the pain and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	25	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.29 cm	61.91 kg	23.7 kg/m2	25AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	17:21

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	25AUG2020 (1)	00:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			P	N	Yes	NOT RELATED/OTHER: PREGNANCY	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Withdrawn	VACCINATION	18SEP2020	PREGNANCY
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	09NOV2020	LOST TO FOLLOW-UP

Narrative Comment
Subject C4591001 1093 10931058, a 25-year-old white female with no reported medical history or previous pregnancies, received Dose 1 on 25 Aug 2020. The subject's urine pregnancy test was positive on 18 Sep 2020 (Day 25) and she had an exposure during pregnancy on 25 Aug 2020, on the same day as Dose 1. Concomitant medication included ethinylestradiol/levonorgestrel (since 01 Jun 2020) for contraception. On 18 Sep 2020 (Day 25), the subject came in for her second vaccination visit and a urine pregnancy test result was positive; therefore, the second dose was not administered. The subject was using birth control during this time. The first day of her last menstrual period was reported as 27 Jul 2020 (Day -29). The subject was discontinued from the study intervention on 18 Sep 2020 because of the exposure during pregnancy and was withdrawn from the study on 09 Nov 2020, as she was lost to follow-up.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	136.82 kg	40.8 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERTROPHIC CARDIOMYOPATHY	Hypertrophic cardiomyopathy	1976	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2018	Present
HYPERTENSION	Hypertension	2019	Present
SEPTAL MYECTOMY	Septal myectomy	12JUL2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	16:54
3	BNT162b2	01MAR2021 (172)	13:23

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	VASC	Hypertension	WORSENING HYPERTENSION	30SEP2020 (20)	00:00	21OCT2020 (41)		22	1	TC/P

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Resolved (21OCT2020)	NOT RELATED/OTHER: UNDERLYING MEDICAL CONDITION	1	20	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11SEP2020	
Withdrawn	VACCINATION	18NOV2020	ADVERSE EVENT
Completed	REPEAT SCREENING 1	01MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1093 10931128, a 57-year-old white male with a pertinent medical history of hypertrophic cardiomyopathy (since 1976), hypercholesterolemia (since 2018), hypertension (since 2019), and septal myectomy (on 12 Jul 2019), received Dose 1 on 11 Sep 2020. The subject experienced worsening hypertension on 30 Sep 2020, 19 days after receiving Dose 1.
On 21 Oct 2020 (Day 41), the worsening hypertension resolved. The subject was discontinued from the study intervention on 18 Nov 2020 because of the worsening hypertension and remains in the study to be evaluated for safety, immunogenicity, and efficacy.
In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first dose of BNT162b2 on 01 Mar 2021 (Day 172) and remains in the study.
In the opinion of the investigator, there was no reasonable possibility that the worsening hypertension was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	50	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	99.7 kg	35.3 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type II Diabetes	Type 2 diabetes mellitus	2000	Present
Hypercholesterolemia	Hypercholesterolaemia	2014	Present
Excessive Perspiration	Hyperhidrosis	2014	Present
Hypertension	Hypertension	2014	Present
Deep Vein Thrombosis	Deep vein thrombosis	2015	Present
Itching of Legs	Pruritus	2015	Present
Osteomyelitis	Osteomyelitis	2017	Past
Post Traumatic Stress Disorder	Post-traumatic stress disorder	2017	Present
Amputation of 10 Toes	Toe amputation	2017	Past
Environmental Allergies	Hypersensitivity	2019	Present
Pain in feet post-op toe amputations	Procedural pain	DEC2019	Present
cataracts right eye	Cataract	JUN2020	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cataracts Left eye	Cataract	JUN2020	Past
Peripheral Neuropathy secondary to Type II Diabetes	Diabetic neuropathy	05JUN2020	Present
Right Eye Cataract Surgery	Cataract operation	12AUG2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	12:35

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	SKIN	Diabetic foot	Diabetic Foot Ulcer R Foot	14SEP2020 (20)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	TCN/P/W	N	Yes	NOT RELATED/OTHER: Diabetes	1	20	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Withdrawn	VACCINATION	16SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	16SEP2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1095 10951141, a 50-year-old white female with a pertinent medical history of type 2 diabetes mellitus (since 2000), toe amputation (in 2017), and diabetic neuropathy (since 05 Jun 2020), received Dose 1 on 26 Aug 2020. The subject was diagnosed with a diabetic foot ulcer (right foot) on 14 Sep 2020, 19 days after receiving Dose 1. The subject was withdrawn from the study on 16 Sep 2020 because of the diabetic foot ulcer (right foot), which was ongoing at the time of withdrawal. In the opinion of the investigator, there was no reasonable possibility that the diabetic foot ulcer was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	22	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
153.67 cm	87.64 kg	37 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
CAT ALLERGY	Allergy to animal	2000	Present
ATHLETIC ASTHMA	Asthma exercise induced	2004	Past
INTERMITTENT HEADACHES	Headache	2005	Present
MASTITIS	Mastitis	2016	Past
CESAREAN SECTION	Caesarean section	08JUN2016	Past
MASTITIS REMOVAL SURGERY	Breast operation	OCT2016	Past

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	14AUG2020 (1)	18:11
3	BNT162b2	03MAR2021 (202)	11:14

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	14AUG2020 (1)		22SEP2020 (40)		40
2	RESP	Oropharyngeal pain	Sore throat	05OCT2020 (53)		07OCT2020 (55)		3
3	INFEC	Urinary tract infection	urinary tract infection	22JAN2021 (162)		ONGOING		

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		P	N	Resolved (22SEP2020)	NOT RELATED/OTHER: PREGNANCY	1	1	Y
2	1	N	N	Resolved (07OCT2020)	NOT RELATED/OTHER: Personal illness	1	53	N
3	1	TC	N	Yes	NOT RELATED/OTHER: unknown	1	162	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Withdrawn	VACCINATION	04SEP2020	PREGNANCY
Completed	REPEAT SCREENING 1	03MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1096 10961031, a 22-year-old white female with a pertinent obstetrical history of 2 previous pregnancies, 1 full-term pregnancy with live birth requiring a cesarean section (on 08 Jun 2016), and a miscarriage at 13 weeks (in Oct 2019) as well as a history of irregular menstrual cycles (since Oct 2019), received Dose 1 on 14 Aug 2020. The subject's pregnancy test was positive on 04 Sep 2020 (Day 22) and she had an exposure during pregnancy on 14 Aug 2020, on the day of Dose 1. On 14 Aug 2020 (Day 1), the subject's pregnancy test at Visit 1 was negative prior to receiving Dose 1. On 04 Sep 2020 (Day 22), during Visit 2 prior to Dose 2, her urine pregnancy test was positive. A repeat pregnancy test was also positive. The subject's first day of her last menstrual period was 04 Jul 2020 and the estimated date of conception was 09 Aug 2020. Gestation at the time of initial exposure was first trimester. An ultrasound examination on 21 Sep 2020 (Day 39) confirmed the pregnancy with a gestational age of 6 weeks 2 days, with no abnormalities. It was reported that the subject did not smoke, drink alcohol, or use illicit drugs during pregnancy. On 22 Sep 2020 (Day 40), the subject underwent an elective abortion at 6 weeks 3 days of gestation. The subject was discontinued from the study intervention on 04 Sep 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received a first dose of BNT162b2 on 03 Mar 2021 (Day 202).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	32	White	Not reported	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	105 kg	35.1 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	2004	Present
bipolar disorder	Bipolar disorder	2004	Present
depression	Depression	2004	Present
Obesity	Obesity	2017	Present
Fatty Liver Disease	Hepatic steatosis	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	16:22
2	Placebo	09SEP2020 (24)	15:35

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PSYCH	Depression suicidal	worsening of depression with suicidal ideation	OCT2020 ()		14NOV2020 (90)		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/P	Y	Resolved (14NOV2020)	NOT RELATED/OTHER: depression	2		Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	01NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	02MAR2021	NO LONGER MEETS ELIGIBILITY CRITERIA

Narrative Comment
Subject C4591001 1096 10961036, a 32-year-old white female with a pertinent medical history of anxiety, depression, and bipolar disorder (all since 2004) and obesity (since 2017), received Dose 1 on 17 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 24). The subject experienced worsening of depression with suicidal ideation on an unspecified date in Oct 2020, approximately 1 month after receiving Dose 2. Concomitant medications included ethinylestradiol/norgestimate (since 2004) for contraception; and citalopram and olanzapine (from 2018 to 30 Oct 2020 and since 01 Nov 2020) for bipolar disorder. The subject received influenza vaccine on 01 Nov 2020 (Day 77). On 02 Mar 2021 (Day 198), during Visit 102 at the study site, the subject reported that she experienced worsening of depression with suicidal ideation on an unspecified date in Oct 2020, resulting in hospitalization for approximately 2 weeks. On 14 Nov 2020 (Day 90), the worsening of depression with suicidal ideation was considered resolved. The subject was unblinded on 22 Feb 2021 (Day 190) and she had received placebo. Per the principal investigator's decision, the first dose of BNT162b2 was not administered. After the data cutoff date of 13 Mar 2021 (with snapshot taken on 25 Mar 2021), it was determined that the subject did not discontinue from the study intervention because of the suicidal depression but discontinued from the study because she no longer met the eligibility criteria. In the opinion of the investigator, there was no reasonable possibility that the worsening of depression with suicidal ideation was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	64	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	66.82 kg	26.9 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
POSTMENOPAUSAL	Postmenopause	1999	Present
ASTHMA	Asthma	2012	Present
HYSTERECTOMY	Hysterectomy	2014	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11SEP2020 (1)	15:37

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain upper	ABDOMINAL PAIN RUQ	SEP2020 ()		30SEP2020 (20)			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	P	N	Resolved (30SEP2020)	NOT RELATED/OTHER: GALLBLADDER DISEASE			Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Withdrawn	VACCINATION	30SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091503, a 64-year-old white female with a pertinent medical history of postmenopause (since 1999), asthma (since 2012), and hysterectomy (in 2014), received Dose 1 on 11 Sep 2020. On an unspecified date in Sep 2020, the subject experienced upper abdominal pain (right quadrant). On 30 Sep 2020 (Day 20), the upper abdominal pain resolved. The subject was discontinued from the study intervention on 30 Sep 2020 because of the upper abdominal pain and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the upper abdominal pain was related to the study intervention, but rather it was related to gallbladder disease.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	77.36 kg	26.7 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Partial Hysterectomy	Hysterectomy	2010	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	14:39

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	SKIN	Pruritus	Generalized Pruritus	12AUG2020 (2)		12AUG2020 (2)	
2	CARD	Tachycardia	Tachycardia	12AUG2020 (2)		12AUG2020 (2)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	3	TC	N	Resolved (12AUG2020)	Study Treatment	1	2	N
2	1	3	TC/P	N	Resolved (12AUG2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Withdrawn	VACCINATION	12AUG2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1112 11121118, a 56-year-old white female with no pertinent medical history, received Dose 1 on 11 Aug 2020. On 12 Aug 2020, 1 day after receiving Dose 1, the subject reported tachycardia, which resolved the same day. On the same day (Day 2), the subject also experienced generalized pruritus, which resolved on the same day. The subject was discontinued from the study intervention on 12 Aug 2020 because of the tachycardia and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the tachycardia was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	52 kg	21.6 kg/m2	06OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	1970	Present
Hysterectomy	Hysterectomy	1984	Past
Ovarian Cysts	Ovarian cyst	1984	Past
Postmenopausal	Postmenopause	1995	Present
Anxiety	Anxiety	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	06OCT2020 (1)	10:38

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Chills	06OCT2020 (1)		07OCT2020 (2)	
2	NERV	Headache	Headaches	06OCT2020 (1)		07OCT2020 (2)	
3	MUSC	Myalgia	Muscle Aches	06OCT2020 (1)		07OCT2020 (2)	
4	GENRL	Pyrexia	Fever	06OCT2020 (1)		07OCT2020 (2)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	2	TC/P	N	Resolved (07OCT2020)	Study Treatment	1	1	Y
2	2	3	TC/P	N	Resolved (07OCT2020)	Study Treatment	1	1	Y
3	2	2	TC	N	Resolved (07OCT2020)	Study Treatment	1	1	N
4	2	2	TC/P	N	Resolved (07OCT2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06OCT2020	
Withdrawn	VACCINATION	07OCT2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1112 11121255, a 65-year-old white female with a pertinent medical history of hypothyroidism (since 1970), ovarian cyst (in 1984), postmenopause (since 1995), and anxiety (since 2000), received Dose 1 on 06 Oct 2020. On 06 Oct 2020, after Dose 1 administration, the subject experienced chills, headache, and pyrexia. On the same day (Day 1), the subject also experienced myalgia. On 07 Oct 2020 (Day 2), the chills, headache, pyrexia, and myalgia resolved. The subject was discontinued from the study intervention on 07 Oct 2020 because of the chills, headache, and pyrexia and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the chills, headache, and pyrexia were related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1941	79	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	77.27 kg	27.4 kg/m2	21OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergic rhinitis	Seasonal allergy	1947	Present
Perennial allergic rhinitis	Rhinitis perennial	1955	Present
Endometriosis	Endometriosis	1972	Past
Hysterectomy	Hysterectomy	1974	Past
Irritable Bowel Syndrome	Irritable bowel syndrome	1980	Present
Osteoarthritis, generalized	Osteoarthritis	1990	Present
Hypertension	Hypertension	1995	Present
Meralgia Paresthetica, right thigh	Meralgia paraesthetica	2005	Present
Hyperlipidemia	Hyperlipidaemia	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Esophageal stricture	Oesophageal stenosis	2010	Present
Diverticulitis	Diverticulitis	2013	Present
Osteopenia	Osteopenia	2013	Present
Asthma, moderate	Asthma	2015	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2015	Present
Diabetes, type 2	Type 2 diabetes mellitus	2015	Present
Depression, situational	Adjustment disorder with depressed mood	APR2017	Present
Vaginal dryness	Vulvovaginal dryness	SEP2017	Present
Fracture, left foot	Foot fracture	20JAN2020	Past
Surgery, left foot	Foot operation	20JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21OCT2020 (1)	17:28

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Diarrhoea	Diarrhea	22OCT2020 (2)		25OCT2020 (5)	
2	GENRL	Fatigue	Fatigue	22OCT2020 (2)		28OCT2020 (8)	
3	NERV	Headache	Headache	22OCT2020 (2)		28OCT2020 (8)	

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
4	MUSC	Myalgia	Muscle Aches	22OCT2020 (2)		28OCT2020 (8)	
5	GASTR	Nausea	Nausea	22OCT2020 (2)		25OCT2020 (5)	
6	GASTR	Vomiting	Vomiting	25OCT2020 (5)		25OCT2020 (5)	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	3	TC/W	N	Resolved (25OCT2020)	Study Treatment	1	2	Y
2	7	2	P	N	Resolved (28OCT2020)	Study Treatment	1	2	Y
3	7	2	TC	N	Resolved (28OCT2020)	Study Treatment	1	2	N
4	7	2	TC	N	Resolved (28OCT2020)	Study Treatment	1	2	N
5	4	2	TC	N	Resolved (25OCT2020)	Study Treatment	1	2	N
6	1	2	N	N	Resolved (25OCT2020)	Study Treatment	1	5	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21OCT2020	
Withdrawn	VACCINATION	26OCT2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	12NOV2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1112 11121337, a 79-year-old white female with a pertinent medical history of perennial allergic rhinitis (since 1955), irritable bowel syndrome (since 1980), generalized osteoarthritis (since 1990), hypertension (since 1995), right meralgia paresthetica (since 2005), diverticulitis (since 2013), asthma (since 2015), gastroesophageal reflux disease (since 2015), type 2 diabetes mellitus (since 2015), and situational depression (since Apr 2017), received Dose 1 on 21 Oct 2020. On 22 Oct 2020, 1 day after receiving Dose 1, the subject experienced diarrhea and fatigue. On 22 Oct 2020 (Day 2), the subject also experienced headache, myalgia, and nausea. On 25 Oct 2020 (Day 5), she experienced vomiting, with resolution of the diarrhea, nausea, and vomiting on the same day (Day 5). On 28 Oct 2020 (Day 8), the symptoms of fatigue, headache, and myalgia resolved. The subject was discontinued from the study intervention on 26 Oct 2020 because of the fatigue and was later withdrawn from the study on 12 Nov 2020 because of the diarrhea. In the opinion of the investigator, there was a reasonable possibility that the diarrhea and fatigue were related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	60 kg	21.3 kg/m2	06OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
VISION IMPAIRMENT, BILATERAL	Visual impairment	1990	Present
ALLERGY, NICKEL	Allergy to metals	1995	Present
DEPRESSION	Depression	2016	Present
ANXIETY	Anxiety	2019	Present
CANNABIS HYPEREMESIS SYNDROME	Cannabinoid hyperemesis syndrome	2019	Present
CANNABIS ABUSE	Drug abuse	2019	Present
VENOUS THROMBOSIS/EMBOLISM	Embolism venous	2019	Present
INSOMNIA	Insomnia	2019	Present
MIGRAINE	Migraine	2019	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
BUTALBITAL USE DISORDER	Drug abuse	15MAR2019	Present
SUICIDAL IDEATION W/ ATTEMPT	Suicide attempt	15MAR2019	Past
MEDICATION TREATEMENT NONCOMPLAINCE	Treatment noncompliance	15MAR2019	Present
SUICIDAL IDEATION W/ ATTEMPT	Suicide attempt	24DEC2019	Past
EPIGASTRIC PAIN W/ ADMISSION	Abdominal pain upper	24SEP2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	06OCT2020 (1)	14:05

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain	ABDOMINAL PAIN	26OCT2020 (21)		27OCT2020 (22)		2	2
2	GASTR	Gastritis	ACUTE GASTRITIS W/O HEMMORRHAGE	23OCT2020 (18)		30NOV2020 (56)		39	2
3	PSYCH	Suicide attempt	SUICIDAL IDEATION WITH ATTEMPT	19OCT2020 (14)		26OCT2020 (21)		8	3
4	GASTR	Vomiting	BILIOUS VOMITING	23OCT2020 (18)		27OCT2020 (22)	01:26	5	3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (27OCT2020)	NOT RELATED/OTHER: ACUTE GASTRITIS	1	21	N
2	TC/TCN	N	Resolved (30NOV2020)	NOT RELATED/OTHER: UNKNOWN ETIOLOGY	1	18	N
3	TC/TCN/P	Y	Resolved (26OCT2020)	NOT RELATED/OTHER: MAJOR DEPRESSION	1	14	Y
4	TC/TCN	N	Resolved (27OCT2020)	NOT RELATED/OTHER: ACTUE GASTRITIS	1	18	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	06OCT2020	
Withdrawn	VACCINATION	26OCT2020	ADVERSE EVENT

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	REPEAT SCREENING 1	01FEB2021	NO LONGER MEETS ELIGIBILITY CRITERIA
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1117 11171186, a 30-year-old black or African American female with a pertinent medical history of depression (since 2016), anxiety, insomnia, drug abuse (cannabis abuse), and cannabinoid hyperemesis syndrome (all since 2019), drug abuse (butalbital use disorder; since 15 Mar 2019), treatment noncompliance (since 15 Mar 2019), and suicide attempts (on 15 Mar 2019 and 24 Dec 2019, resulting in admission), received Dose 1 on 06 Oct 2020. The subject had not previously disclosed the prior history of depression, including suicide attempts, treatment noncompliance, drug abuse (cannabis abuse and butalbital/aspirin/caffeine use disorder), anxiety, and insomnia, at the time of screening. The subject attempted suicide on 19 Oct 2020, 13 days after receiving Dose 1. Concomitant medications included aspirin/butalbital/caffeine for migraine, lorazepam for anxiety, ondansetron for nausea/vomiting, mirtazapine (7.5 mg from Jun 2020 and 30 mg from an unspecified date), celecoxib and loperamide hydrochloride for anxiety, omeprazole, sertraline hydrochloride, and topiramate for unspecified indications, and trazodone for sleep (all from unknown dates). On 19 Oct 2020 (Day 14), the subject experienced depression and presented to the emergency department (ED) via emergency medical services and was hospitalized, as she reported suicidal ideation and attempted to end her life (by (b) (6)) because of depression related to family issues and stress a few days prior. She was treated with haloperidol 5 mg, lorazepam 2 mg, and trazodone 100 mg (all on 19 Oct 2020), hydroxyzine 25 mg (on 19 Oct 2020 and 20 Oct 2020), sertraline 100 mg (on 20 Oct 2020), and fluoxetine 10 mg (since 21 Oct 2020). She had abdominal distress since 24 Oct 2020 (Day 19). On 26 Oct 2020 (Day 21), she denied suicidal ideation and thoughts of self-harm. On that same day (Day 21), the suicide attempt was considered resolved and the subject was discharged from the hospital. The subject was discontinued from the study intervention on 26 Oct 2020 because of the suicide attempt and remains in the study to be evaluated for safety, immunogenicity, and efficacy. On 26 Oct 2020 (Day 21), the subject was readmitted to the ED, as she experienced abdominal pain (epigastric pain) and was diagnosed with acute gastritis without hemorrhage and bilious vomiting with nausea (onset date of acute gastritis without hemorrhage and bilious vomiting reported to be 23 Oct 2020 [Day 18]). The subject refused advised treatments and requested pain medication and benzodiazepines; the request for pain medication and benzodiazepines was refused by the ED. The subject was treated medically with diphenhydramine 25 mg, famotidine 20 mg, hydroxyzine 25 mg, ioversol at 350/100 mL, aluminum/magnesium/simethicone/lidocaine 40 mL, metoclopramide 10 mg, morphine 1 mg, and ondansetron 4 mg (all on 26 Oct 2020). The abdominal pain and bilious vomiting resolved on 27 Oct 2020 (Day 22). The subject was discharged from the ED on 27 Oct 2020 (Day 22) with the following medications: aripiprazole 2 mg, famotidine 20 mg, and fluoxetine 10 mg; all starting on 27 Oct 2020. The acute gastritis without hemorrhage resolved on 30 Nov 2020 (Day 56). The subject was withdrawn from the study on 01 Feb 2021 because she no longer met eligibility criteria. In the opinion of the investigator, there was no reasonable possibility that the suicide attempt was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to major depression. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1945	74	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
189 cm	130.4 kg	36.5 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	1990	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	1990	Present
hyperlipidemia	Hyperlipidaemia	2005	Present
Allergy to Allbuterol	Drug hypersensitivity	2020	Present
Post Traumatic stress disorder	Post-traumatic stress disorder	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	13:18

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Diarrhoea	Diarrhea	12AUG2020 (2)		14AUG2020 (4)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	3	TC/P/W	N	Resolved (14AUG2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Withdrawn	VACCINATION	14AUG2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	14AUG2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1120 11201127, a 74-year-old white male with a pertinent medical history of chronic obstructive pulmonary disease (since 1990), gastroesophageal reflux disease (since 1990), hyperlipidemia (since 2005), and posttraumatic stress disorder (since Jan 2020), received Dose 1 on 11 Aug 2020. The subject experienced diarrhea on 12 Aug 2020, 1 day after receiving Dose 1. The subject was withdrawn from the study on 14 Aug 2020 because of the diarrhea, which resolved on the same day (Day 4). In the opinion of the investigator, there was a reasonable possibility that the diarrhea was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	24	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline
No Vital Signs - Baseline

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	NERV	Presyncope	pre-syncope	11SEP2020 (1)		11SEP2020 (1)		1
2	GASTR	Vomiting	vomiting	11SEP2020 (1)		11SEP2020 (1)		1

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	W	N	Resolved (11SEP2020)	NOT RELATED/OTHER: blood draw			Y
2	1	W	N	Resolved (11SEP2020)	NOT RELATED/OTHER: blood draw			Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
	VACCINATION		
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	11SEP2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1122 11221026, a 24-year-old white male with no reported medical history, reported presyncope and vomiting during the prevaccination blood sample collection on 11 Sep 2020 (Day 1), which resolved that same day. The subject was withdrawn from the study before administration of study vaccination on 11 Sep 2020 because of the presyncope and vomiting. In the opinion of the investigator, there was no reasonable possibility that the presyncope and vomiting were related to the study intervention, but rather they were related to the blood sample collection.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2003	17	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	60 kg	22 kg/m2	08DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergies	Seasonal allergy	2004	Present
Tonsillectomy	Tonsillectomy	2005	Past
Tonsillitis	Tonsillitis	2005	Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	08DEC2020 (1)	18:03

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	NERV	Headache	Grade 3 Headache	09DEC2020 (2)		09DEC2020 (2)	
2	GENRL	Injection site pain	Grade 3 Pain at Injection site	09DEC2020 (2)		09DEC2020 (2)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	3	TC/P	N	Resolved (09DEC2020)	Study Treatment	1	2	Y
2	1	3	P	N	Resolved (09DEC2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08DEC2020	
Withdrawn	VACCINATION	09DEC2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1125 11251243, a 17-year-old white male with a pertinent medical history of seasonal allergy (since 2004), received Dose 1 on 08 Dec 2020. The subject experienced severe headache and injection site pain on 09 Dec 2020, 1 day after receiving Dose 1. On the same day (Day 2), the headache and injection site pain resolved. The subject was discontinued from the study intervention on 09 Dec 2020 because of the headache and injection site pain and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the headache and injection site pain were related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	34	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	59.1 kg	22.5 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Major Depression, in full remission	Major depression	21MAR2014	Present
Insect Venom Allergic Reaction	Allergy to arthropod sting	13MAR2015	Past
Allergy to Bee Venom	Allergy to arthropod sting	13MAR2015	Present
Intermittent Asthma	Asthma	31MAR2015	Past
Hypertension	Hypertension	18JUN2015	Past
Iron Deficiency without Anemia	Iron deficiency	01OCT2015	Present
Migraine with Aura	Migraine with aura	15JUL2018	Present
Coagulopathy, Unspecified Type	Coagulopathy	01MAR2019	Present
Cervical High Risk HPV test positive	Human papilloma virus test positive	05APR2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13AUG2020 (1)	12:09
2	Placebo	01SEP2020 (20)	12:32
3	BNT162b2	07JAN2021 (148)	11:32

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Acute sinusitis	Acute sinusitis	15AUG2020 (3)	04:00	20AUG2020 (8)	12:00	6
2	MUSC	Myalgia	Muscle aches	08JAN2021 (149)		09JAN2021 (150)		2
3	GASTR	Nausea	Nausea	07JAN2021 (148)	12:50	07JAN2021 (148)	14:00	1
4	SKIN	Urticaria	Hives, abdomen	07JAN2021 (148)	14:50	08JAN2021 (149)		2
5	IMMUN	Allergy to vaccine	VACCINE ALLERGIC REACTION	07JAN2021 (148)	11:37	08JAN2021 (149)		2
6	VASC	Flushing	Facial Flushing	07JAN2021 (148)	11:37	08JAN2021 (149)		2
7	GENRL	Swelling face	Facial swelling	07JAN2021 (148)	11:37	08JAN2021 (149)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (20AUG2020)	NOT RELATED/OTHER: UNKNOWN	1	3	N

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	1	N	N	Resolved (09JAN2021)	Study Treatment	3	2	N
3	1	TC/TCN	N	Resolved (07JAN2021)	Study Treatment	3	1	N
4	1	TC/TCN	N	Resolved (08JAN2021)	Study Treatment	3	1	N
5	2	TC/TCN/P	N	Resolved (08JAN2021)	Study Treatment	3	1	Y
6	2	TC/TCN	N	Resolved (08JAN2021)	Study Treatment	3	1	N
7	2	TC/TCN	N	Resolved (08JAN2021)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Influenza vaccine (Fluarix quadrivalent)	INFLUENZA VACCINE INACT SPLIT 4V	21SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	01OCT2020	
Completed	REPEAT SCREENING 1	07JAN2021	
Withdrawn	OPEN LABEL TREATMENT	28JAN2021	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1126 11261017, a 34-year-old white female with a pertinent medical history of allergy to arthropod sting (since 13 Mar 2015), received Dose 1 on 13 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 20).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 07 Jan 2021 (Day 148).

On the same day (Day 148), 5 minutes after the first dose of BNT162b2 administration, the subject developed facial swelling and facial flushing considered to be an allergic reaction to the vaccine. She also experienced nausea, 1 hour 18 minutes after the first dose of BNT162b2 administration, and urticaria (hives on abdomen), 3 hours 18 minutes after the first dose of BNT162b2 administration. On the same day, the nausea resolved. On 08 Jan 2021 (Day 149), the urticaria, facial flushing, facial swelling, and allergic reaction to the vaccine resolved.

The subject was discontinued from the study intervention on 28 Jan 2021 because of the allergic reaction to vaccine and remains in the study.

In the opinion of the investigator, there was a reasonable possibility that the allergic reaction to vaccine was related to BNT162b2.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.83 cm	67.95 kg	25.3 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	1970	Present
shellfish allergy	Food allergy	2011	Present
hypothyroidism	Hypothyroidism	2011	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	16:32
2	Placebo	21SEP2020 (22)	15:28

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Breast cancer	Breast Cancer	NOV2020 ()		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC/W	N	Yes	NOT RELATED/OTHER: Breast Cancer	2		Y

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Adriamycin	DOXORUBICIN	NOV2020	ONGOING	INTRAVENOUS

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	22OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1128 11281241, a 52-year-old white female with no pertinent medical history, received Dose 1 on 31 Aug 2020 and Dose 2 on 21 Sep 2020 (Day 22). The subject was diagnosed with breast cancer on an unspecified date in Nov 2020. The subject started treatment with intravenous doxorubicin in Nov 2020. After the data cutoff date of 13 Mar 2021 (with snapshot taken on 25 Mar 2021), it was determined that the subject was withdrawn from the study on 15 Mar 2021 because of the breast cancer, which was ongoing at the time of withdrawal. In the opinion of the investigator, there was no reasonable possibility that the breast cancer was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	99.82 kg	30.6 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	2011	Present
Percutaneous Transluminal Coronary Angioplasty	Coronary angioplasty	2015	Past
Cardiac Stent Placement	Coronary arterial stent insertion	2015	Past
Coronary Artery Disease	Coronary artery disease	2015	Present
Hypertension	Hypertension	2015	Present
Hypothyroidism	Hypothyroidism	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10AUG2020 (1)	10:22
2	Placebo	31AUG2020 (22)	13:39
3	BNT162b2	02FEB2021 (177)	14:49

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	CARD	Angina pectoris	CHEST PAIN (CARDIC)	02FEB2021 (177)		ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			2	P	N	Yes	Study Treatment	3	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10AUG2020	
Completed	VACCINATION	28SEP2020	
Completed	REPEAT SCREENING 1	02FEB2021	
Withdrawn	OPEN LABEL TREATMENT	02FEB2021	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1134 11341019, a 59-year-old white male with a pertinent medical history of coronary artery disease and hypertension (both since 2015), coronary angioplasty and coronary arterial stent insertion (both in 2015), and hypothyroidism (since 2016), received Dose 1 on 10 Aug 2020 and Dose 2 on 31 Aug 2020 (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first dose of BNT162b2 on 02 Feb 2021 (Day 177). On the same day, he experienced cardiac chest pain (angina pectoris). The subject was discontinued from the study intervention on 02 Feb 2021 because of the angina pectoris and remains in the study. The angina pectoris was ongoing at the time of the last available report. In the opinion of the investigator, there was a reasonable possibility that the angina pectoris was related to BNT162b2.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156.21 cm	57.73 kg	23.6 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tonsillitis	Tonsillitis	1990	Past
tonsillectomy	Tonsillectomy	1993	Past
anxiety	Anxiety	2000	Present
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	2000	Present
cholecystectomy	Cholecystectomy	2008	Past
allergic rhinitis	Rhinitis allergic	2010	Present
breast cancer	Breast cancer	2016	Past
bilateral mastectomy	Mastectomy	2017	Past
post menopausal	Postmenopause	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	16:10

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Abdominal discomfort	upset stomach	25AUG2020 (2)		21SEP2020 (29)	
2	GASTR	Diarrhoea	diarrhea	25AUG2020 (2)		25AUG2020 (2)	
3	GASTR	Diarrhoea	loose stools	25AUG2020 (2)		21SEP2020 (29)	
4	EYE	Eye pain	right eye pain	25AUG2020 (2)		21SEP2020 (29)	
5	GENRL	Fatigue	fatigue	25AUG2020 (2)		21SEP2020 (29)	
6	NERV	Headache	headache	25AUG2020 (2)		25AUG2020 (2)	
7	NERV	Headache	headache	25AUG2020 (2)		25AUG2020 (2)	
8	MUSC	Muscular weakness	muscle weakness	25AUG2020 (2)		21SEP2020 (29)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	28	2	TC	N	Resolved (21SEP2020)	Study Treatment	1	2	N
2	1	1	N	N	Resolved (25AUG2020)	Study Treatment	1	2	N
3	28	2	N	N	Resolved (21SEP2020)	Study Treatment	1	2	N

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	28	2	P	N	Resolved (21SEP2020)	Study Treatment	1	2	Y
5	28	2	N	N	Resolved (21SEP2020)	Study Treatment	1	2	N
6	1	1	N	N	Resolved (25AUG2020)	Study Treatment	1	2	N
7	1	2	TC	N	Resolved (25AUG2020)	Study Treatment	1	2	N
8	28	2	N	N	Resolved (21SEP2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	
Withdrawn	VACCINATION	25AUG2020	ADVERSE EVENT

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1134 11341153, a 44-year-old white female with a pertinent medical history of anxiety (since 2000), attention deficit hyperactivity disorder (since 2000), allergic rhinitis (since 2010), and breast cancer (in 2016), received Dose 1 on 24 Aug 2020. On 25 Aug 2020, the subject reported right eye pain, 1 day after receiving Dose 1. On 25 Aug 2020 (Day 2), the subject also experienced fatigue, headache (2 episodes), abdominal discomfort, diarrhea, loose stools, and muscular weakness. The diarrhea and headache resolved on the same day (Day 2). On 21 Sep 2020 (Day 29), the abdominal discomfort, loose stools, right eye pain, fatigue, and muscular weakness resolved. The subject was discontinued from the study intervention on 25 Aug 2020 because of the right eye pain and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the right eye pain was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.75 cm	79.18 kg	31.4 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hospitalization for childbirth	Delivery	2015	Past
hospitalization for childbirth	Delivery	2017	Past
headache	Headache	2018	Present
stress induced muscle pain in back	Back pain	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	11:05

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Chest discomfort	CHEST TIGHTNESS	30AUG2020 (5)		06SEP2020 (12)		8
2	NERV	Headache	WORSENING HEADACHE	27AUG2020 (2)		03SEP2020 (9)		8
3	METAB	Hypokalaemia	HYPOKALEMIA	30AUG2020 (5)		01SEP2020 (7)		3
4	GENRL	Injection site pain	PAIN AT INJECTION SITE	26AUG2020 (1)		30AUG2020 (5)		5
5	MUSC	Pain in extremity	ARM PAIN (LEFT)	28AUG2020 (3)		02SEP2020 (8)		6

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Resolved (06SEP2020)	Study Treatment	1	5	N
2	2	TC/P	N	Resolved (03SEP2020)	Study Treatment	1	2	Y
3	1	TC	N	Resolved (01SEP2020)	NOT RELATED/OTHER: IDIOPATHIC	1	5	N
4	3	N	N	Resolved (30AUG2020)	Study Treatment	1	1	N
5	3	TC	N	Resolved (02SEP2020)	Study Treatment	1	3	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Withdrawn	VACCINATION	30AUG2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1134 11341174, a 36-year-old white female with a pertinent medical history of headache (since 2018) and back pain (since Jun 2020), received Dose 1 on 26 Aug 2020. On 26 Aug 2020, after Dose 1 administration, the subject experienced severe injection site pain. On 27 Aug 2020, 1 day after receiving Dose 1, she experienced worsening of headache. On 28 Aug 2020 (Day 3), she experienced pain in extremity (left arm pain). On 30 Aug 2020 (Day 5), the injection site pain resolved and the subject developed chest discomfort. The pain in extremity, worsening headache, and chest discomfort resolved on 02 Sep 2020 (Day 8), 03 Sep 2020 (Day 9), and 06 Sep 2020 (Day 12), respectively. On 30 Aug 2020, the subject was discontinued from the study intervention because of the worsening headache and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the worsening headache was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.78 cm	91.82 kg	29.3 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Peritonsillar abscess	Peritonsillar abscess	1984	Past
(+) purified protein derivative	Tuberculin test positive	1984	Past
Idiopathic Urticaria	Idiopathic urticaria	2008	Present
Deviated septum repair	Nasal septal operation	2009	Past
Fever of Unknown Origin	Pyrexia	2012	Past
High cholesterol	Blood cholesterol increased	JAN2012	Present
hypertension	Hypertension	JAN2012	Present
GERD	Gastrooesophageal reflux disease	AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04AUG2020 (1)	15:01

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	SKIN	Urticaria	urticaria	13AUG2020 (10)		13AUG2020 (10)		1	2	TC/P/W	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (13AUG2020)	NOT RELATED/OTHER: idiopathic urticaria (pre-existing on med hx)	1	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Withdrawn	VACCINATION	22SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	22SEP2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1140 11401035, a 62-year-old white male with a pertinent medical history of idiopathic urticaria (since 2008), received Dose 1 on 04 Aug 2020. The subject reported urticaria on 13 Aug 2020, 9 days after receiving Dose 1. On 13 Aug 2020 (Day 10), the urticaria resolved. The subject was withdrawn from the study on 22 Sep 2020 because of the urticaria. In the opinion of the investigator, there was no reasonable possibility that the urticaria was related to the study intervention, but rather it was related to preexisting idiopathic urticaria.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.4 cm	82 kg	23.3 kg/m2	22OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin allergy	Drug hypersensitivity	1971	Present
acid reflux	Gastrooesophageal reflux disease	1988	Past
left tarsal bone fracture, foot	Foot fracture	2002	Past
left avulsion fracture, foot	Avulsion fracture	2007	Past
fundal plication	Oesophagogastric fundoplasty	2007	Past
eye allergies	Eye allergy	2010	Present
osteoarthritis, both knees	Osteoarthritis	2016	Present
hypothyroidism	Hypothyroidism	2018	Present
Chronic Spastic Paraparesis	Paraparesis	SEP2020	Present

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22OCT2020 (1)	16:23

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NERV	Amnesia	short term memory loss	07NOV2020 (17)	19:00	10NOV2020 (20)	08:00	4	1	TC/TCN/P	Y
2	EYE	Eye pain	Bilateral Eye Pain	07NOV2020 (17)		01JAN2021 (72)		56	1	N	N
3	NERV	Paraparesis	Worsening of Chronic Spastic Paraparesis	07NOV2020 (17)	14:00	ONGOING			3	TC/TCN/P	N
4	EYE	Visual impairment	Change in Visual Perception	07NOV2020 (17)	14:00	09NOV2020 (19)	10:30	3	3	P/W	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (10NOV2020)	NOT RELATED/OTHER: unknown at this time	1	17	Y

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	Resolved (01JAN2021)	NOT RELATED/OTHER: visual correction improved which was the cause (corrected vision with glasses)	1	17	N
3	Yes	NOT RELATED/OTHER: Unknown at this time	1	17	Y
4	Resolved (09NOV2020)	NOT RELATED/OTHER: Spontaneous resolution, cause is unknown	1	17	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22OCT2020	
Withdrawn	VACCINATION	13NOV2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	23FEB2021	ADVERSE EVENT

Narrative Comment

Subject C4591001 1140 11401306, a 53-year-old white male with a pertinent medical history of eye allergy (since 2010), hypothyroidism (since 2018), and paraparesis (chronic spastic paraparesis) and left leg weakness (both since Sep 2020), received Dose 1 on 22 Oct 2020. The subject experienced amnesia (short-term memory loss), visual impairment, and worsening of chronic spastic paraparesis on 07 Nov 2020, 16 days after receiving Dose 1.

Concomitant medications included omeprazole (since 2007) for acid reflux prevention, olopatadine hydrochloride eye drops (since 2010) for eye allergies, and levothyroxine (since 2018) for hypothyroidism.

On 07 Nov 2020 (Day 17), the subject visited the emergency room because of a sudden onset of change in visual perception and short-term memory loss. On the same day (Day 17), he was diagnosed with worsening of chronic spastic paraparesis and bilateral eye pain. He was hospitalized for further blood workup, a lumbar puncture, and imaging studies. A blood test on 07 Nov 2020 (Day 17) showed C-reactive protein of 2.1 mg/L (upper limit of normal [ULN]: <8 mg/L), blood copper of 96 µg/dL (normal range [NR]: 72-166 µg/dL), blood folate of 10.47 ng/mL (lower limit of normal: 4.77 ng/mL), and vitamin B_{12} of 753 pg/mL (NR: 211-946 pg/mL). A nonenhanced head computed tomography scan showed no intracranial hemorrhage or acute territorial infarction. There was mild asymmetry of the lateral ventricles with dilatation of the atrium of the right lateral ventricle; however, the remainder of the ventricles were normal in size and configuration. The basal cisterns and foramen magnum were patent and there were no depressed calvarial fractures. The extracranial soft tissue structures were unremarkable, and the paranasal sinuses and mastoid air cells were clear. A computed tomography angiography (CTA) of the head showed that the intracranial segments of the internal carotid arteries and basilar, anterior, middle, and posterior cerebral arteries were patent without flow-limiting stenosis. No aneurysm or arteriovenous malformation was visualized. The CTA of the neck showed conventional branching of the great vessels from the aortic arch. The origins of the great vessels and vertebral arteries were patent. There was no occlusion of the common carotid, external carotid, cervical segments of the internal carotid arteries, or cervical segments of the vertebral arteries. The vertebral arteries were codominant. The imaging results of lungs, thyroid, and bones were unremarkable. A magnetic resonance imaging (MRI) of the brain to evaluate possible encephalitis in comparison with CTA of the head performed on 07 Nov 2020 (Day 17) showed no abnormal signal intensity within the brain parenchyma. A developmental venous anomaly was observed in the right frontal lobe. There was asymmetric enlargement of the atrium and occipital horn of the right lateral ventricle. There were no intraventricular masses seen and the basal cisterns were patent. No

acute intracranial hemorrhage, evidence of acute infarction, space-occupying mass, shift of the midline structures, or abnormal extra-axial fluid collections were observed. The pituitary gland was not enlarged and the pineal and cervicomedullary regions were normal. Normal flow voids of the major intracranial arterial vessels were observed and there was no abnormal enhancement following contrast administration. Mild mucosal thickening was present in the maxillary, ethmoid, sphenoid, and frontal sinuses. The subject's visual correction improved with eyeglasses.

On 08 Nov 2020 (Day 18), the subject was seen by a neurologist, at which time the subject reported the symptoms of mental fogginess associated with visual changes that was described as poor depth perception. He also reported subtle unsteadiness and admitted to having a longer history of clumsiness. On examination, he was noted to have mild spasticity in the legs, brisk reflexes in the legs, and bilateral Babinski sign. His gait was slightly abnormal because of subtle circumduction of the right leg and he had mild issues with tandem gait. On 08 Nov 2020 (Day 18), a syphilis immunoglobulin M/immunoglobulin G (IgM/IgG) screen test (*Treponema* test) was nonreactive and the human T-lymphotropic virus-1/-2 antibody test was negative. Autoimmune workup performed on the same day (Day 18) was within normal limits, with centromere antibody of 4 AU/mL (NR: 0-99 AU/mL), double-stranded deoxyribonucleic acid of 9 AU/mL (NR: 0-99 AU/mL), histone antibody of 16 AU/mL (NR: 0-99 AU/mL), Jo-1 autoantibody of 5 AU/mL (NR: 0-99 AU/mL), ribonucleoprotein autoantibody of 31 U/mL (NR: 0-99 U/mL), scleroderma-70 autoantibody of 15 AU/mL (NR: 0-99 AU/mL), Smith autoantibody of 10 AU/mL (NR: 0-99 AU/mL), Sjogren's syndrome-A (SSA) autoantibody of 35 AU/mL (NR: 0-99 AU/mL), Sjogren's syndrome-B (SSB) autoantibody of 10 AU/mL (NR: 0-99 AU/mL), and glutamic acid decarboxylase 65-kilodalton isoform (GAD-65) autoantibody of <5.0 U/mL (NR: 0.0-5.0 U/mL). The visual impairment was considered resolved on 09 Nov 2020 (Day 19).

On 10 Nov 2020 (Day 20), the hepatitis panel (hepatitis A, B, and C virus) and human immunodeficiency virus (antigen/antibody combination) tests were nonreactive. An MRI of the cervical spine was performed (unknown date) for possible transverse myelitis, which showed no evidence of transverse myelitis or other acute or chronic process in the spinal cord. Mild multilevel spinal canal stenosis secondary to disc bulging and small disc protrusions were present at C2-C3 and C4-C5 through C6-C7. There was no spinal cord impingement. Diffuse degenerative disc desiccation was noted. An MRI of the thoracic spine was obtained (unknown date) with and without gadolinium contrast for possible myelopathy, which revealed minimal to mild degenerative changes in the thoracic spine. Vertebral body heights were maintained, and the bone marrow signals were within normal limits. No spondylolisthesis or high-grade central canal or neural foraminal stenosis was observed. The spinal cord demonstrated normal signal intensity. No evidence of abnormal enhancement was noted. There were no intradural or extradural masses, and the paraspinal soft tissues were unremarkable. On 10 Nov 2020 (Day 20), a lumbar puncture was performed and the cerebrospinal fluid (CSF) analysis showed clear and colorless CSF with a red blood cell count of 114/µL (ULN: <2/µL), total nucleated cells of <3/µL (ULN: <5/µL); white blood cell count of 3+, CSF glucose of 66, and protein of 51 (units and normal ranges not provided). The Gram stain showed no organisms, and culture results showed no growth for 5 days. The amnesia was considered resolved on 10 Nov 2020 (Day 20). On 11 Nov 2020 (Day 21), the subject reported that he might have had mild injection site discomfort for 3 days after receiving Dose 1; however, he did not report it to the site at that time. The subject remained hospitalized at the time of this report.

The subject was discontinued from the study intervention on 13 Nov 2020 because of the amnesia, visual impairment, and worsening of chronic spastic paraparesis. The eye pain was considered resolved on 01 Jan 2021 (Day 72). The subject was withdrawn from the study on 23 Feb 2021 because of the visual impairment. The worsening of chronic spastic paraparesis was ongoing at the time of withdrawal.

In the opinion of the investigator, there was no reasonable possibility that the worsening of chronic spastic paraparesis was related to the study intervention.

In the opinion of the investigator, there was no reasonable possibility that the amnesia and visual impairment were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	64	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	74.09 kg	23.4 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SHOULDER PAIN	Arthralgia	2015	Present
SHINGLES VACCINE DOSE 1 [vaccination]	Herpes zoster immunisation	13FEB2020	Past
SHINGLES VACCINE DOSE 2 [vaccination]	Herpes zoster immunisation	25JUL2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04SEP2020 (1)	12:30
3	BNT162b2	19JAN2021 (138)	11:43
4	BNT162b2	09FEB2021 (159)	11:07

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Parkinsonism	parkinsonism	18SEP2020 (15)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	P	N	Yes	NOT RELATED/OTHER: natural progression of parkinsonism	1	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
flu shot	INFLUENZA VACCINE	06OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Withdrawn	VACCINATION	21SEP2020	ADVERSE EVENT
Completed	REPEAT SCREENING 1	19JAN2021	
Completed	OPEN LABEL TREATMENT	09MAR2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1145 11451076, a 64-year-old Asian male with no pertinent medical history, received Dose 1 on 04 Sep 2020. The subject was diagnosed with parkinsonism on 18 Sep 2020, 14 days after receiving Dose 1. The subject was discontinued from the study intervention on 21 Sep 2020 because of the parkinsonism, which was ongoing at the time of the last available report. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 19 Jan 2021 (Day 138) and 09 Feb 2021 (Day 159), respectively, and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the parkinsonism was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
149.86 cm	58.91 kg	26.2 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Penicillin Allergy	Drug hypersensitivity	1970	Present
allergy to black olives	Food allergy	1975	Present
Aspirin Allergy	Drug hypersensitivity	1985	Present
Breast Surgery for Fibrocystic Removal (right)	Breast cyst excision	1990	Past
Fibrocystic Right Breast	Fibrocystic breast disease	1990	Past
Gall Bladder Removal	Cholecystectomy	2001	Past
Gall Bladder Stones	Cholelithiasis	2001	Past
Breast Surgery for Fibrocystic Removal (left)	Breast cyst excision	2005	Past
Fibrocystic Left Breast	Fibrocystic breast disease	2005	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25SEP2020 (1)	09:33

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	EAR	Deafness unilateral	hearing loss right ear	14OCT2020 (20)		23OCT2020 (29)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	10	3	TC/P	N	Resolved (23OCT2020)	Study Treatment	1	20	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
Withdrawn	VACCINATION	15OCT2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1152 11521476, a 61-year-old white female with no pertinent medical history, received Dose 1 on 25 Sep 2020. The subject was diagnosed with unilateral deafness (right ear) on 14 Oct 2020, 19 days after receiving Dose 1. On 23 Oct 2020 (Day 29), the unilateral deafness resolved. The subject was discontinued from the study intervention on 15 Oct 2020 because of the unilateral deafness and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the unilateral deafness was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	25	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.8 cm	69.1 kg	23.4 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seafood Allergy	Food allergy	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	16:05

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	21AUG2020 (1)	12:25	ONGOING				P	N

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Yes	NOT RELATED/OTHER: THERE IS NOT AN UNDERLYING CAUSE. THIS EVENT IS A STANDARD PREGNANCY.	1	1	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Withdrawn	VACCINATION	28SEP2020	PREGNANCY
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1156 11561015, a 25-year-old black or African American female with no pertinent medical history, received Dose 1 on 21 Aug 2020. On 21 Aug 2020, the subject had an exposure during pregnancy, the day of receiving Dose 1. On 28 Sep 2020 (Day 39), at Visit 2, she underwent laboratory tests and procedures that included urine human chorionic gonadotropin, which was positive. The subject's first day of her last menstrual period was 04 Aug 2020. The estimated date of conception was 21 Aug 2020, which was also the same day of initial exposure. The gestational age at the time of the initial exposure was first trimester. The mother did not smoke, drink alcohol, or use illicit drugs. She was gravida 5 para 5. Her partner was 23 years old and was unemployed. The subject was discontinued from the study intervention on 28 Sep 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	30	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	69.55 kg	26.3 kg/m2	07AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07AUG2020 (1)	12:19
3	BNT162b2	19JAN2021 (166)	10:34
4	BNT162b2	08FEB2021 (186)	10:08

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	SKIN	Dermatitis allergic	Allergic Reaction upper body rash	08AUG2020 (2)	08:00	25AUG2020 (19)	
2	IMMUN	Drug hypersensitivity	Allergic Reaction to study investigational product	08AUG2020 (2)	08:00	25AUG2020 (19)	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	18	2	TC	N	Resolved (25AUG2020)	Study Treatment	1	2	N
2	18	2	TC/P	N	Resolved (25AUG2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Withdrawn	VACCINATION	08AUG2020	ADVERSE EVENT
Completed	REPEAT SCREENING 1	19JAN2021	
Completed	OPEN LABEL TREATMENT	08MAR2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1163 11631059, a 30-year-old white female with no reported medical history, received Dose 1 on 07 Aug 2020. The subject developed drug hypersensitivity (allergic reaction to study intervention) on 08 Aug 2020, 1 day after receiving Dose 1. On 08 Aug 2020 (Day 2), the subject developed allergic dermatitis (allergic reaction upper body rash). The drug hypersensitivity and allergic dermatitis resolved on 25 Aug 2020 (Day 19). The subject was discontinued from the study intervention on 08 Aug 2020 because of the drug hypersensitivity. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 19 Jan 2021 (Day 166) and 08 Feb 2021 (Day 186), respectively, and remains in the study. In the opinion of the investigator, there was a reasonable possibility that the drug hypersensitivity was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.3 cm	60.7 kg	19.3 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Flat feet	Foot deformity	1980	Present
Scoliosis	Scoliosis	1980	Present
Smoker	Tobacco user	1988	Present
Left leg femoral artery repair	Arterial repair	2011	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	14:56

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Dizziness	Dizziness	31AUG2020 (1)	15:30	31AUG2020 (1)	17:30

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	P	N	Resolved (31AUG2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Withdrawn	VACCINATION	31AUG2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1166 11661047, a 50-year-old black or African American male with a pertinent medical history of left leg femoral artery repair (in 2011), received Dose 1 on 31 Aug 2020. On 31 Aug 2020, approximately half an hour after receiving Dose 1, the subject reported mild dizziness at 1530 hours, which resolved on the same day at 1730 hours. The subject was discontinued from the study intervention on 31 Aug 2020 because of the dizziness and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the dizziness was related to the study intervention.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1987	33	Asian	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
165 cm	52.15 kg	19.2 kg/m2	13AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	13AUG2020 (1)	16:30
2	Placebo	08SEP2020 (27)	08:37

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure During Pregnancy	NOV2020 ()		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			W	N	Yes	NOT RELATED/OTHER: Pregnancy	2		Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccine	INFLUENZA VACCINE	21SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	06OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	04JAN2021	PREGNANCY

Narrative Comment
Subject C4591001 1170 11701013, a 33-year-old Asian female with no reported medical history, received Dose 1 on 13 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 27). The subject had an exposure during pregnancy in Nov 2020. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo. On an unspecified date, before taking the pregnancy test at Visit 101, the subject notified the site that she was pregnant and did not receive BNT162b2. The subject was withdrawn from the study on 04 Jan 2021 because of the exposure during pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	100 kg	29.8 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Testicular Cancer	Testis cancer	FEB1998	Past
Orchiectomy	Orchidectomy	MAR1998	Past
Chemotherapy	Chemotherapy	APR1998	Past
Hypothyroidism	Hypothyroidism	2000	Present
Left Foot Toe Surgery	Toe operation	2000	Past
Hernia Repair	Hernia repair	2012	Past
Seasonal Allergies	Seasonal allergy	2015	Present
Laparoscopic Surgery	Laparoscopic surgery	2018	Past
Meniscus Tear	Meniscus injury	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	09:40
2	Placebo	02SEP2020 (20)	09:24
3	BNT162b2	09FEB2021 (180)	11:25

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	SKIN	Angioedema	Angioedema - Forehead	11FEB2021 (182)	12:00	16FEB2021 (187)	
2	SKIN	Urticaria	Urticaria on forehead, posterior neck, bilateral posterior hands and bilateral plantar areas	10FEB2021 (181)	12:00	16FEB2021 (187)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	6	1	TC/P	N	Resolved (16FEB2021)	Study Treatment	3	3	Y
2	7	2	TC/P	N	Resolved (16FEB2021)	Study Treatment	3	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	30SEP2020	
Completed	REPEAT SCREENING 1	09FEB2021	
Withdrawn	OPEN LABEL TREATMENT	09MAR2021	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1171 11711023, a 47-year-old white male with a pertinent medical history of seasonal allergy (since 2015), received Dose 1 on 14 Aug 2020 and Dose 2 on 02 Sep 2020 (Day 20). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first dose of BNT162b2 on 09 Feb 2021 (Day 180). He experienced urticaria on the forehead, posterior neck, bilateral posterior hands, and bilateral plantar areas on 10 Feb 2021, 1 day after receiving the first dose of BNT162b2. He developed angioedema on the forehead on 11 Feb 2021, 2 days after receiving the first dose of BNT162b2. The urticaria and angioedema resolved on 16 Feb 2021, 7 days after receiving the first dose of BNT162b2. The subject was discontinued from the study intervention on 09 Mar 2021 because of the urticaria and angioedema, and remains in the study. In the opinion of the investigator, there was a reasonable possibility that the urticaria and angioedema were related to BNT162b2.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156 cm	64 kg	26.3 kg/m2	30OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INV	Blood pressure increased	Increasing of systolic and diastolic blood pressure	30OCT2020 (1)	14:55	30OCT2020 (1)		1	2	W	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (30OCT2020)	NOT RELATED/OTHER: Blood pressure values of volunteer were high during vaccine preparation period.			Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30OCT2020	
	VACCINATION		
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	30OCT2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1205 12051028, a 38-year-old white male with no reported medical history, experienced increased blood pressure before administration of study vaccination on 30 Oct 2020, which resolved on the same day. The subject was withdrawn from the study before administration of study vaccination on 30 Oct 2020 because of the increased blood pressure. In the opinion of the investigator, there was no reasonable possibility that the increased blood pressure was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
155 cm	65 kg	27.1 kg/m2	30OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30OCT2020 (1)	11:55

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	INJ&P	Exposure during pregnancy	exposure during pregnancy	30OCT2020 (1)		ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1			P	N	Yes	NOT RELATED/OTHER: subject pregnant	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Hepatitis A Vaccination	HEPATITIS A VACCINE	09NOV2020
Hepatitis B Vaccination	HEPATITIS B VACCINE	09NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30OCT2020	
Withdrawn	VACCINATION	07DEC2020	PREGNANCY
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1217 12171031, a 35-year-old white female with a pertinent obstetrical history of 3 previous pregnancies resulting in 2 live births and 1 miscarriage (in 2019), received Dose 1 on 30 Oct 2020. The subject's urine pregnancy test was positive on 07 Dec 2020 (Day 39) and she had an exposure during pregnancy on 30 Oct 2020, on the day of Dose 1.

On 30 Oct 2020 (Day 1), the subject had her Visit 1 and received Dose 1; Dose 2 was delayed because of hepatitis A and B vaccinations that she received on 09 Nov 2020 (Day 11). Hence, the subject came to the site for Dose 2 administration on 07 Dec 2020 (Day 39) and tested positive for pregnancy on the same day. Her β-human chorionic gonadotropin level was 5466 mIU/mL [normal range (NR): 1000-50,000 mIU/mL]). The subject's first day of her last menstrual period was 26 Oct 2020. The gestational age at the time of initial exposure was first trimester. The subject's other laboratory test results showed ferritin of 6.1 ng/mL (NR: 11-306.8 ng/mL), free thyroxine of 0.68 ng/mL (NR: 0.57-1.09 ng/mL), free tri-iodothyronine of 3.05 ng/mL (NR: 2.54-3.99 ng/mL), folic acid of >48 ng/mL (NR: 3.1-19.09 ng/mL), fasting blood glucose of 95.03 mg/dL (NR: 74-106 mg/dL), thyroid-stimulating hormone of 1.471 mIU/mL (NR: 0.52-4.33 mIU/mL), and vitamin B12 of 215 ng/mL (NR: 145-505 ng/mL).

On 08 Dec 2020 (Day 40), an ultrasound scan showed a gestational sac. The subject was treated with folic acid 5 mg orally on 08 Dec 2020 (Day 40). On 18 Dec 2020 (Day 50), an ultrasound scan confirmed 1 fetus; the estimated date of birth was between the last week of Jul 2021 and the first week of Aug 2021, and the estimated date of pregnancy was reported as 26 Oct 2020 according to this ultrasound scan. The subject and her partner confirmed that they were using condoms during the study and reported that they did not smoke, drink alcohol, or use illicit drugs during this pregnancy. It was also reported that the subject's 36-year-old male partner was also part of the C4591001 study and he received his first dose on 30 Oct 2020 and second dose on 19 Nov 2020. The obstetrician also stated that there was no need to terminate the pregnancy, which was also the decision of the principal investigator, and if there was a pathological condition or any anomaly, it would be miscarried.

The subject was discontinued from the study intervention on 07 Dec 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.43 cm	65.45 kg	22.5 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Acne	Acne	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	10:47

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	01FEB2021 (162)	14:24
4	BNT162b2	22FEB2021 (183)	10:50

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INV	Blood pressure increased	Increased Blood Pressure	24AUG2020 (1)		10SEP2020 (18)	
2	GASTR	Diarrhoea	Diarrhea	24AUG2020 (1)		06SEP2020 (14)	
3	GENRL	Fatigue	Fatigue	24AUG2020 (1)		02SEP2020 (10)	
4	INV	Heart rate irregular	Irregular Heart Rate	24AUG2020 (1)		10SEP2020 (18)	
5	GENRL	Pyrexia	Feverish Chills	24AUG2020 (1)		02SEP2020 (10)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	18	2	N	N	Resolved (10SEP2020)	Study Treatment	1	1	N
2	14	2	N	N	Resolved (06SEP2020)	Study Treatment	1	1	N
3	10	2	N	N	Resolved (02SEP2020)	Study Treatment	1	1	N
4	18	2	P	N	Resolved (10SEP2020)	Study Treatment	1	1	Y
5	10	2	N	N	Resolved (02SEP2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	
Withdrawn	VACCINATION	05SEP2020	ADVERSE EVENT
Completed	REPEAT SCREENING 1	01FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1224 12241065, a 30-year-old white female with no pertinent medical history, received Dose 1 on 24 Aug 2020. The subject was diagnosed with an irregular heart rate on 24 Aug 2020, the day of Dose 1 administration. On 24 Aug 2020 (Day 1), the subject also experienced increased blood pressure, diarrhea, fatigue, and pyrexia. The fatigue and pyrexia resolved on 02 Sep 2020 (Day 10), the diarrhea resolved on 06 Sep 2020 (Day 14), and the increased blood pressure and irregular heart rate resolved on 10 Sep 2020 (Day 18). The subject was withdrawn from the study intervention on 05 Sep 2020 because of the irregular heart rate. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 01 Feb 2021 (Day 162) and 22 Feb 2021 (Day 183), respectively, and remains in the study. In the opinion of the investigator, there was a reasonable possibility that the irregular heart rate was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	42	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169.5 cm	83.7 kg	29.1 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	2010	Present
Anxiety	Anxiety	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	09:52

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	MUSC	Myalgia	Muscle pain (shoulders and neck, on the right body side)	18AUG2020 (8)		ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			2	TC/P/W	N	Yes	Study Treatment	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Withdrawn	VACCINATION	01SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	14OCT2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1226 12261072, a 42-year-old white female with a pertinent medical history of hypothyroidism (since 2010) and anxiety (since 2016), received Dose 1 on 11 Aug 2020. The subject experienced myalgia (shoulders and neck, on the right body side) on 18 Aug 2020, 7 days after receiving Dose 1. The subject was discontinued from the study intervention on 01 Sep 2020 and was withdrawn from the study on 14 Oct 2020 because of the myalgia, which was ongoing at the time of withdrawal. In the opinion of the investigator, there was a reasonable possibility that the myalgia was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1993	27	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	53.9 kg	20.5 kg/m2	28SEP2020 (-1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
C-Section	Caesarean section	08OCT2015	Past
Preeclampsia	Pre-eclampsia	08OCT2015	Past
HIV	HIV test positive	SEP2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29SEP2020 (1)	13:54

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure during Pregnancy	20OCT2020 (22)	10:25	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			P	N	Yes	NOT RELATED/OTHER: Pregnancy	1	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29SEP2020	
Withdrawn	VACCINATION	20OCT2020	PREGNANCY
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1230 12301045, a 27-year-old black or African American female with a pertinent obstetrical history of 1 previous pregnancy with a live birth requiring cesarean section due to preeclampsia (on 08 Oct 2015) and a positive human immunodeficiency virus (HIV) test (since Sep 2018), received Dose 1 on 29 Sep 2020. The subject reported an exposure during pregnancy on 20 Oct 2020, 21 days after receiving Dose 1. Concomitant medications included dolutegravir sodium/lamivudine/tenofovir disoproxil fumarate (Acriptega) (since Sep 2018) for HIV infection and norethisterone (since Sep 2019) for contraception. On 28 Sep 2020, at Visit 1 (prior to receiving Dose 1), the subject confirmed the use of contraceptives (norethisterone and use of condoms by her partner) and her pregnancy test was negative. On 20 Oct 2020 (Day 22), during Visit 2, her pregnancy test was positive. The subject's first day of her last menstrual period could not be confirmed as she had vaginal bleeding on 01 Sep 2020, which was not considered a normal menstrual period because of her use of the injectable hormonal contraceptive norethisterone. The gestational age at the time of initial exposure was first trimester. It was reported that the subject did not smoke, drink alcohol, or use illicit drugs during this pregnancy. However, it was also reported that during the pregnancy, the subject's partner smoked and drank alcohol with no use of illicit drugs. The subject was discontinued from the study intervention on 20 Oct 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
188 cm	54.25 kg	15.3 kg/m2	15AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Syncope	Syncope	15AUG2020 (1)	15:40	15AUG2020 (1)	15:41	1	2
2	GASTR	Vomiting	vomits	15AUG2020 (1)	15:30	15AUG2020 (1)	15:40	1	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN/P/W	N	Resolved (15AUG2020)	NOT RELATED/OTHER: post phlebotomy			Y
2	TCN/P/W	N	Resolved (15AUG2020)	NOT RELATED/OTHER: post sincopal recovery			Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15AUG2020	
	VACCINATION		
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	15AUG2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1231 12311409, a 38-year-old white male with no reported medical history, experienced syncope and vomiting after the prevaccination phlebotomy on 15 Aug 2020 (Day 1), which resolved on the same day. The subject was withdrawn from the study before administration of study vaccination on 15 Aug 2020 because of the syncope and vomiting. In the opinion of the investigator, there was no reasonable possibility that the syncope and vomiting were related to the study intervention, but rather they were related to the phlebotomy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	59	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	50.9 kg	18.7 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
demyelinating disease	Demyelination	01JAN1966	Present
Meningitis	Meningitis	01JAN1966	Past
paresthesias in 4th and 5th fingers of the left hand	Paraesthesia	01JAN1966	Present
smoker	Tobacco user	01JAN1982	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	16:40

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Injection site pain	Pain in injection site	18SEP2020 (33)	07:00	18SEP2020 (33)	19:00	1
2	NEOPL	Lymphoproliferative disorder	REACTIVE LYMPHOID PROLIFERATION SUPRACLAVICULAR	06SEP2020 (21)	15:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (18SEP2020)	Study Treatment	1	33	N
2	1	P	N	Yes	NOT RELATED/OTHER: Unknown	1	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Withdrawn	VACCINATION	06SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311815, a 59-year-old white female with a pertinent medical history of demyelination (since 01 Jan 1966), paresthesia (in the fourth and fifth fingers of the left hand, since 01 Jan 1966), and tobacco use (since 01 Jan 1982), received Dose 1 on 17 Aug 2020. The subject was diagnosed with lymphoproliferative disorder (supraclavicular reactive lymphoid proliferation) on 06 Sep 2020, 20 days after receiving Dose 1. The subject was discontinued from the study intervention on 06 Sep 2020 because of the lymphoproliferative disorder, which was ongoing at the time of the last available report, and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the lymphoproliferative disorder was related to the study intervention.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1988	32	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
174 cm	77 kg	25.4 kg/m2	18AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

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Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	NERV	Syncope	Syncope	18AUG2020 (1)	10:25	18AUG2020 (1)	13:30	1

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	W	N	Resolved (18AUG2020)	NOT RELATED/OTHER: Post blood extraction			Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18AUG2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	VACCINATION		
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	18AUG2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1231 12311926, a 32-year-old white male with no reported medical history, experienced syncope during the prevaccination blood sample collection on 18 Aug 2020 (Day 1); the syncope resolved on the same day. The subject was withdrawn from the study before administration of study vaccination on 18 Aug 2020 because of the syncope. In the opinion of the investigator, there was no reasonable possibility that the syncope was related to the study intervention, but rather it was related to blood sample collection.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	91 kg	32.2 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
lung adenocarcinoma	Lung adenocarcinoma	01JUL2019	Past
Depressive syndrome	Depression	01OCT2019	Present
Hypothyroidism	Hypothyroidism	13DEC2019	Present
Thyroidectomy	Thyroidectomy	13DEC2019	Past
Left Lobectomy	Exeresis	07JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	14:58

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Metastases to central nervous system	Brain metastasis	28AUG2020 (9)		ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/P	Y	Yes	NOT RELATED/OTHER: history of primary lung adenocarcinoma	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Withdrawn	VACCINATION	28AUG2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1231 12312577, a 46-year-old white female with a pertinent medical history of lung adenocarcinoma (from 01 Jul 2019 to 07 Jan 2020; left lobectomy on 07 Jan 2020), depression (since 01 Oct 2019), hypothyroidism (since 13 Dec 2019), and thyroidectomy (benign nodule; on 13 Dec 2019), received Dose 1 on 20 Aug 2020. The subject was diagnosed with brain metastasis on 28 Aug 2020, 8 days after receiving Dose 1.

Concomitant medications included quetiapine (since 01 Oct 2019) for depressive disorder and levothyroxine (since 13 Dec 2019) for hypothyroidism.

The subject reported that a routine monitoring brain computed tomography (CT) scan performed on 28 Aug 2020 (Day 9) revealed an abnormal brain image finding. A gadolinium magnetic resonance imaging (MRI)–spectroscopy performed on 08 Sep 2020 (Day 20) revealed 2 focal images in the right hemisphere and 1 in the right cerebellar hemisphere that were not present in the previous MRI. These lesions were considered as a secondary proliferative etiology of the primary tumor (lung adenocarcinoma in Jul 2019). The subject's oncologist recommended brain radiosurgery for the treatment of the brain metastasis. The subject reported that she received radiosurgery therapy (daily course) and dexamethasone treatment 8 mg once daily (QD) on 05 Oct 2020 (Day 47), followed by 4 mg QD until 09 Oct 2020 (Day 51) for the brain metastasis. The subject tolerated the procedure well. On 07 Oct 2020 (Day 49), during the course of radiosurgery therapy, the subject had involuntary leg movements as lower limb focal seizures, which lasted for a few hours. Her oral dexamethasone dose was increased to 16 mg QD from 07 Oct 2020 to 08 Oct 2020, then decreased to 12 mg QD from 09 Oct 2020 to 11 Oct 2020, to 8 mg QD from 12 Oct 2020 to 18 Oct 2020, and to 4 mg QD from 19 Oct 2020. On 25 Oct 2020 (Day 67), the subject had involuntary movements in the right ankle that lasted a few seconds. On 26 Oct 2020 (Day 68), she was started on levetiracetam 500 mg 3 times a day and continued with prednisone 4 mg QD. The focal seizures did not recur. On 18 Nov 2020 (Day 91), the subject received levetiracetam 500 mg twice daily (BID) and dexamethasone 4 mg BID. On 27 Nov 2020 (Day 100), the subject's oncologist suggested that the subject continue levetiracetam 500 mg BID and decrease dexamethasone to 4 mg QD. The seizures did not recur. The CT of the abdomen, thorax, and pelvis performed on 03 Dec 2020 (Day 106) showed that the lenticular liquid image within the walls, with

postcontrast reinforcement, was slightly smaller than that from the previous visit on 28 Aug 2020 (Day 9). The nodular images on the right lung were noted without changes from the previous visit. On 05 Dec 2020 (Day 108), a brain MRI showed mild regression of one of the perirolandic metastatic lesions (brain metastatic lesions smaller). The subject continued treatment with oral levetiracetam 500 mg BID and dexamethasone 4 mg QD. On 22 Dec 2020 (Day 125), her oncologist suggested a decrease in the dose of dexamethasone from 4 mg to 2 mg QD, and to continue with the same dose of levetiracetam. On 26 Jan 2021 (Day 160), the dexamethasone dose was tapered from 2 mg to 1 mg QD and the dose of levetiracetam was not changed. Brain MRI and CT scan of the abdomen, thorax, and pelvis were scheduled in Feb 2021. The subject remained asymptomatic. On 19 Feb 2021 (Day 184), a CT scan of the neck and paranasal sinuses and an enhanced CT scan of the thorax, abdomen, and pelvis were performed; the results were compared with images of 28 Aug 2020 (Day 9) and 03 Dec 2020 (Day 106), and showed postsurgical changes in the pulmonary parenchyma related to total left pneumonectomy associated with the reduction in volume of the hemithorax and mediastinal lateralization to the same side. The liquid density and wall reinforcement seen in the image were described in the previous studies from 28 Aug 2020 (Day 9) and 03 Dec 2020 (Day 106). Signs of centrilobular emphysema were seen and the rest of the results were unremarkable, with the conclusion of an image without major changes and no signs of progression of underlying disease. A brain enhanced MRI done on 25 Feb 2021 (Day 190), compared with the MRI of 05 Dec 2020 (Day 108), revealed a perirolandic parasagittal lesion with a diameter of 9.7 mm × 5.8 mm × 15 mm (anteroposterior, transversal, and cephalocaudal diameter, respectively, compared with the previous measurement of 13 mm × 10 mm × 19 mm). The lesion had a reinforcement sector after the administration of gadolinium, which was visible in the previous image. The lesion was situated laterally to the previously described one with similar characteristics, was also smaller, measuring 6.6 mm × 8 mm × 6.3 mm (anteroposterior, transversal, and cephalocaudal diameter, respectively, compared with the previous measurement of 10 mm × 11 mm × 10 mm). The images showed edema of the perilesional white matter of probably vasogenic origin (with no significant changes). The lesion on the right cerebellar hemisphere was without significant changes (9 mm × 14 mm × 9 mm). No new focal images compatible with secondary spread were noted. Conclusion: reduction of size of the known metastatic lesion on the right cerebral hemisphere and stability of the one on the cerebellum. On 28 Feb 2021 (Day 193), the subject reported feeling well. On 03 Mar 2021 (Day 196), her oncologist confirmed that there were no signs of progression of underlying disease in the chest CT scan and brain MRI. The subject continued taking levetiracetam at the same dose. On 05 Mar 2021 (Day 198), during a follow-up, the investigator recommended blood testing prior to unblinding. On 11 Mar 2021 (Day 204), the blood test results showed a red blood cell count of 4.27×10^6/µL, hematocrit of 42.8%, hemoglobin of 13.7 g/dL, mean corpuscular volume of 100.1 femtoliters, mean corpuscular hemoglobin of 32 pg, leukoocyte count of 10.1×10^3/µL, neutrophil percentage of 63.67%, absolute neutrophil count of 6.45×10^3/µL, lymphocyte percentage of 25.34%, absolute lymphocyte count of 2.57×10^3/µL, basophil percentage of 1.02%, absolute basophil count of 0.10×10^3/µL, monocyte percentage of 6%, absolute monocyte count of 0.60×10^3/µL, eosinophil percentage of 3.95%, and absolute eosinophil count of 0.40×10^3/µL, (normal ranges [NRs] not reported); erythrocyte sedimentation rate of 95 mm/hour (NR: 2-12 mm/hour), indirect bilirubin of 0.15 mg/dL (NR: 0.20-0.80 mg/dL), glutamic oxaloacetic transaminase of 43 U/L (NR: 10-35 U/L), total cholesterol of 242 mg/dL (NR: 150-200 mg/dL), thyrotropin of 8.4730 µIU/mL (NR: 0.3500-4.9400 µIU/mL), C-reactive protein of 23.34 mg/L (NR: 0.00-5.00 mg/L), and the rest of the values were unremarkable. The subject was scheduled for her next imaging and oncologist appointment in May 2021. The brain metastasis was ongoing at the time of the last available report. The investigator considered the brain metastasis to be a medically significant event.

The subject was discontinued from the study intervention on 28 Aug 2020 because of the brain metastasis due to lung adenocarcinoma and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

In the opinion of the investigator, there was no reasonable possibility that the brain metastasis was related to the study intervention, concomitant medications, or clinical trial procedures, but rather considered to be related to the previous history of primary lung adenocarcinoma diagnosed on 01 Jul 2019. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	37	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156 cm	54 kg	22.2 kg/m2	30AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30AUG2020 (1)	10:34

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Injection site pain	pain at injection site	30AUG2020 (1)	10:34	16SEP2020 (18)	09:00

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	18	2	TC/P/W	N	Resolved (16SEP2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30AUG2020	
Withdrawn	VACCINATION	05OCT2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	05OCT2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1231 12315429, a 37-year-old white female with no reported medical history, received Dose 1 on 30 Aug 2020. The subject reported moderate injection site pain on 30 Aug 2020, after Dose 1 administration. The injection site pain resolved on 16 Sep 2020 (Day 18). The subject was withdrawn from the study on 05 Oct 2020 because of the injection site pain. In the opinion of the investigator, there was a reasonable possibility that the injection site pain was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	50 kg	19.1 kg/m2	30AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 2 Diabetes	Type 2 diabetes mellitus	30AUG2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30AUG2020 (1)	11:32

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	PSYCH	Depression	Depressive syndrome	10SEP2020 (12)	13:00	24JAN2021 (148)	21:57	137

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC/P	N	Resolved (24JAN2021)	NOT RELATED/OTHER: unknown	1	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30AUG2020	
Withdrawn	VACCINATION	22OCT2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12315441, a 34-year-old white female with no pertinent medical history, received Dose 1 on 30 Aug 2020. The subject reported depression on 10 Sep 2020, 11 days after receiving Dose 1. The subject was discontinued from the study intervention on 22 Oct 2020 because of the depression, which resolved on 24 Jan 2021 (Day 148), and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the depression was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
198.12 cm	156.36 kg	39.7 kg/m2	03SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03SEP2020 (1)	09:55

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	VASC	Hypertension	high blood pressure	25SEP2020 (23)	00:00	23OCT2020 (51)	00:00	29

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	P	N	Resolved (23OCT2020)	NOT RELATED/OTHER: unknown	1	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Withdrawn	VACCINATION	25SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1232 12321175, a 49-year-old white male with no reported medical history, received Dose 1 on 03 Sep 2020. The subject experienced hypertension on 25 Sep 2020, 22 days after receiving Dose 1. The subject was discontinued from the study intervention on 25 Sep 2020 because of the hypertension, which resolved on 23 Oct 2020 (Day 51), and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the hypertension was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	23	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	108.18 kg	43.5 kg/m2	09SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09SEP2020 (1)	11:46

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy	01OCT2020 (23)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			P	N	Yes	NOT RELATED/OTHER: Pregnancy	1	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Withdrawn	VACCINATION	30OCT2020	PREGNANCY
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1232 12321213, a 23-year-old black or African American female with a pertinent obstetrical history of 2 previous pregnancies resulting in 2 live births, received Dose 1 on 09 Sep 2020. The subject reported an exposure during pregnancy on 01 Oct 2020, 22 days after receiving Dose 1. On 01 Oct 2020 (Day 23), at Visit 2, the subject's urine pregnancy test was positive. The information available at the time of this report was that the subject's partner did not take any medications during this pregnancy. The subject was discontinued from the study intervention on 30 Oct 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	32	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	95.45 kg	34.9 kg/m2	01OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01OCT2020 (1)	12:36

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	INJ&P	Exposure during pregnancy	Exposure During Pregnancy	22OCT2020 (22)	15:19	ONGOING	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1			P	N	Yes	NOT RELATED/OTHER: pregnancy	1	22	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01OCT2020	
Withdrawn	VACCINATION	22OCT2020	PREGNANCY
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1232 12321293, a 32-year-old black or African American female with no reported medical or obstetrical history, received Dose 1 on 01 Oct 2020. The subject reported an exposure during pregnancy on 22 Oct 2020, 21 days after receiving Dose 1. On 22 Oct 2020 (Day 22), during Visit 2, the subject reported to the site that she had a positive pregnancy test (no further details were reported). Her pregnancy was confirmed to be positive by a serum pregnancy (β-human chorionic gonadotropin) test done on the same day (Day 22). The subject's first day of her last menstrual period and the estimated date of conception were unspecified. The gestational age at the time of initial exposure was unknown. It was reported that the subject did not smoke, drink alcohol, or use illicit drugs during this pregnancy. The subject was discontinued from the study intervention on 22 Oct 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1965	55	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
185.42 cm	81.82 kg	23.7 kg/m2	06OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	06OCT2020 (1)	10:13

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	VASC	Hypertension	Hypertension	06OCT2020 (1)	00:00	ONGOING		

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	W	N	Yes	NOT RELATED/OTHER: blood pressure level elevated	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06OCT2020	
Withdrawn	VACCINATION	06OCT2020	PHYSICIAN DECISION
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	29OCT2020	LOST TO FOLLOW-UP

Narrative Comment
After the data cutoff date of 13 Mar 2021 (with database snapshot taken on 25 Mar 2021), it was determined that Subject C4591001 1232 12321299 was not withdrawn from the study for safety reasons, but was lost to follow-up.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159.5 cm	85.6 kg	33.6 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Headache	Headache	JUL2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	09:37
2	Placebo	09SEP2020 (23)	09:30
3	BNT162b2	05FEB2021 (172)	13:46

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Injection site pain	Injection site pain	06FEB2021 (173)		06FEB2021 (173)		1
2	INJ&P	Maternal exposure during pregnancy	Maternal exposure during pregnancy	10FEB2021 (177)		ONGOING		

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (06FEB2021)	Study Treatment	3	2	N
2		P	N	Yes	NOT RELATED/OTHER: Pregnacy	3	6	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	07OCT2020	
Completed	REPEAT SCREENING 1	05FEB2021	
Withdrawn	OPEN LABEL TREATMENT	25FEB2021	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1241 12411208, a 35-year-old black or African American female with a pertinent obstetrical history of 2 previous pregnancies (2 children), eclampsia during the first pregnancy, and gestational hypertension during the second pregnancy, received Dose 1 on 18 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 23). Concomitant medication included ethinylestradiol/levonorgestrel (from 2019 to 25 Feb 2021) as an oral contraceptive. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 05 Feb 2021 (Day 172). She reported a maternal exposure during pregnancy with an estimated date of conception of 10 Feb 2021, 5 days after receiving the first dose of BNT162b2. On 25 Feb 2021 (Day 192), the subject visited the site to receive the second dose of BNT162b2. On that day, her urine and serum (β-human chorionic gonadotropin) pregnancy tests were positive. The first day of her last menstrual period was on 27 Jan 2021 (Day 163) and the gestational age at the time of initial exposure was first trimester. The subject and her 45-year-old partner did not smoke, drink alcohol, or use illicit drugs during this pregnancy. No obstetric ultrasonography was available at the time of this report. The subject was discontinued from the study intervention on 25 Feb 2021 because of the maternal exposure during pregnancy and she remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	76.5 kg	27.1 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
chronic low back pain	Back pain	2013	Present
Bariatric surgery	Metabolic surgery	05JAN2013	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	12:25

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
3	BNT162b2	16FEB2021 (182)	11:46
4	BNT162b2	09MAR2021 (203)	08:33

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Chills	Chills	16FEB2021 (182)	20:00	19FEB2021 (185)		4
2	INJ&P	Exposure during pregnancy	Exposure during pregnancy	10SEP2020 (23)		14OCT2020 (57)		35
3	GENRL	Injection site pain	Injection site pain	16FEB2021 (182)	20:00	19FEB2021 (185)		4
4	MUSC	Myalgia	Myalgia	16FEB2021 (182)	20:00	19FEB2021 (185)		4
5	PREG	Retained products of conception	RETAINED PRODUCTS OF CONCEPTION	14OCT2020 (57)		14OCT2020 (57)		1
6	REPRO	Vaginal haemorrhage	Vaginal bleeding	05OCT2020 (48)		14OCT2020 (57)		10

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (19FEB2021)	Study Treatment	3	1	N
2		P	N	Resolved (14OCT2020)	NOT RELATED/OTHER: Pregnancy	1	23	Y
3	1	N	N	Resolved (19FEB2021)	Study Treatment	3	1	N
4	1	N	N	Resolved (19FEB2021)	Study Treatment	3	1	N
5	3	TC	Y	Resolved (14OCT2020)	NOT RELATED/OTHER: Vaginal bleeding	1	57	Y
6	1	TC	N	Resolved (14OCT2020)	NOT RELATED/OTHER: threat of abortion	1	48	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19AUG2020	
Withdrawn	VACCINATION	10SEP2020	PREGNANCY
Completed	REPEAT SCREENING 1	16FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1241 12411279, a 35-year-old black or African American female with a pertinent medical history of 3 prior pregnancies complicated by gestational hypertension during the first pregnancy and ectopic pregnancy as the second pregnancy, received Dose 1 on 19 Aug 2020. The subject had an exposure during pregnancy on 10 Sep 2020, 22 days after receiving Dose 1, and reported retained products of conception on 14 Oct 2020, 56 days after receiving Dose 1. Concomitant medication included ketoprofen (from 09 Sep 2020 to 10 Sep 2020) for back pain. The date of the subject's last menstrual period was 09 Aug 2020 (Day -10) and the estimated date of conception was 22 Aug 2020 (Day 4). On 10 Sep 2020 (Day 23), at Visit 2, the subject's urine and serum (β-human chorionic gonadotropin) pregnancy tests were positive. The gestational age at the time of initial exposure was first trimester. The subject denied smoking, alcohol use, or use of illicit drugs during the pregnancy. It was reported that during the pregnancy, her partner drank alcohol (socially), but he did not smoke or use illicit drugs. The subject was discontinued from the study intervention on 10 Sep 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. On 05 Oct 2020 (Day 48), the subject experienced a vaginal hemorrhage. On 07 Oct 2020 (Day 50), she received scopolamine butylbromide and metamizole sodium, both for colic. On 14 Oct 2020 (Day 57), she presented to the emergency room and a transvaginal ultrasonography showed a retained abortion with gestational age of approximately 7 weeks 5 days, and a serious adverse event of retained products of conception was reported, resulting in hospitalization. The subject underwent uterine curettage and had a spontaneous abortion. The procedure was performed without complications. The subject received metamizole sodium, ferrous sulfate, and general anesthesia during this procedure. On 14 Oct 2020 (Day 57), the retained products of conception and vaginal hemorrhage were considered resolved. On 16 Oct 2020 (Day 59), the subject was discharged from the hospital. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 16 Feb 2021 (Day 182) and 09 Mar 2021 (Day 203), respectively, and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the event of retained products of conception was related to the investigational product, concomitant medications, or clinical trial procedure. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1987	33	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	59.5 kg	22.7 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic rhinitis	Rhinitis allergic	2000	Present
Migraine	Migraine	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	16:28

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	23SEP2020 (23)	16:07
3	BNT162b2	27JAN2021 (149)	10:23

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Injection site pain	Injection site pain	28JAN2021 (150)		29JAN2021 (151)		2
2	INJ&P	Maternal exposure during pregnancy	Maternal exposure during pregnancy	05FEB2021 (158)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (29JAN2021)	Study Treatment	3	2	N
2		P	N	Yes	NOT RELATED/OTHER: Pregnancy	3	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	21OCT2020	
Completed	REPEAT SCREENING 1	27JAN2021	
Withdrawn	OPEN LABEL TREATMENT	17FEB2021	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1241 12411514, a 33-year-old multiracial female with no pertinent medical history, received Dose 1 on 01 Sep 2020 and Dose 2 on 23 Sep 2020 (Day 23). Concomitant medication included propranolol (since Nov 2019) for migraine. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 27 Jan 2021 (Day 149). She reported a maternal exposure during pregnancy with an estimated date of conception of 05 Feb 2021, 9 days after receiving the first dose of BNT162b2. On 17 Feb 2021 (Day 170), the subject visited the site to receive a second dose of BNT162b2 and on that day, her urine pregnancy test was positive. A β-human chorionic gonadotropin blood test performed on that same day at an external laboratory was positive (±3 weeks) at 294.0 mIU/mL (normal range: <1 mIU/mL). The first day of her last menstrual period was 22 Jan 2021 (Day 144) and the gestational age at the time of initial exposure was first trimester. She and her 33-year-old partner did not smoke, drink alcohol, or use illicit drugs during the pregnancy. No obstetric ultrasonography was available at the time of the report. The subject was discontinued from the study intervention on 17 Feb 2021 because of the maternal exposure during pregnancy and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	34	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	81.3 kg	27.2 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic rhinitis	Rhinitis allergic	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16SEP2020 (1)	18:21

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	INJ&P	Maternal exposure during pregnancy	Maternal exposure during pregnancy	17SEP2020 (2)		ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1			P	N	Yes	NOT RELATED/OTHER: Pregnancy	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16SEP2020	
Withdrawn	VACCINATION	09OCT2020	PREGNANCY
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1241 12411766, a 34-year-old white female with a pertinent medical history of 1 previous pregnancy and miscarriage in Aug 2019, received Dose 1 on 16 Sep 2020. The subject reported a maternal exposure during pregnancy with an estimated date of conception of 17 Sep 2020, 1 day after receiving Dose 1.

On 09 Oct 2020 (Day 24), at Visit 2, the subject's urine and serum pregnancy tests were positive. The β-human chorionic gonadotropin was 9157.8 mIU/mL (normal range: 5.0-25.0 mIU/mL). The date of her last menstrual period was 03 Sep 2020 (Day -13) and the estimated date of conception was 17 Sep 2020 (Day 2). The gestational age at the time of initial exposure was first trimester. On 21 Oct 2020 (Day 36), an obstetric ultrasonography dated the pregnancy at 6 weeks 5 days. On 26 Nov 2020 (Day 72), an obstetric ultrasonography dated the pregnancy at 12 weeks 5 days. It was also reported that the subject's 38-year-old male partner was also part of this study. She and her partner did not smoke, drink alcohol, or use illicit drugs during this pregnancy. The subject's partner had no relevant history and did not take any drugs (over-the-counter or prescription) during this pregnancy. It was reported that the subject received folic acid (since 04 Oct 2020) and vitamin D (since 21 Oct 2020) during this pregnancy as vitamin supplements.

The subject was discontinued from the study intervention on 09 Oct 2020 because of the maternal exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	63	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154 cm	78.9 kg	33.3 kg/m2	17SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tubal ligation	Female sterilisation	1990	Past
Appendectomy	Appendicectomy	2011	Past
Type 2 diabetes mellitus	Type 2 diabetes mellitus	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17SEP2020 (1)	16:27
2	Placebo	08OCT2020 (22)	14:53
3	BNT162b2	29JAN2021 (135)	15:02
4	BNT162b2	19FEB2021 (156)	13:41

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Gastrointestinal haemorrhage	High digestive bleeding	12MAR2021 (177)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		4	W	Y	Yes	NOT RELATED/OTHER: Unknown	4	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17SEP2020	
Completed	VACCINATION	12NOV2020	
Completed	REPEAT SCREENING 1	29JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1241 12411829, a 63-year-old multiracial female with a pertinent medical history of appendectomy (in 2011) and type 2 diabetes mellitus (since 2018), received Dose 1 on 17 Sep 2020 and Dose 2 on 08 Oct 2020 (Day 22). Concomitant medications included metformin and gliclazide (both since 2018) for type 2 diabetes mellitus. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 29 Jan 2021 (Day 135) and 19 Feb 2021 (Day 156), respectively. She was diagnosed with a gastrointestinal hemorrhage on 12 Mar 2021, 21 days after receiving the second dose of BNT162b2. The subject was hospitalized for gastrointestinal hemorrhage on 12 Mar 2021 for 4 days. After the data cutoff date of 13 Mar 2021 (with database snapshot taken on 25 Mar 2021), it was reported that the subject died on 16 Mar 2021, 25 days after receiving the second dose of BNT162b2. The causes of death listed in the death certificate were hypovolemic shock and gastrointestinal hemorrhage. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the gastrointestinal hemorrhage was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	79 kg	26.4 kg/m2	19OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic rhinitis	Rhinitis allergic	1990	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19OCT2020 (1)	18:02

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	11NOV2020 (24)	16:24
3	BNT162b2	28JAN2021 (102)	10:13

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Injection site pain	Injection site pain	28JAN2021 (102)	19:00	29JAN2021 (103)		2
2	INJ&P	Maternal exposure during pregnancy	Maternal exposure during pregnancy	21JAN2021 (95)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (29JAN2021)	Study Treatment	3	1	N
2		P	N	Yes	NOT RELATED/OTHER: Pregnancy	2	72	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19OCT2020	
Completed	VACCINATION	10DEC2020	
Completed	REPEAT SCREENING 1	28JAN2021	
Withdrawn	OPEN LABEL TREATMENT	01MAR2021	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1241 12412369, a 38-year-old multiracial female with no pertinent medical history, received Dose 1 on 19 Oct 2020 and Dose 2 on 11 Nov 2020 (Day 24). The family medical history was breast cancer. The subject reported a maternal exposure during pregnancy with an estimated date of conception on 21 Jan 2021, 71 days after receiving Dose 2. Concomitant medication included drospirenone/ethinylestradiol Betadex clathrate (from 2010 to 20 Feb 2021) as an oral contraceptive. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 28 Jan 2021 (Day 102). On 01 Mar 2021 (Day 134), the subject informed the site about her pregnancy based on her laboratory and ultrasonography test reports. The subject's laboratory tests included a β-human chorionic gonadotropin of 1278 mIU/mL (normal range: 5-25 mIU/mL) on 23 Feb 2021 (Day 128). On 25 Feb 2021 (Day 130), an obstetric ultrasonography revealed 5 weeks of gestation. The first day of her last menstrual period was 16 Jan 2021 (Day 90) and the gestational age at the time of initial exposure was first trimester. The subject and her partner did not smoke or use illicit drugs during the pregnancy; however, they drank alcohol 3 times per month. The subject's partner did not take any medication during the pregnancy. The subject was discontinued from the study intervention on 01 Mar 2021 because of the maternal exposure during pregnancy and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1987	33	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	74.5 kg	28.4 kg/m2	20OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic rhinitis	Rhinitis allergic	1997	Present
Lactose intolerance	Lactose intolerance	2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20OCT2020 (1)	17:32

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
2	Placebo	10NOV2020 (22)	11:55
3	BNT162b2	08FEB2021 (112)	17:23

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	NEOPL	Fibroadenoma of breast	Right breast fibroadenoma	NOV2020 ()		ONGOING		
2	NERV	Headache	Headache	08FEB2021 (112)	20:00	10FEB2021 (114)		3
3	GENRL	Injection site pain	Injection site pain	08FEB2021 (112)	20:00	10FEB2021 (114)		3
4	INJ&P	Maternal exposure during pregnancy	Maternal exposure during pregnancy	12FEB2021 (116)		ONGOING		
5	MUSC	Myalgia	Myalgia	08FEB2021 (112)	20:00	10FEB2021 (114)		3
6	GENRL	Pyrexia	Fever	08FEB2021 (112)	20:00	10FEB2021 (114)		3

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Yes	NOT RELATED/OTHER: Unknown			N
2	1	N	N	Resolved (10FEB2021)	Study Treatment	3	1	N
3	1	N	N	Resolved (10FEB2021)	Study Treatment	3	1	N
4		P	N	Yes	NOT RELATED/OTHER: Pregnancy	3	5	Y
5	1	N	N	Resolved (10FEB2021)	Study Treatment	3	1	N
6	1	N	N	Resolved (10FEB2021)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20OCT2020	
Completed	VACCINATION	10DEC2020	
Completed	REPEAT SCREENING 1	08FEB2021	
Withdrawn	OPEN LABEL TREATMENT	08MAR2021	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1241 12412411, a 33-year-old multiracial female with a pertinent medical history of allergic rhinitis (since 1997), received Dose 1 on 20 Oct 2020 and Dose 2 on 10 Nov 2020 (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 08 Feb 2021 (Day 112). She had an exposure during pregnancy on 12 Feb 2021, 4 days after receiving the first dose of BNT162b2. On 08 Mar 2021 (Day 140), at Visit 104, the subject reported that she had a positive serum pregnancy test on 03 Mar 2021 (Day 135). The β-human chorionic gonadotropin was 458.12 mIU/mL (normal range: 5.0-25.0 mIU/mL). The first day of her last menstrual period was 05 Feb 2021 (Day 109) and the estimated date of conception was 12 Feb 2021 (Day 116). The gestational age at the time of initial exposure was first trimester. No obstetric ultrasonography was available. The subject had a family history of eclampsia, spontaneous abortion, premature rupture of membranes, glucose intolerance (prediabetes), and autism. The subject had no previous pregnancy reported. She and her partner did not smoke or use illicit drugs during this pregnancy. However, it was reported that during the pregnancy, the subject drank alcohol 2 times per month and her partner drank alcohol 1 time per week. The subject was discontinued from the study intervention on 08 Mar 2021 (Day 140) because of the exposure during pregnancy and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	62 kg	21 kg/m2	28SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hysterectomy	Hysterectomy	1998	Past
Asthma	Asthma	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28SEP2020 (1)	10:30

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	SKIN	Urticaria	Intermittent urticaria generalised.	07OCT2020 (10)		02NOV2020 (36)	
2	SKIN	Urticaria	urticaria generalized	29SEP2020 (2)	00:01	02OCT2020 (5)	18:15

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	27	2	TC/P	N	Resolved (02NOV2020)	Study Treatment	1	10	Y
2	4	3	TC	N	Resolved (02OCT2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28SEP2020	
Withdrawn	VACCINATION	19OCT2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1246 12461025, a 45-year-old white female with a pertinent medical history of asthma (in 2015), received Dose 1 on 28 Sep 2020. The subject reported urticaria on 2 occasions after receiving Dose 1. The subject had an initial episode of urticaria on 29 Sep 2020 (Day 2) lasting until 02 Oct 2020 (Day 5). The second episode took place on 07 Oct 2020 (Day 10) lasting until 02 Nov 2020 (Day 36). The subject was discontinued from the study intervention on 19 Oct 2020 because of the additional episode of urticaria and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the urticaria was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.9 cm	43 kg	16.4 kg/m2	30SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	1991	Present
Post Menopausal	Postmenopause	2002	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30SEP2020 (1)	13:39

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	16FEB2021 (140)	10:33
4	BNT162b2	09MAR2021 (161)	09:31

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NERV	Cerebellar infarction	Chronic cerebelar infarcts	23OCT2020 (24)	11:34	ONGOING			1	N	N
2	NERV	Cerebral atrophy	Cerebral atrophy	23OCT2020 (24)	11:34	ONGOING			1	N	N
3	NERV	Cerebral infarction	Left Middle Cerebral Artery Infarct	21OCT2020 (22)		ONGOING			3	TC/TCN/P	Y
4	GENRL	Injection site pain	Local injection site pain	17FEB2021 (141)		ONGOING			1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: CT finding	1	24	N
2	Yes	NOT RELATED/OTHER: CT Findings	1	24	N
3	Yes	NOT RELATED/OTHER: Pt.68 years old; and 50 pack year history of smoking as risk factors for event.	1	22	Y
4	Yes	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30SEP2020	
Withdrawn	VACCINATION	21OCT2020	ADVERSE EVENT
Completed	REPEAT SCREENING 1	16FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1247 12471135, a 69-year-old white female with no pertinent medical history, received Dose 1 on 30 Sep 2020. The subject had a history of smoking since 1962 (50 packs a year). The subject was diagnosed with a cerebral infarction on 21 Oct 2020, 21 days after receiving Dose 1. Concomitant medications included salbutamol and budesonide (both since 1991) for asthma; and ibuprofen, paracetamol, and tramadol (all since 28 May 2020) for chronic left arm pain. On 21 Oct 2020 (Day 22), the subject had slurred speech and presented to the emergency department. The clinical examination revealed expressive aphasia and a left facial droop. That same day (Day22), her vital signs included a blood pressure of 134/57 mmHg, heart rate of 119 beats/min, body temperature of 35.7℃, respiratory rate of 20 breaths/min, and oxygen saturation of 96% on room air. An electrocardiogram showed p-pulmonale, which was not clinically significant. Laboratory test results showed a platelet count of 290 × 109/L, glucose of 5.5 mmol/L, and high urea level of 8.4 mmol/L (normal ranges not reported), with all other laboratory test results within normal limits. The subject was hospitalized and was treated with simvastatin 20 mg and aspirin 150 mg, both orally daily since 21 Oct 2020 (Day 22). A computed tomography scan on 23 Oct 2020 (Day 24) revealed an acute infarct in the middle cerebral artery distribution on the left side, along with chronic cerebellar infarcts and cerebral atrophy. The subject was diagnosed with cerebral infarction (left middle cerebral artery infarct) with an onset date of 21 Oct 2020 (Day 22). She also received physiotherapy, occupational therapy, and speech therapy. Her clinical condition improved and her speech was also improving. She was discharged on 28 Oct 2020 (Day 29) and was advised to follow up with speech therapy. No COVID-19 test was performed. The cerebral atrophy and chronic cerebellar infarction were ongoing at the time of the last available report. The subject was discontinued from the study intervention on 21 Oct 2020 because of the cerebral infarction, which was ongoing at the time of the last available report. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 16 Feb 2021 (Day 140) and 09 Mar 2021 (Day 161), respectively, and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the cerebral infarction was related to the study intervention, concomitant medications, or clinical trial procedures, but rather related to the age of the subject and history of smoking. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	26	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174.5 cm	69.4 kg	22.8 kg/m2	20SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	NERV	Syncope	vasovagal syncope	20SEP2020 (1)	13:54	20SEP2020 (1)	14:52	1	2
2	GASTR	Vomiting	Vomiting	20SEP2020 (1)	14:52	21SEP2020 (2)	14:53	2	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	W	N	Resolved (20SEP2020)	NOT RELATED/OTHER: Study Procedure (phlebotomy)			Y
2	TCN	N	Resolved (21SEP2020)	NOT RELATED/OTHER: unknown			N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20SEP2020	
Withdrawn	VACCINATION	21SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	21SEP2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1248 12481218, a 26-year-old white male with no reported medical history, reported syncope during the prevaccination blood sample collection on 20 Sep 2020 (Day 1), which resolved on the same day. On 20 Sep 2020 (Day 1), the subject also reported vomiting, which resolved on 21 Sep 2020 (Day 2). The subject was withdrawn from the study before the administration of study vaccination on 21 Sep 2020 because of the syncope. In the opinion of the investigator, there was no reasonable possibility that the syncope was related to the study intervention, but rather it was related to the study procedure (phlebotomy).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	112.73 kg	38.8 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin drug allergy	Drug hypersensitivity	1968	Present
mole	Melanocytic naevus	2005	Past
MOLE REMOVAL	Mole excision	2005	Past
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2010	Present
RIGHT CATARACT	Cataract	2017	Past
hypercholesterolemia	Hypercholesterolaemia	2017	Present
hypertension	Hypertension	2017	Present
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
diabetes mellitus Type 2	Type 2 diabetes mellitus	2018	Present
RIGHT CATARACT SURGERY	Cataract operation	21JUL2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	13:55
2	Placebo	14SEP2020 (20)	12:49
3	BNT162b2	26JAN2021 (154)	14:39
4	BNT162b2	16FEB2021 (175)	14:39

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Chills	17FEB2021 (176)		18FEB2021 (177)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	W	N	Resolved (18FEB2021)	Study Treatment	4	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	26JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
After the data cutoff date of 13 Mar 2021 (with database snapshot taken on 25 Mar 2021), it was determined that Subject C4591001 1254 12541006 did not withdraw from the study because of the chills and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	21	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.6 cm	63.05 kg	23.8 kg/m2	12SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	2015	Present
Recurrent Miscarriage	Abortion spontaneous	2016	Past
Seasonal Allergies	Seasonal allergy	2017	Present
Benedryl Allergy	Drug hypersensitivity	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12SEP2020 (1)	13:13

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain upper	stomach pain	15SEP2020 (4)	09:00	15SEP2020 (4)	14:00	1	2
2	SKIN	Alopecia	hair loss	OCT2020 ()		ONGOING			1
3	INV	Body temperature increased	elevated body temperature at 100.0F	13SEP2020 (2)	07:30	14SEP2020 (3)	04:00	2	1
4	INV	Body temperature increased	elevated body temperature at 100.0F	14SEP2020 (3)	10:00	15SEP2020 (4)		2	2
5	GENRL	Chills	intermittent chills	12SEP2020 (1)	22:00	25SEP2020 (14)		14	1
6	EYE	Eye irritation	left eye irritation	12SEP2020 (1)	16:00	14SEP2020 (3)		3	1
7	NERV	Headache	headache intermittent	15SEP2020 (4)		25SEP2020 (14)		11	2
8	INJ&P	Maternal exposure during pregnancy	Maternal Exposure During Pregnancy	12SEP2020 (1)		ONGOING			
9	GASTR	Nausea	Nausea	26SEP2020 (15)		ONGOING			1
10	EYE	Ocular hyperaemia	left eye redness	12SEP2020 (1)	16:00	14SEP2020 (3)		3	1
11	GENRL	Pyrexia	fever at 102.0F	14SEP2020 (3)	04:00	14SEP2020 (3)	08:00	1	2
12	INV	Weight decreased	weight loss	OCT2020 ()		ONGOING			1

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (15SEP2020)	NOT RELATED/OTHER: unknown etiology but due to gas	1	4	N
2	N	N	Yes	NOT RELATED/OTHER: pregnancy	1		N
3	N	N	Resolved (14SEP2020)	Study Treatment	1	2	N
4	TC	N	Resolved (15SEP2020)	Study Treatment	1	3	N
5	N	N	Resolved (25SEP2020)	Study Treatment	1	1	N
6	N	N	Resolved (14SEP2020)	NOT RELATED/OTHER: unknown etiology	1	1	N
7	TC	N	Resolved (25SEP2020)	Study Treatment	1	4	N
8	P	N	Yes	NOT RELATED/OTHER: pregnancy	1	1	Y
9	N	N	Yes	NOT RELATED/OTHER: Likely From Pregnancy	1	15	N
10	N	N	Resolved (14SEP2020)	NOT RELATED/OTHER: unknown etiology	1	1	N
11	TC	N	Resolved (14SEP2020)	Study Treatment	1	3	N
12	N	N	Yes	NOT RELATED/OTHER: pregnancy	1		N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12SEP2020	
Withdrawn	VACCINATION	07OCT2020	PREGNANCY
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1254 12541142, a 21-year-old white female with a pertinent obstetrical history of spontaneous abortion (in 2016) and 4 previous pregnancies that resulted in 2 spontaneous abortions in 2018 and 2019, 1 therapeutic abortion in 2018, and 1 live birth in May 2020, received Dose 1 on 12 Sep 2020. The subject's pregnancy test was positive on 02 Oct 2020 (Day 21) and she had a maternal exposure during pregnancy on 12 Sep 2020, on the day of Dose 1. On 02 Oct 2020 (Day 21), the subject requested that the site reschedule Visit 2, as she had been suffering from nausea for the past week. She visited her physician that same day for her ongoing nausea, as well as for vaginal spotting and unprotected intercourse. A urine pregnancy test was performed at this visit (02 Oct 2020), which was positive. On 03 Oct 2020 (Day 22), the subject had a transvaginal obstetric ultrasound examination, which showed a pregnancy of 7 weeks 2 days' duration, with positive fetal cardiac activity. It was determined that the first day of her last menstrual period was 12 Sep 2019, and she reported that it was not uncommon for her not to have menses postpartum for several months (last delivery was approximately 4 months prior to Visit 1). It was reported that her urine pregnancy test was negative at Visit 1. The gestational age at the time of initial exposure was 4 weeks. The subject did not smoke, drink alcohol, or use illicit drugs during this pregnancy. Following the initial study visit, the subject reported several adverse events starting on 12 Sep 2020 (Day 1), which included left eye irritation, left eye redness, and intermittent chills. On 14 Sep 2020 (Day 3), the left eye irritation and left eye redness resolved. The subject also reported elevated temperature of 100.0°F from 13 Sep 2020 (Day 2) to 14 Sep 2020 (Day 3), fever of 102.0°F from 14 Sep 2020 (Day 3) at 0400 hours to 14 Sep 2020 (Day 3) at 0800 hours, elevated temperature of 100.0°F from 14 Sep 2020 (Day 3) to 15 Sep 2020 (Day 4), stomach pain on 15 Sep 2020 (Day 4), headache from 15 Sep 2020 (Day 4) to 25 Sep 2020 (Day 14), and nausea since 26 Sep 2020 (Day 15). The subject was counseled to take paracetamol (Tylenol) for her headache and fever as well as simethicone (Gas-X) for stomach pain. On 25 Sep 2020 (Day 14), the intermittent chills resolved. The subject was discontinued from the study intervention on 07 Oct 2020 because of the maternal exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	51	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	71.2 kg	23.5 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
MILD EXERCISE INDUCED ASTHMA	Asthma exercise induced	1990	Present
MILD IRRITABLE BOWEL SYNDROME	Irritable bowel syndrome	1995	Present
Intermittent Eye Infection	Eye infection	2019	Present
MALE PATTERN BALDNESS	Androgenetic alopecia	JAN2019	Present
IMPAIRED GLUCOSE TOLERANCE	Glucose tolerance impaired	JUN2019	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	15OCT2020 (1)	16:19
2	Placebo	06NOV2020 (23)	10:00
3	BNT162b2	27JAN2021 (105)	11:39
4	BNT162b2	17FEB2021 (126)	11:52

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	MUSC	Arthralgia	generalized joint pain	18FEB2021 (127)		24FEB2021 (133)	
2	NERV	Headache	Headache	27JAN2021 (105)	18:00	28JAN2021 (106)	
3	NERV	Headache	headache	18FEB2021 (127)		19FEB2021 (128)	
4	GENRL	Injection site pain	Soreness at the Injection Site	27JAN2021 (105)	18:00	28JAN2021 (106)	
5	GENRL	Injection site pain	soreness at injection site	18FEB2021 (127)		24FEB2021 (133)	
6	GENRL	Pain	bodyaches	18FEB2021 (127)		20FEB2021 (129)	
7	GENRL	Pyrexia	fever of 100.7F	18FEB2021 (127)		19FEB2021 (128)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	7	2	TC	N	Resolved (24FEB2021)	Study Treatment	4	2	N
2	2	1	N	N	Resolved (28JAN2021)	Study Treatment	3	1	N
3	2	2	TC/W	N	Resolved (19FEB2021)	Study Treatment	4	2	Y
4	2	1	N	N	Resolved (28JAN2021)	Study Treatment	3	1	N

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	7	2	TC	N	Resolved (24FEB2021)	Study Treatment	4	2	N
6	3	2	TC	N	Resolved (20FEB2021)	Study Treatment	4	2	N
7	2	2	N	N	Resolved (19FEB2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15OCT2020	
Completed	VACCINATION	04DEC2020	
Completed	REPEAT SCREENING 1	27JAN2021	

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
After the data cutoff date of 13 Mar 2021 (with database snapshot taken on 25 Mar 2021), it was determined that Subject C4591001 1254 12541189 did not withdraw from the study because of the headache and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	74	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.5 cm	102.2 kg	36.4 kg/m2	22SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	1950	Present
Seasonal allergies (molds and spores)	Seasonal allergy	1950	Present
Tubal ligation	Female sterilisation	1974	Past
Sulfa allergy (hives)	Urticaria	1980	Present
Skin biopsy (benign)	Biopsy skin normal	1985	Past
Penicillin allergy (hives)	Urticaria	2000	Present
Amoxicillin allergy (hives)	Urticaria	2000	Present
Osteoarthritis	Osteoarthritis	2010	Present
Latex allergy	Rubber sensitivity	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Pre-diabetes elevated HgbA1C	Glucose tolerance impaired	2011	Present
Meningioma (asymptomatic, stable, no treatment plans)	Meningioma	2015	Present
Acupuncture	Acupuncture	NOV2015	Past
Inner ear pain 14d post shingles vaccine	Ear pain	NOV2015	Past
Tinnitus 14d post shingles vaccine	Tinnitus	NOV2015	Past
Vertigo 14d post shingles vaccine	Vertigo	NOV2015	Past
Vitiligo	Vitiligo	2016	Present
Breast biopsy (benign)	Biopsy breast normal	2018	Past
Eczema	Eczema	MAR2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22SEP2020 (1)	14:50
3	BNT162b2	03MAR2021 (163)	10:14

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Cheilitis	Cheilitis	07OCT2020 (16)		09NOV2020 (49)	
2	GASTR	Dry mouth	Dry mouth	07OCT2020 (16)		ONGOING	
3	NERV	Dysgeusia	Dysgeusia	07OCT2020 (16)		13NOV2020 (53)	

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
4	SKIN	Eczema	Worsening eczema	07OCT2020 (16)		ONGOING	
5	NERV	Parosmia	Hyperosmia	07OCT2020 (16)		13NOV2020 (53)	
6	SKIN	Pruritus	Pruritus, abdomen	07OCT2020 (16)		ONGOING	
7	SKIN	Rash maculo-papular	Rash maculo-papular, abdomen	07OCT2020 (16)		ONGOING	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	34	2	TC	N	Resolved (09NOV2020)	Study Treatment	1	16	N
2		2	P	N	Yes	Study Treatment	1	16	Y
3	38	1	N	N	Resolved (13NOV2020)	Study Treatment	1	16	N
4		2	P	N	Yes	Study Treatment	1	16	Y
5	38	1	N	N	Resolved (13NOV2020)	Study Treatment	1	16	N
6		2	TCN/P	N	Yes	Study Treatment	1	16	Y
7		1	TCN/P	N	Yes	Study Treatment	1	16	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22SEP2020	
Withdrawn	VACCINATION	14OCT2020	ADVERSE EVENT
Completed	REPEAT SCREENING 1	03MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1264 12641195, a 74-year-old black or African American female with a pertinent medical history of asthma and seasonal allergy (molds and spores; both since 1950), sulfa allergy (hives) (since 1980), amoxicillin allergy (hives) and penicillin allergy (hives) (both since 2000), latex allergy (since 2010), and eczema (since Mar 2018), received Dose 1 on 22 Sep 2020. The subject developed dry mouth, worsening of eczema, pruritus (abdomen), and maculopapular rash (abdomen) on 07 Oct 2020, 15 days after receiving Dose 1. On 07 Oct 2020 (Day 16), the subject also experienced cheilitis, dysgeusia, and parosmia. The cheilitis resolved on 09 Nov 2020 (Day 49) and the dysgeusia and parosmia resolved on 13 Nov 2020 (Day 53). The subject was discontinued from the study intervention on 14 Oct 2020 because of the dry mouth, worsening of eczema, pruritus, and maculopapular rash, which were ongoing at the time of the last available report. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 03 Mar 2021 (Day 163) and remains in the study. In the opinion of the investigator, there was a reasonable possibility that the dry mouth, worsening of eczema, pruritus, and maculopapular rash were related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	91.5 kg	28.9 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	05JAN2011	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	05JUN2011	Present
Chronic Deep Vein Thrombosis of bilateral legs	Deep vein thrombosis	06JUL2011	Present
Factor V Leiden Mutation, heterozygous	Factor V Leiden mutation	06JUL2011	Present
Hyperlipidemia	Hyperlipidaemia	06JUL2011	Present
Diabetes Mellitus 2	Type 2 diabetes mellitus	06JUL2011	Present
Spinal stenosis of lumbar spine with neurogenic claudication	Lumbar spinal stenosis	28JUL2011	Present
Erectile dysfunction	Erectile dysfunction	21NOV2016	Present
Peripheral neuropathy	Neuropathy peripheral	21NOV2016	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Actinic keratosis	Actinic keratosis	20SEP2017	Present
Insomnia	Insomnia	20SEP2017	Present
Anxiety	Anxiety	18DEC2017	Present
Lumbar radiculopathy	Lumbar radiculopathy	11MAY2018	Present
Arthritis of bilateral hips	Arthritis	27FEB2019	Present
Osteoarthritis of right knee	Osteoarthritis	27FEB2019	Present
Chronic pain syndrome	Pain	07MAR2019	Present
Allergy to Tramadol	Drug hypersensitivity	30MAY2019	Present
Genital Herpes Simplex	Genital herpes simplex	03APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	11:00

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Pulmonary embolism	Pulmonary embolism	23SEP2020 (21)		ONGOING		

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC/P	Y	Yes	NOT RELATED/OTHER: Factor V Leiden Mutation	1	21	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	03SEP2020	
Withdrawn	VACCINATION	02NOV2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	12JAN2021	WITHDRAWAL BY SUBJECT

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Narrative Comment
Subject C4591001 1270 12701057, a 65-year-old white male with a pertinent medical history of deep vein thrombosis (DVT; bilateral legs), factor V Leiden mutation, hyperlipidemia, and type 2 diabetes mellitus (all since 06 Jul 2011), received Dose 1 on 03 Sep 2020. The subject was diagnosed with a pulmonary embolism on 23 Sep 2020, 20 days after receiving Dose 1. Concomitant medications included albuterol (since 30 Mar 2015) for asthma, metformin (since 25 Dec 2015) for type 2 diabetes mellitus, dabigatran etexilate mesylate (from 25 Jul 2018 to 25 Sep 2020) for recurrent DVT, lovastatin (since 30 Aug 2019) for hyperlipidemia, acyclovir (since 03 Apr 2020) for genital herpes simplex, famotidine (since 03 Apr 2020) for gastroesophageal reflux disease, and ciclesonide (since 20 Aug 2020) for asthma. On 24 Sep 2020 (Day 22), the subject presented to the emergency department (ED) because of shortness of breath and cough starting on 04 Sep 2020 (Day 2) and chest tightness since 23 Sep 2020 (Day 21). The subject thought these symptoms were related to the smoke in the air and his inhalers were not helping. The SARS-CoV-2 test result was negative and the troponin I level was <0.02 ng/mL (normal range [NR]: 0.00-0.04 ng/mL). The subject received an albuterol inhaler once, acetylsalicylic acid 325 mg once orally, and normal saline bolus once intravenously. On 24 Sep 2020 (Day 22), he went home against medical advice, as he was admitted to the COVID-19 area of the emergency room. After he was back home, the symptoms improved but were still present; therefore, the subject returned to the ED on 25 Sep 2020 (Day 23). A computed tomography angiogram of the chest performed on 25 Sep 2020 (Day 23) was positive for acute pulmonary embolism, which was reported to be life-threatening and medically significant. On 25 Sep 2020 (Day 23), troponin I was <0.02 ng/mL, prothrombin time (PT) was 15.5 seconds (NR: 11.7-14.3 seconds), and international normalized ratio (INR) was 1.3 (NR: 2.0-3.0). The subject discontinued treatment with dabigatran etexilate mesylate and received enoxaparin 80 mg subcutaneously. He was discharged home on the same day (Day 23) in stable condition with a prescription for enoxaparin and warfarin and was referred to hematology/oncology. The subject continued to experience shortness of breath since 26 Sep 2020 (Day 24) and chest tightness since 27 Sep 2020 (Day 25). He was advised to postpone travel for 6 weeks, continue anticoagulant therapy with enoxaparin and warfarin, and monitor PT/INR values. On 29 Sep 2020 (Day 27), the PT was 21.7 seconds and the INR was 2.0. On 01 Oct 2020 (Day 29), the PT was 23.6 seconds and the INR was in therapeutic range at 2.2, and the subject was advised to discontinue treatment with enoxaparin and continue warfarin. He continued to have shortness of breath, fatigue, and mild cough on 02 Oct 2020 (Day 30). On 05 Oct 2020 (Day 33), a repeat SARS-CoV-2 NAAT result was negative; the PT was 33.2 seconds and the INR was above therapeutic range at 3.3. On 09 Oct 2020 (Day 37), the PT was 32.9 seconds and the INR was 3.3, and warfarin doses were titrated. On 15 Oct 2020 (Day 43), the INR was in therapeutic range (value not reported), and a trial weekly dose of warfarin was recommended. On 21 Oct 2020 (Day 49), the PT was 22.6 seconds and the INR was in therapeutic range at 2.1. On 28 Oct 2020 (Day 56), the PT was 19.9 seconds and the INR was subtherapeutic at 1.8, and the subject was instructed to increase the dose of warfarin and recheck the INR in 1 week. The subject was discontinued from the study intervention on 02 Nov 2020 because of the pulmonary embolism, which was ongoing at the time of the last available report. The subject requested withdrawal from the study on 12 Jan 2021. In the opinion of the investigator, there was no reasonable possibility that the pulmonary embolism was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to factor V Leiden mutation. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	29	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	77.9 kg	27.9 kg/m2	25SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25SEP2020 (1)	16:20

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	25SEP2020 (1)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			P	N	Yes	NOT RELATED/OTHER: not applicable	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
Withdrawn	VACCINATION	15OCT2020	PREGNANCY
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	11NOV2020	WITHDRAWAL BY SUBJECT

Narrative Comment

Subject C4591001 4444 44441979, a 29-year-old white female with an obstetrical history of 1 previous pregnancy that resulted in a live birth via a cesarean section because of polyhydramnios, received Dose 1 on 25 Sep 2020. The subject's pregnancy test was positive on 09 Oct 2020 (Day 15) and she had an exposure during pregnancy on 25 Sep 2020, on the same day as Dose 1.

On 09 Oct 2020 (Day 15), the subject informed the site that she had a positive urine pregnancy test that day. The first day of her last menstrual period was 05 Sep 2020 (Day -20) and the estimated date of conception was 05 Sep 2020 (Day -20). The gestational age at the time of initial exposure was first trimester. The subject smoked (10 cigarettes per day); however, she did not drink alcohol or use illicit drugs during this pregnancy. Her partner smoked (2 cigarettes per day); however, he did not drink alcohol or use illicit drugs.

The subject was discontinued from the study intervention on 15 Oct 2020 because of the exposure during pregnancy, and she decided to withdraw from the study on 11 Nov 2020.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	68 kg	25 kg/m2	27SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Panic Attacks	Panic attack	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27SEP2020 (1)	18:15

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	PSYCH	Panic attack	Worsening of panic attacks	15OCT2020 (19)	10:00	ONGOING			3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	P/W	N	Yes	NOT RELATED/OTHER: Basic psychiatric pathology (panic attacks)	1	19	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27SEP2020	
Withdrawn	VACCINATION	02NOV2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	02NOV2020	ADVERSE EVENT

Narrative Comment

Subject C4591001 4444 44442319, a 41-year-old white male with a pertinent medical history of panic attacks (since 2015), received Dose 1 on 27 Sep 2020. The subject reported worsening of panic attacks on 15 Oct 2020, 18 days after receiving Dose 1.

The subject was withdrawn from the study on 02 Nov 2020 because of the worsening of panic attacks, which was ongoing at the time of withdrawal.

In the opinion of the investigator, there was no reasonable possibility that the worsening of panic attacks was related to the study intervention, but rather it was related to a medical history of panic attacks.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	102 kg	33.3 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Prostate Cancer	Prostate cancer	1988	Past
Sleep Apnea	Sleep apnoea syndrome	1990	Present
Chronic Myeloid Leukemia	Chronic myeloid leukaemia	1991	Present
Hypertension	Hypertension	2000	Present
Elevated Lipids	Lipids increased	2019	Present
chronic kidney disease, mild	Chronic kidney disease	AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	13:30
2	Placebo	21SEP2020 (20)	10:13
3	BNT162b2	28JAN2021 (149)	15:55
4	BNT162b2	19FEB2021 (171)	10:22

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	IMMUN	Anaphylactic shock	anaphylactic shock	09OCT2020 (38)		09OCT2020 (38)		1	4
2	INJ&P	Arthropod bite	ant bite, left ankle	09OCT2020 (38)	15:00	10OCT2020 (39)		2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (09OCT2020)	NOT RELATED/OTHER: anaphylactic shock to ant bite	2	19	Y
2	N	N	Resolved (10OCT2020)	NOT RELATED/OTHER: NA	2	19	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	19OCT2020	
Completed	REPEAT SCREENING 1	28JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1090 10901300, a 68-year-old white male with a pertinent medical history of sleep apnea syndrome (since 1990), chronic myeloid leukemia (since 1991), hypertension (since 2000), and chronic kidney disease (since Aug 2019), received Dose 1 on 02 Sep 2020 and Dose 2 on 21 Sep 2020 (Day 20). The subject was diagnosed with anaphylactic shock on 09 Oct 2020, 18 days after receiving Dose 2. Concomitant medications included lisinopril, hydrochlorothiazide, and amlodipine (all since 2010), all for hypertension; citalopram (since 2010) for depression; imatinib (since 2015) for chronic myeloid leukemia; and atorvastatin (since Aug 2019) for elevated lipids. On 09 Oct 2020 (Day 38), the subject went to an emergency room because of tongue and throat swelling in response to an ant bite on his left ankle. He reported a small red spot associated with itching for a short time, thought to be an ant bite. He was treated with epinephrine, intravenous prednisone, and diphenhydramine. The symptoms resolved 90 minutes after treatment; however, the subject was kept overnight for observation and monitored for 20 hours. The anaphylactic shock was considered resolved on 09 Oct 2020 (Day 38), and he was discharged from the hospital on 10 Oct 2020 (Day 39). He continued to receive prednisone until 15 Oct 2020 (Day 44). The anaphylactic shock was considered medically significant and life-threatening by the investigator. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 28 Jan 2021 (Day 149) and 19 Feb 2021 (Day 171), respectively, and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the anaphylactic shock was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to the ant bite. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	40	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
183.79 cm	102.09 kg	30.2 kg/m2	31JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	01NOV1985	Present
Allergy to cats	Allergy to animal	01AUG1988	Present
Allergy to bees	Allergy to arthropod sting	01AUG1988	Present
allergy to penicillin	Drug hypersensitivity	01AUG1988	Present
Allergy to shrimp	Food allergy	01AUG1988	Present
Gout	Gout	01SEP2013	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31JUL2020 (1)	09:28
2	BNT162b2	20AUG2020 (21)	14:57

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	IMMUN	Anaphylactic reaction	Anaphylaxis Status Post Bee Sting	28AUG2020 (29)	14:00	28AUG2020 (29)	20:00	1	4	TC
2	INFEC	Infected bite	Cellulitis Status Post Bee Sting	30AUG2020 (31)	08:00	09SEP2020 (41)	08:00	11	2	TC
3	GENRL	Injection site pain	Injection Site Pain	31JUL2020 (1)	12:00	01AUG2020 (2)	08:00	2	1	N
4	GENRL	Injection site swelling	Injection Site Swelling	31JUL2020 (1)	12:00	01AUG2020 (2)	08:00	2	2	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (28AUG2020)	NOT RELATED/OTHER: Subject with history of allergy to bee venom	2	9	Y
2	N	Resolved (09SEP2020)	NOT RELATED/OTHER: Subject with history of allergy to bee venom	2	11	N
3	N	Resolved (01AUG2020)	Study Treatment	1	1	N
4	N	Resolved (01AUG2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31JUL2020	
Completed	VACCINATION	17SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1140 11401009, a 40-year-old white male with a pertinent medical history of asthma (since 01 Nov 1985) and multiple allergies, including to animals (cats) and arthropod stings (bees), drug hypersensitivity (penicillin), and food allergy (shrimp) (all since 01 Aug 1988), received Dose 1 on 31 Jul 2020 and Dose 2 on 20 Aug 2020 (Day 21). The subject was diagnosed with an anaphylactic reaction on 28 Aug 2020, 8 days after receiving Dose 2. Concomitant medications included salbutamol sulfate (since 01 Nov 1985) for asthma, montelukast sodium (since 01 Sep 2014) for asthma, and allopurinol (since 01 Sep 2014) for gout. On 17 Sep 2020, during his follow-up visit, the subject reported that he was stung by a bee on his second right toe on 28 Aug 2020 (Day 29), which resulted in a visit to the emergency department (ED). He initially attempted to treat the sting by applying ice and taking diphenhydramine. However, he developed a high-pitched voice and his epinephrine medication at home was expired. He was subsequently taken to the ED for anaphylaxis treatment. The anaphylactic reaction was considered life-threatening. While in the ED, the subject was noted to have stridor and was treated with epinephrine, famotidine, and methylprednisolone sodium succinate. His condition improved after treatment and the anaphylactic reaction resolved on the same day (Day 29), which resulted in the subject being discharged from the ED. On 30 Aug 2020 (Day 31), the subject developed an infected bite (cellulitis secondary to bee sting) and was treated with Keflex. No relevant tests were reported. On 09 Sep 2020 (Day 41), the infected bite resolved. In the opinion of the investigator, there was no reasonable possibility that the anaphylactic reaction was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a history of allergy to bee venom. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	22	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	71.7 kg	26 kg/m2	29OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	29OCT2020 (1)	15:52
2	Placebo	19NOV2020 (22)	13:31

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	18FEB2021 (113)	15:30
4	BNT162b2	11MAR2021 (134)	15:51

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Facial paralysis	Bell's Palsy	13MAR2021 (136)		ONGOING	
2	GENRL	Injection site pain	Injection site pain	19FEB2021 (114)	08:00	22FEB2021 (117)	08:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC	N	Yes	Study Treatment	4	3	Y
2	4	1	N	N	Resolved (22FEB2021)	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29OCT2020	
Completed	VACCINATION	17DEC2020	
Completed	REPEAT SCREENING 1	18FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1007 10071441, a 22-year-old white female with no reported medical history, received Dose 1 on 29 Oct 2020 and Dose 2 on 19 Nov 2020 (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 18 Feb 2021 (Day 113) and 11 Mar 2021 (Day 134), respectively, and remains in the study. The subject experienced facial paralysis on 13 Mar 2021, 2 days after receiving the second dose of BNT162b2. The facial paralysis was ongoing at the time of the last available report. In the opinion of the investigator, there was a reasonable possibility that the facial paralysis was related to BNT162b2.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	112.73 kg	36.6 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasectomy	Vasectomy	OCT1981	Past
Hypertension	Hypertension	SEP1989	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	16:09

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	15SEP2020 (20)	09:07
3	BNT162b2	08FEB2021 (166)	09:53
4	BNT162b2	01MAR2021 (187)	10:05

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Facial paralysis	bell's palsy	25DEC2020 (121)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	TC	N	Yes	NOT RELATED/OTHER: viral infection	2	102	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	15OCT2020	
Completed	REPEAT SCREENING 1	08FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1016 10161199, a 73-year-old white male with a pertinent medical history of hypertension (since Sep 1989), received Dose 1 on 27 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 20). On 25 Dec 2020, 101 days after receiving Dose 2, the subject experienced facial paralysis, which was ongoing at the time of the last available report. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 08 Feb 2021 (Day 166) and 01 Mar 2021 (Day 187), respectively, and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the facial paralysis was related to the study intervention, but rather it was related to a viral infection.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	100.1 kg	33.1 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
CHRONIC SINUS INFECTIONS	Chronic sinusitis	1960	Past
APPENDICITIS	Appendicitis	1965	Past
HYPERTENSION	Hypertension	2005	Present
TRANSIENT ISCHEMIC ATTACK	Transient ischaemic attack	2005	Past
ASTHMA	Asthma	2006	Present
BELL'S PALSY, RIGHT SIDE	Facial paralysis	2013	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	12:55
2	BNT162b2	08SEP2020 (23)	11:26

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	NERV	Facial paralysis	BELL'S PALSY, RIGHT SIDE	25OCT2020 (70)		23NOV2020 (99)		30	2	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Resolved (23NOV2020)	NOT RELATED/OTHER: REOCCURENCE OF PAST CONDITION	2	48	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINE	INFLUENZA VACCINE	11SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	06OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1077 10771049, a 62-year-old white male with a pertinent medical history of transient ischemic attack (in 2005), hypertension (since 2005), and facial paralysis (Bell's palsy, right side, in 2013), received Dose 1 on 17 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 23). The subject experienced recurrent facial paralysis (Bell's palsy, right side) on 25 Oct 2020, 47 days after receiving Dose 2. The facial paralysis resolved on 23 Nov 2020 (Day 99). In the opinion of the investigator, there was no reasonable possibility that the facial paralysis was related to the study intervention, but rather it was considered a reoccurrence of a past condition.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179.5 cm	92 kg	28.6 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type I Diabetes	Type 1 diabetes mellitus	1982	Present
Hernia Repair (L)	Hernia repair	2009	Past
Depression	Depression	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14AUG2020 (1)	13:04
2	BNT162b2	08SEP2020 (26)	11:49

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Facial paralysis	Bell's Palsy right face	10SEP2020 (28)		12SEP2020 (30)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	1	TC	N	Resolved (12SEP2020)	Study Treatment	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	12OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1090 10901187, a 53-year-old white male with a pertinent medical history of type 1 diabetes mellitus (since 1982), received Dose 1 on 14 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 26). The subject experienced facial paralysis (Bell's palsy, right side of the face) on 10 Sep 2020, 2 days after receiving Dose 2. The subject had no prior history of facial paralysis. He was treated with acyclovir 400 mg and prednisone 60 mg for 7 days (dates not specified) and the facial paralysis resolved on 12 Sep 2020 (Day 30). In the opinion of the investigator, there was a reasonable possibility that the facial paralysis was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1980	40	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.45 cm	102 kg	34.6 kg/m2	06OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hepatitis C	Hepatitis C	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	06OCT2020 (1)	10:06
2	BNT162b2	27OCT2020 (22)	09:00

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Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	CHILLS	27OCT2020 (22)	13:00	28OCT2020 (23)	06:00
2	NERV	Facial paralysis	Bell's Palsy	04NOV2020 (30)		10JAN2021 (97)	
3	NERV	Headache	HEADACHE	27OCT2020 (22)	13:00	28OCT2020 (23)	06:00
4	GASTR	Nausea	NAUSEA	27OCT2020 (22)	13:00	28OCT2020 (23)	06:00
5	GENRL	Pain	BODY ACHES	27OCT2020 (22)	13:00	28OCT2020 (23)	06:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (28OCT2020)	Study Treatment	2	1	N
2	68	2	TC	N	Resolved (10JAN2021)	Study Treatment	2	9	Y
3	2	1	N	N	Resolved (28OCT2020)	Study Treatment	2	1	N
4	2	1	N	N	Resolved (28OCT2020)	Study Treatment	2	1	N
5	2	1	N	N	Resolved (28OCT2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06OCT2020	
Completed	VACCINATION	24NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1134 11341378, a 40-year-old white male with a pertinent medical history of hepatitis C (since 2018), received Dose 1 on 06 Oct 2020 and Dose 2 on 27 Oct 2020 (Day 22). The subject experienced facial paralysis on 04 Nov 2020, 8 days after receiving Dose 2. The facial paralysis resolved on 10 Jan 2021 (Day 97). In the opinion of the investigator, there was a reasonable possibility that the facial paralysis was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	51	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	84.36 kg	30 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
vasectomy	Vasectomy	1987	Past
left rotator cuff repair	Rotator cuff repair	1989	Past
left rotator cuff tear	Rotator cuff syndrome	1989	Past
vasectomy reversal	Vasectomy reversal	2001	Past
left rotator cuff repair	Rotator cuff repair	2014	Past
left rotator cuff tear	Rotator cuff syndrome	2014	Past
nephrolithiasis	Nephrolithiasis	2015	Past
left rotator cuff repair	Rotator cuff repair	2015	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
left rotator cuff tears	Rotator cuff syndrome	2015	Past
allergy to guava	Food allergy	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03SEP2020 (1)	12:43
2	BNT162b2	22SEP2020 (20)	11:17

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Facial paralysis	Bell's palsy - L side	23FEB2021 (174)		ONGOING			2
2	GENRL	Pain	Body aches	23SEP2020 (21)		23SEP2020 (21)		1	1
3	INFEC	Viral infection	Viral infection	23FEB2021 (174)		ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Yes	NOT RELATED/OTHER: virus	2	155	Y

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	TC	N	Resolved (23SEP2020)	Study Treatment	2	2	N
3	TC	N	Yes	NOT RELATED/OTHER: microbial infection	2	155	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine, 0.5mL, IM	INFLUENZA VACCINE	13OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1152 11521316, a 51-year-old white male with no pertinent medical history, received Dose 1 on 03 Sep 2020 and Dose 2 on 22 Sep 2020 (Day 20). The subject was diagnosed with facial paralysis on 23 Feb 2021, 154 days after receiving Dose 2. The subject received influenza vaccine on 13 Oct 2020 (Day 41). On 23 Feb 2021 (Day 174), the subject had a viral infection and subsequently developed facial paralysis (Bell's palsy, left side). The facial paralysis and viral infection were ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the facial paralysis was related to the study intervention, but rather it was related to a virus.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	American Indian or Alaska Native	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	94.6 kg	32.7 kg/m2	12NOV2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12NOV2020 (1)	16:04
2	Placebo	03DEC2020 (22)	12:30

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	07JAN2021 (57)	12:35
4	BNT162b2	27JAN2021 (77)	10:45

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Facial paralysis	Bell's Palsy - Left	10JAN2021 (60)		21JAN2021 (71)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	12	1	TC/TCN	N	Resolved (21JAN2021)	Study Treatment	3	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12NOV2020	
Completed	VACCINATION	07JAN2021	
Completed	REPEAT SCREENING 1	07JAN2021	
Completed	OPEN LABEL TREATMENT	25FEB2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1218 12181015, a 34-year-old American Indian or Alaska native female with no reported medical history, received Dose 1 on 12 Nov 2020 and Dose 2 on 03 Dec 2020 (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 07 Jan 2021 (Day 57). She experienced facial paralysis (Bell's palsy, left side) on 10 Jan 2021, 3 days after receiving the first dose of BNT162b2. The facial paralysis resolved on 21 Jan 2021, 14 days after receiving the first dose of BNT162b2. The subject received the second dose of BNT162b2 on 27 Jan 2021 (Day 77) and remains in the study. In the opinion of the investigator, there was a reasonable possibility that the facial paralysis was related to BNT162b2.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161 cm	82.55 kg	31.8 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Palpitations	Palpitations	01JAN2008	Present
Breast Cancer	Breast cancer	01MAR2012	Past
Acoustic Neuroma	Acoustic neuroma	01NOV2013	Past
Arterial Hypertension	Hypertension	01JAN2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	20:45
2	Placebo	15SEP2020 (23)	12:48
3	BNT162b2	21JAN2021 (151)	14:25
4	BNT162b2	12FEB2021 (173)	14:51

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Facial paresis	right peripheral facial hemiparesis	16OCT2020 (54)	08:00	30OCT2020 (68)	20:00	15

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (30OCT2020)	NOT RELATED/OTHER: Unknown	2	32	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	19OCT2020	
Completed	REPEAT SCREENING 1	21JAN2021	
Completed	OPEN LABEL TREATMENT	12MAR2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313755, a 71-year-old white female with a pertinent medical history of breast cancer (on 01 Mar 2012), acoustic neuroma (on 01 Nov 2013), and hypertension (since 01 Jan 2015), received Dose 1 on 24 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 23). The subject experienced facial paresis (right peripheral facial hemiparesis) on 16 Oct 2020, 31 days after receiving Dose 2. The facial paresis resolved on 30 Oct 2020 (Day 68). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 21 Jan 2021 (Day 151) and 12 Feb 2021 (Day 173), and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the facial paresis was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2001	19	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	85 kg	34.5 kg/m2	09OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bells Palsy Left facial hemipareses	Facial paralysis	2011	Past
Bells Palsy Left facial hemipareses	Facial paralysis	2014	Past
Bells Palsy Left facial hemipareses	Facial paralysis	FEB2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09OCT2020 (1)	09:53
2	Placebo	29OCT2020 (21)	10:48
3	BNT162b2	03FEB2021 (118)	11:12

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	NERV	Facial paralysis	Recurrence of Left Bells Palsy Left facial hemipareses	11FEB2021 (126)		ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			2	TC	N	Yes	Study Treatment	3	9	Y

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Prednisone	PREDNISONE	11FEB2021	21FEB2021	ORAL

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09OCT2020	
Completed	VACCINATION	26NOV2020	
Completed	REPEAT SCREENING 1	03FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1247 12471244, a 19-year-old multiracial female with a pertinent history of facial paralysis (Bell's palsy left facial hemiparesis in 2011, 2014, and Feb 2018), received Dose 1 on 09 Oct 2020 and Dose 2 on 29 Oct 2020 (Day 21). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 03 Feb 2021 (Day 118) and remains in the study. On 11 Feb 2021 (Day 126), 8 days after receiving the first dose of BNT162b2, the subject had recurrent facial paralysis (Bell's palsy left facial hemiparesis). The subject received oral prednisone (from 11 Feb 2021 to 21 Feb 2021). The facial paralysis was ongoing at the time of the last available report. In the opinion of the investigator, there was a reasonable possibility that the facial paralysis was related to BNT162b2.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	70	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
181 cm	119 kg	36.3 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
depression	Depression	01MAY2015	Present
Hypercholesterolemia	Hypercholesterolaemia	01JUN2016	Present
arterial hypertension	Hypertension	01JUN2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25SEP2020 (1)	17:30
2	BNT162b2	09DEC2020 (76)	17:59

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Facial paralysis	Left peripheral facial palsy	31OCT2020 (37)	08:00	20NOV2020 (57)	08:00	21

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/TCN	N	Resolved (20NOV2020)	NOT RELATED/OTHER: Unknown	1	37	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
Completed	VACCINATION	02MAR2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 4444 44442012, a 70-year-old white male with a pertinent medical history of hypertension and hypercholesterolemia (both since 01 Jun 2016), received Dose 1 on 25 Sep 2020 and Dose 2 on 09 Dec 2020 (Day 76). The subject experienced facial paralysis (left peripheral facial palsy) on 31 Oct 2020, 36 days after receiving Dose 1. The facial paralysis resolved on 20 Nov 2020 (Day 57). In the opinion of the investigator, there was no reasonable possibility that the facial paralysis was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	52	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	76.82 kg	24.6 kg/m2	05JUN2020 (-12)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Penicillin Allergy	Drug hypersensitivity	1972	Present
Elevated Cholesterol	Blood cholesterol increased	2014	Present
hernia Injury	Hernia	2017	Past
Hernia Surgery	Hernia repair	2017	Past
Chronic Lower Back Pain	Back pain	2018	Present
Chronic Groin Pain	Groin pain	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17JUN2020 (1)	11:24
2	BNT162b2	08JUL2020 (22)	09:50

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	appendicitis	19SEP2020 (95)		23SEP2020 (99)		5

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (23SEP2020)	NOT RELATED/OTHER: appendicitis	2	74	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05JUN2020	
Completed	VACCINATION	11AUG2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1003 10031038, a 52-year-old white male with a pertinent medical history of drug hypersensitivity (penicillin allergy since 1972), blood cholesterol increased (since 2014), hernia and hernia repair (both in 2017), and back pain and groin pain (both since 2018), received Dose 1 on 17 Jun 2020 and Dose 2 on 08 Jul 2020 (Day 22).

The subject presented to an emergency room with intolerable abdominal pain. He was diagnosed with uncomplicated appendicitis on 19 Sep 2020, 73 days after receiving Dose 2. He was hospitalized on 19 Sep 2020 (Day 95). He tested negative for COVID-19 on admission and underwent a laparoscopic appendectomy. No pathology report was available for the appendectomy. The subject was treated with antibiotics and the appendicitis resolved on 23 Sep 2020 (Day 99). On an unspecified date, the subject was discharged from the hospital with pain medications, including ibuprofen and paracetamol.

In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	77	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	75.82 kg	28.6 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Postmenopausal	Postmenopause	1994	Present
Dilation and Curettage	Uterine dilation and curettage	1998	Past
Uterine Bleeding	Uterine haemorrhage	1998	Past
Facelift	Face lift	2001	Past
Insomnia	Insomnia	2015	Present
Overactive Bladder	Hypertonic bladder	2018	Present
Shingles	Herpes zoster	01APR2020	Past
Post Herpetic Neuralgia	Post herpetic neuralgia	10APR2020	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	13AUG2020 (1)	16:47
2	Placebo	31AUG2020 (19)	14:13
3	BNT162b2	18JAN2021 (159)	15:01
4	BNT162b2	08FEB2021 (180)	13:30

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	INFEC	Appendicitis perforated	Perforated Appendicitis	12SEP2020 (31)	08:00	15SEP2020 (34)		4	3
2	INFEC	Peritonitis	Feculant Peritonitis	14SEP2020 (33)		18SEP2020 (37)		5	3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN	Y	Resolved (15SEP2020)	NOT RELATED/OTHER: Appendicitis	2	13	Y
2	TC/TCN	Y	Resolved (18SEP2020)	NOT RELATED/OTHER: Perforated Appendicitis	2	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	01OCT2020	
Completed	REPEAT SCREENING 1	18JAN2021	
Completed	OPEN LABEL TREATMENT	08MAR2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1011 10111029, a 77-year-old white female with no pertinent medical history, received Dose 1 on 13 Aug 2020 and Dose 2 on 31 Aug 2020 (Day 19). The subject was diagnosed with perforated appendicitis on 12 Sep 2020, 12 days after receiving Dose 2, and peritonitis on 14 Sep 2020, 14 days after receiving Dose 2. Concomitant medications included mirabegron (since 2019) for overactive bladder and pregabalin (since 10 Apr 2020) for postherpetic neuralgia. On 12 Sep 2020 (Day 31), the subject experienced abdominal pain and subjective fever. On 14 Sep 2020 (Day 33), she presented to the emergency room with right lower quadrant pain and was hospitalized. She underwent a laparoscopic appendectomy on the same day and was found to have feculent peritonitis. A surgical drain was placed, and she was treated with intravenous antibiotics. On 14 Sep 2020 (Day 33), a SARS-CoV-2 nasal swab test was negative. On 15 Sep 2020 (Day 34), the perforated appendicitis was considered resolved. On 17 Sep 2020 (Day 36), the subject had diarrhea, and a Clostridium test was negative. The subject was discharged from the hospital on 17 Sep 2020 (Day 36) with the following medications: metronidazole 500 mg 3 times a day and ceftriaxone sodium for 9 days following discharge, along with acetaminophen 650 mg 4 times a day, cefuroxime 500 mg twice a day, Lactobacillus acidophilus 1 capsule once daily, tramadol 50 mg as needed (PRN), and zolpidem 5 mg at bedtime PRN. On 18 Sep 2020 (Day 37), the peritonitis resolved. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 18 Jan 2021 (Day 159) and 08 Feb 2021 (Day 180), respectively, and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the perforated appendicitis and peritonitis were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	35	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	78.82 kg	24.9 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1995	Present
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2013	Present
Cholecystectomy	Cholecystectomy	2016	Past
Cholecystitis	Cholecystitis	2016	Past
Hyperlipidemia	Hyperlipidaemia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03AUG2020 (1)	13:05
2	Placebo	24AUG2020 (22)	09:54
3	BNT162b2	19JAN2021 (170)	10:39
4	BNT162b2	09FEB2021 (191)	10:34

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Appendicitis	Appendicitis	06JAN2021 (157)	10:00	08JAN2021 (159)	14:00	3	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (08JAN2021)	NOT RELATED/OTHER: appendicitis; cause unknown	2	136	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	25SEP2020	
Completed	REPEAT SCREENING 1	19JAN2021	
Completed	OPEN LABEL TREATMENT	10MAR2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1018 10181031, a 35-year-old white male with a pertinent medical history of seasonal allergy (since 1995), cholecystectomy and cholecystitis (in 2016), and hyperlipidemia (since 2019), received Dose 1 on 03 Aug 2020 and Dose 2 on 24 Aug 2020 (Day 22). The subject was diagnosed with appendicitis on 06 Jan 2021, 135 days after receiving Dose 2. On 06 Jan 2021 (Day 157), the subject had right-sided abdominal pain. On 07 Jan 2021 (Day 158), the subject visited an urgent care facility for worsening of the pain. A computed tomography scan without contrast showed an enlarged appendix. He was referred to the hospital emergency room. He was admitted for appendicitis and his appendix was removed on the same day (Day 158). The appendicitis was considered life-threatening. On 08 Jan 2021 (Day 159), the appendicitis resolved. On an unknown date, the subject was discharged from the hospital. On 13 Jan 2021 (Day 164), during follow-up, the subject was told that he was "fine." In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 19 Jan 2021 (Day 170) and 09 Feb 2021 (Day 191), respectively, and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.8 cm	68.8 kg	22.8 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 2 diabetes	Type 2 diabetes mellitus	2005	Present
Diabetic neuropathy	Diabetic neuropathy	FEB2005	Present
Hyperlipidemia	Hyperlipidaemia	2010	Present
Hypertension	Hypertension	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	13:30
2	BNT162b2	21SEP2020 (22)	12:00

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis perforated	Perforated appendicitis	31AUG2020 (1)	19:00	16SEP2020 (17)		17
2	GENRL	Fatigue	Fatigue	21SEP2020 (22)	16:00	21SEP2020 (22)	20:00	1
3	GENRL	Injection site pain	Injection Site Pain	31AUG2020 (1)	18:00	03SEP2020 (4)	08:00	4
4	GENRL	Injection site pain	Injection site pain	22SEP2020 (23)	08:00	24SEP2020 (25)	08:00	3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (16SEP2020)	NOT RELATED/OTHER: bacterial infection	1	1	Y
2	1	N	N	Resolved (21SEP2020)	Study Treatment	2	1	N
3	1	N	N	Resolved (03SEP2020)	Study Treatment	1	1	N
4	1	N	N	Resolved (24SEP2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu Vaccine	INFLUENZA VACCINE	30OCT2020
Shingrix Dose 1	VARICELLA ZOSTER VACCINE RGE (CHO)	19DEC2020
Shingrix Dose 2	VARICELLA ZOSTER VACCINE RGE (CHO)	19JAN2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1055 10551153, a 63-year-old Asian male with a pertinent medical history of type 2 diabetes mellitus (since 2005), hypertension (since 2010), and gastroesophageal reflux disease (since 29 Aug 2020), received Dose 1 on 31 Aug 2020 and Dose 2 on 21 Sep 2020 (Day 22). The subject was diagnosed with perforated appendicitis on 31 Aug 2020, approximately 5 hours after receiving Dose 1. Concomitant medications included atorvastatin (since 2010) for hyperlipidemia; acetylsalicylic acid (since 2010) as prophylaxis; losartan (since 2010) for hypertension; liraglutide (since 2010), metformin hydrochloride/sitagliptin (since 2015), and human insulin (since 2017), all for type 2 diabetes; and simethicone (since 29 Aug 2020) for gastroesophageal reflux disease. On 31 Aug 2020 (Day 1), in the evening following Dose 1, the subject presented to the emergency room (ER) with abdominal pain and fever of 101.4 F°. A COVID-19 test was negative. An abdominal computed tomography scan revealed a perforated appendix (complication of appendicitis) and the subject was hospitalized. He was treated with intravenous (IV) piperacillin sodium/tazobactam sodium and a single dose of IV metronidazole. On 01 Sep 2020 (Day 2), the subject underwent a laparoscopic appendectomy without complications. Surgical pathology results revealed acute appendicitis and gross features consistent with a perforated appendix. On 03 Sep 2020 (Day 4), the subject was discharged on oral amoxicillin/clavulanic acid for 2 weeks. On 16 Sep 2020 (Day 17), the perforated appendicitis resolved. In the opinion of the investigator, there was no reasonable possibility that the perforated appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	50	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161 cm	66 kg	25.5 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Acne	Acne	1996	Present
Migraines	Migraine	1996	Present
Hysterectomy	Hysterectomy	2005	Past
Seasonal Allergies	Seasonal allergy	2017	Present
Insomnia	Insomnia	2018	Present
Neck Pain	Neck pain	JAN2019	Present
Lower back pain	Back pain	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	09:19
2	BNT162b2	10SEP2020 (23)	08:48

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	PSYCH	Anxiety	Anxiety	SEP2020 ()		ONGOING			2	TC	N
2	INFEC	Appendicitis	Appendicitis	09FEB2021 (175)		09FEB2021 (175)		1	3	TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: Pt believes anxiety began when her dog died.			N
2	Resolved (09FEB2021)	NOT RELATED/OTHER: Appendicitis	2	153	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	08OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1080 10801059, a 50-year-old white female with no pertinent medical history, received Dose 1 on 19 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 23). The subject was diagnosed with appendicitis on 09 Feb 2021, 152 days after receiving Dose 2. Concomitant medications included spironolactone (since 2015) for acne, rizatriptan (since 2015) for migraines, mometasone furoate (since 2017) for seasonal allergies, melatonin (since 2019) for insomnia, cyclobenzaprine (since 2019) for lower back pain, and venlafaxine hydrochloride (since 12 Oct 2020) for anxiety. On 09 Feb 2021 (Day 175), the subject presented to an emergency room with pain in the abdomen and an abdominal computed tomography scan performed on the same day showed appendicitis. Subsequently, the subject was hospitalized and underwent an appendectomy. A SARS-CoV-2 polymerase chain reaction test on the same day was negative. The appendicitis resolved on 09 Feb 2021 (Day 175) and the subject was discharged from the hospital on the next day (Day 176) with a prescription for oxycodone for pain management, which she took for 3 days. She visited her primary care physician on 15 Feb 2021 (Day 181) and a follow-up appointment with the surgeon was scheduled in Mar 2021. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	51	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.75 cm	72.82 kg	28.8 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma-Stable, No change within 6 weeks of screening	Asthma	1980	Present
Seasonal Allergies	Seasonal allergy	1980	Present
C-Section	Caesarean section	1991	Past
Bilateral Tubal Ligation	Female sterilisation	1991	Past
COPD	Chronic obstructive pulmonary disease	2018	Present

Reason(s) for Narrative: Appendicitis
Unique Subject ID: C4591001 1081 10811036; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 13AUG2020; Date of Last Dose: 03SEP2020

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	13AUG2020 (1)	15:09
2	BNT162b2	03SEP2020 (22)	15:38

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	BLOOD	Anaemia	Anemia	02NOV2020 (82)		ONGOING			2	N	N
2	INFEC	Appendicitis	Appendicitis	21AUG2020 (9)		23AUG2020 (11)		3	3	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: Unknown, no mention of cause/disease in med record	2	61	N
2	Resolved (23AUG2020)	NOT RELATED/OTHER: Acute Infection	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	01OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1081 10811036, a 51-year-old black or African American female with a pertinent medical history of asthma (since 1980), seasonal allergy (since 1980), cesarean section (in 1991), female sterilization (in 1991), and chronic obstructive pulmonary disease (since 2018), received Dose 1 on 13 Aug 2020 and Dose 2 on 03 Sep 2020 (Day 22). The subject was diagnosed with appendicitis on 21 Aug 2020, 8 days after receiving Dose 1. On 21 Aug 2020 (Day 9), the subject was hospitalized for an emergency appendectomy. After the appendectomy, she was treated with amoxicillin/clavulanic acid 875/125 mg orally (PO) daily for postappendectomy prophylaxis, ondansetron 4 mg PO as needed (PRN) for nausea, and oxycodone 5 mg PO PRN for pain (all from 21 Aug 2020 to 02 Sep 2020). On 23 Aug 2020 (Day 11), the appendicitis resolved and the subject was discharged from the hospital. On 24 Aug 2020 (Day 12), the pathology findings showed an appendix with mild focal inflammation. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.4 cm	87.1 kg	25.3 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
acne	Acne	1980	Present
dry skin	Dry skin	1980	Present
Myopia	Myopia	1980	Present
athletes foot	Tinea pedis	1980	Present
GERD	Gastrooesophageal reflux disease	2000	Present
Hemorrhoids	Haemorrhoids	2000	Present
Seasonal Allergies	Seasonal allergy	2000	Present
left foot 4th metatarsal fracture	Foot fracture	2004	Past
Vasectomy	Vasectomy	2007	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Colonoscopy	Colonoscopy	2013	Past
prostatitis	Prostatitis	OCT2017	Past
Colonoscopy	Colonoscopy	2019	Past
Biliary Hyperkinesis	Biliary tract disorder	MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12AUG2020 (1)	14:29
2	BNT162b2	02SEP2020 (22)	12:01

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	Appendicitis	20DEC2020 (131)		22DEC2020 (133)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (22DEC2020)	NOT RELATED/OTHER: Appendicitis	2	110	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	30SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1084 10841141, a 52-year-old white male with a pertinent medical history of gastroesophageal reflux disease (since 2000), colonoscopy (in 2013 and 2019), prostatitis (in Oct 2017), and biliary tract disorder (since May 2020), received Dose 1 on 12 Aug 2020 and Dose 2 on 02 Sep 2020 (Day 22). The subject was diagnosed with appendicitis on 20 Dec 2020, 109 days after receiving Dose 2. Concomitant medications included cetirizine hydrochloride (since 2000) for seasonal allergies and pantoprazole (since 2000) for gastroesophageal reflux disease. On 20 Dec 2020 (Day 131), the subject was hospitalized and a computed tomography scan of the abdomen and pelvis confirmed appendicitis. The subject underwent an appendectomy and was treated with intravenous (IV) iopamidol, IV piperacillin-tazobactam 3.375 g, and IV sodium chloride 20 mL. The subject was discharged from the hospital after 5 hours. On 22 Dec 2020 (Day 133), the appendicitis resolved. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.3 cm	87.5 kg	33.2 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
broken jaw repair surgery	Fracture treatment	1992	Past
Broken jaw	Jaw fracture	1992	Past
occasional migraines	Migraine	1995	Present
allergic rhinitis	Rhinitis allergic	2000	Present
Bilateral carpal tunnel syndrome	Carpal tunnel syndrome	2005	Past
Bilateral carpal tunnel release	Carpal tunnel decompression	2011	Past
menorrhagia	Menorrhagia	2015	Past
Reduction Mammoplasty (breast reduction)	Mammoplasty	DEC2018	Past
endometrial ablation	Endometrial ablation	DEC2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15SEP2020 (1)	10:48
2	BNT162b2	06OCT2020 (22)	09:32

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INFEC	Appendicitis	Appendicitis	21OCT2020 (37)		22OCT2020 (38)	05:55	2	4	TCN
2	GENRL	Chills	Chills	06OCT2020 (22)	21:30	07OCT2020 (23)	08:00	2	1	N
3	GENRL	Injection site pain	Injection Site Pain	06OCT2020 (22)	13:00	07OCT2020 (23)		2	1	N
4	GENRL	Injection site pain	soreness at injection site	16SEP2020 (2)		17SEP2020 (3)		2	1	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (22OCT2020)	NOT RELATED/OTHER: Inflammation of Appendix, Unknown Cause	2	16	Y
2	N	Resolved (07OCT2020)	Study Treatment	2	1	N
3	N	Resolved (07OCT2020)	Study Treatment	2	1	N
4	N	Resolved (17SEP2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	27OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15SEP2020	
Completed	VACCINATION	06NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1091 10911300, a 46-year-old white female with a pertinent medical history of endometrial ablation (in Dec 2019), received Dose 1 on 15 Sep 2020 and Dose 2 on 06 Oct 2020 (Day 22). The subject was diagnosed with appendicitis on 21 Oct 2020, 15 days after receiving Dose 2. Concomitant medications included cetirizine (since 2000) for allergic rhinitis and paracetamol (on 06 Oct 2020) for chills. On 21 Oct 2020 (Day 37), the subject experienced a rapid onset of right-sided lower abdominal pain and went to the emergency room. On 22 Oct 2020 (Day 38), a computed tomography scan of the abdomen and pelvis showed acute appendicitis without evidence of collection or perforation and scattered colonic diverticula without inflammatory changes. Laboratory tests showed a white blood cell count of 15 × 103/mm3 (normal range [NR]: 4.0-10.5 × 103/mm3), absolute neutrophils of 10.3 × 103/mm3 (NR: 2.0-7.3 × 103/mm3), and alanine aminotransferase of 58 U/µL (NR: 7-52 U/µL). The subject was not hospitalized, as all the hospital beds were full at the facility. She underwent a laparoscopic appendectomy without any complications and was discharged from the operating room with prescriptions for docusate and oxycodone/acetaminophen. Pathologic examination of the appendix revealed adhesions in attached portion of pink-yellow adipose tissue measuring 4.5 × 2.0 × 1.8 cm; staple line on the proximal margin. Sectioning of the appendix revealed hemorrhagic red-gray cut surface with the lumen diameter measuring to 0.4 cm and a wall thickness measuring up to 0.3 cm. On 22 Oct 2020 (Day 38), the appendicitis resolved. The appendicitis was considered medically significant by the investigator. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	27	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	90.91 kg	27.1 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
RECONSTRUCTIVE RIGHT EAR SURGERY	Otoplasty	01JAN2013	Past
SEASONAL ALLERGIES	Seasonal allergy	2015	Present
BILATERAL LASIK SURGERY	Keratomileusis	01JAN2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	13:15
2	BNT162b2	04SEP2020 (25)	14:18

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INFEC	Appendicitis	ACUTE APPENDICITIS	17AUG2020 (7)		02SEP2020 (23)		17	4	TC	Y
2	INFEC	Peritoneal abscess	Peritoneal Abscess	17AUG2020 (7)		02SEP2020 (23)		17	4	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (02SEP2020)	NOT RELATED/OTHER: ACUTE APPENDICITIS WITH PERITONEAL ABSCESS	1	7	Y
2	Resolved (02SEP2020)	NOT RELATED/OTHER: Acute appendicitis with peritoneal abscess	1	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	30SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091204, a 27-year-old white male with no pertinent medical history, received Dose 1 on 11 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 25). The subject was diagnosed with acute appendicitis and a peritoneal abscess on 17 Aug 2020, 6 days after receiving Dose 1. Concomitant medication included cetirizine hydrochloride (dates not reported) for allergies. On 17 Aug 2020 (Day 7), the subject was hospitalized for abdominal pain and diagnosed with acute appendicitis and a peritoneal abscess. He was treated with piperacillin/tazobactam 2.25 g intravenous piggyback every 6 hours (from 17 Aug 2020 to 22 Aug 2020) and acetaminophen/oxycodone 325/5 mg (from 21 Aug 2020 to 22 Aug 2020) for pain. Appendectomy was not indicated. A SARS-CoV-2 test was not performed. The subject was discharged from the hospital on 21 Aug 2020 (Day 11) on ciprofloxacin and metronidazole (from 22 Aug 2020 to 25 Aug 2020); he was treated with amoxicillin 500 mg orally twice a day (from 26 Aug 2020 to 02 Sep 2020). The acute appendicitis with peritoneal abscess resolved on 02 Sep 2020 (Day 23). The subject was instructed to delay the second dose of study vaccination until completion of antibiotic treatment. In the opinion of the investigator, there was no reasonable possibility that the acute appendicitis and peritoneal abscess were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	62	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	59.91 kg	20 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
MIGRAINE HEADACHES	Migraine	01JAN1989	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	01JAN2005	Present
BREAST CANCER	Breast cancer	01JAN2012	Past
ANXIETY	Anxiety	01JAN2015	Present
DEPRESSION	Depression	01JAN2015	Present
HYSTERECTOMY	Hysterectomy	01JAN2019	Past
POSTMENOPAUSAL	Postmenopause	01JAN2019	Present
OSTEOPOROSIS	Osteoporosis	01JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	09:35
2	Placebo	09SEP2020 (20)	13:11
3	BNT162b2	27FEB2021 (191)	13:37

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Complicated appendicitis	Acute appendicitis with necrosis	30SEP2020 (41)	23:00	02OCT2020 (43)	11:00	3	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (02OCT2020)	NOT RELATED/OTHER: Infection of appendix	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	27FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091276, a 62-year-old white female with no pertinent medical history, received Dose 1 on 21 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 20). The subject was diagnosed with complicated appendicitis (acute appendicitis with necrosis) on 30 Sep 2020, 21 days after receiving Dose 2. Concomitant medications included atorvastatin (since 2010) for high cholesterol; levothyroxine sodium and liothyronine (both since 2015) for hypothyroidism; desvenlafaxine succinate and clonazepam (both since 2018) for anxiety; topiramate (since 2018) and zolmitriptan (since 08 Jan 2020), both for migraine; and ibandronate sodium (since Jan 2020) for osteoporosis. On 30 Sep 2020 (Day 41), the subject was hospitalized for appendicitis. She was treated with intravenous medications (unspecified) and underwent an appendectomy. Pathology findings revealed acute appendicitis with necrosis. On 01 Oct 2020 (Day 42), a SARS-CoV-2 nasopharyngeal swab test was negative. On 02 Oct 2020 (Day 43), the complicated appendicitis resolved and the subject was discharged from the hospital. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 27 Feb 2021 (Day 191) and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the complicated appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179 cm	93.7 kg	29.2 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
diabetes mellitus 2	Type 2 diabetes mellitus	JAN2018	Present
vasectomy	Vasectomy	NOV2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	17:45

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	22SEP2020 (22)	16:10
3	BNT162b2	15FEB2021 (168)	16:12
4	BNT162b2	09MAR2021 (190)	13:48

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	Acute Appendicitis	07DEC2020 (98)		10DEC2020 (101)		4
2	GASTR	Colitis ulcerative	Ulcerative Colitis	07DEC2020 (98)		ONGOING		
3	GASTR	Gastritis	Gastritis	07DEC2020 (98)		ONGOING		
4	GENRL	Injection site pain	Pain at site injection (left deltoid)	15FEB2021 (168)	23:30	16FEB2021 (169)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (10DEC2020)	NOT RELATED/OTHER: unknown	2	77	Y
2	2	TC	N	Yes	NOT RELATED/OTHER: Unknown	2	77	N
3	1	TC/TCN	N	Yes	NOT RELATED/OTHER: Unknown	2	77	N
4	1	N	N	Resolved (16FEB2021)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	20OCT2020	
Completed	REPEAT SCREENING 1	15FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1110 11101187, a 46-year-old white male with a pertinent medical history of type 2 diabetes mellitus (since Jan 2018), received Dose 1 on 01 Sep 2020 and Dose 2 on 22 Sep 2020 (Day 22). The subject was diagnosed with appendicitis on 07 Dec 2020, 76 days after receiving Dose 2. On 07 Dec 2020 (Day 98), the subject presented to the emergency room with the complaints of generalized weakness, fever, chills, and diffuse lower abdominal pain lateralizing to the right lower quadrant and was hospitalized with a diagnosis of acute appendicitis. He reported diarrhea for the last month after he had taken macrogol/potassium chloride/sodium bicarbonate/sodium chloride/sodium sulfate for a colon cleanse. On 07 Dec 2020 (Day 98), a urinalysis showed a red blood cell count of 13 per high-power field (HPF) (normal range [NR]: 0-2 per HPF) and presence of calcium oxalate crystals; an abdominal/pelvic computed tomography scan with intravenous contrast showed a normal-sized fluid-filled appendix and hepatic steatosis; a complete blood count was normal; and Clostridium difficile and SARS-CoV-2 tests were negative. On the same day (Day 98), the subject was also diagnosed with ulcerative colitis and gastritis (which were reported as nonserious adverse events). On 08 Dec 2020 (Day 99), the subject underwent a laparoscopic appendectomy and a sample was sent to the pathology department, but the results were not available. On 10 Dec 2020 (Day 101), the appendicitis was considered resolved and the subject was discharged on amoxicillin/clavulanic acid 500 mg orally (PO) every 8 hours, metformin 500 mg PO twice a day, and tramadol 50 mg every 6 hours as needed. The ulcerative colitis and gastritis were ongoing at the time of the last available report. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 15 Feb 2021 (Day 168) and 09 Mar 2021 (Day 190), respectively, and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156.21 cm	61.77 kg	25.3 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Headaches	Headache	1990	Present
Migraine Headaches	Migraine	1998	Present
History of Shingles	Herpes zoster	2006	Present
Drug Allergy: Z-pack	Drug hypersensitivity	2017	Present
Anxiety	Anxiety	2018	Present
Facial Acne	Acne	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18AUG2020 (1)	16:17
2	BNT162b2	09SEP2020 (23)	10:40

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Appendicitis	APPENDICITIS	15JAN2021 (151)	21:00	16JAN2021 (152)		2	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (16JAN2021)	NOT RELATED/OTHER: APPENDICITIS	2	129	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	16OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1128 11281123, a 38-year-old white female with a pertinent medical history of herpes zoster (since 2006), drug hypersensitivity (Z-pack; since 2017), and anxiety (since 2018), received Dose 1 on 18 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 23). The subject was diagnosed with appendicitis on 15 Jan 2021, 128 days after receiving Dose 2. Concomitant medications included ibuprofen (since 2000) for headaches, eletriptan hydrobromide (since 2008) for migraine headaches, citalopram (since 2018) for anxiety, spironolactone (since Jun 2020) for facial acne, and drospirenone (since Jun 2020) for contraception. On 15 Jan 2021 (Day 151), during a regular visit at the clinic, the subject reported that she had abdominal pain. The next day (16 Jan 2021 [Day 152]), she was hospitalized, where she was diagnosed with appendicitis and underwent an appendectomy. She received intravenous (IV) tramadol twice, IV morphine once, and anesthesia. On 16 Jan 2021 (Day 152), the appendicitis was considered resolved and the subject was discharged from the hospital. Pathology findings revealed acute appendicitis and periappendicitis. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1997	23	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	73.95 kg	22.1 kg/m2	08SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	08SEP2020 (1)	13:06
2	BNT162b2	29SEP2020 (22)	13:50

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	Acute Appendicitis	05DEC2020 (89)		06DEC2020 (90)		2
2	NERV	Headache	Headache	30SEP2020 (23)		01OCT2020 (24)		2
3	GENRL	Injection site pain	Injection site pain	30SEP2020 (23)		01OCT2020 (24)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	Y	Resolved (06DEC2020)	NOT RELATED/OTHER: Appendicitis	2	68	Y
2	2	N	N	Resolved (01OCT2020)	Study Treatment	2	2	N
3	2	N	N	Resolved (01OCT2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	02NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1142 11421202, a 23-year-old white male with no reported medical history, received Dose 1 on 08 Sep 2020 and Dose 2 on 29 Sep 2020 (Day 22). The subject was diagnosed with appendicitis on 05 Dec 2020, 67 days after receiving Dose 2.

On 05 Dec 2020 (Day 89), the subject presented to the emergency room with complaints of sudden onset of right groin pain and dysuria. On examination, he had abdominal tenderness in the right lower quadrant. A computed tomography scan of the abdomen/pelvis showed acute appendicitis and traces of free fluid; no free air or abscess was noted. Relevant laboratory test results showed an elevated white blood cell count of 14.93 × 103/mm3 (normal range [NR]: 4.20-10.70 × 103/mm3) and elevated absolute neutrophil count of 11.15 × 103/mm3 (NR: 1.99-6.95 × 103/mm3), and normal values for the following: granulocyte count of 0.06 × 103/mm3 (NR: 0.00-0.06 × 103/mm3), lymphocyte count of 2.60 × 103/mm3 (NR: 1.09-3.23 × 103/mm3), blood urea nitrogen of 19 mg/dL (NR: 7-23 mg/dL), and estimated glomerular filtration rate (non-African American) of 131.1 mL/min/1.73 m2 (NR not reported); urinalysis was also normal. A SARS-CoV-2 test was negative. The subject was admitted for a laparoscopic appendectomy on that same day (Day 89) and he tolerated the procedure well. The histology report showed pink-purple vermiform appendix with attached yellow lobulated mesoappendix. The appendix serosa had attached tan-white purulent exudate; the appendix was serially sectioned to reveal a patent lumen, ranging from pinpoint to 0.5 cm, containing bloody fecal material. The appendicitis resolved on 06 Dec 2020 (Day 90) and the subject was discharged from the hospital on the same day.

In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2000	19	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	63.18 kg	20.5 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
heart murmur	Cardiac murmur	2000	Past
depression	Depression	2016	Present
chronic ear infections	Ear infection	2018	Present
fribromyalgia	Fibromyalgia	2019	Present
gallbladder disease	Gallbladder disorder	2019	Past
generalized joint hyper-mobility syndrome	Hypermobility syndrome	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	14:31
2	Placebo	18SEP2020 (22)	11:26
3	BNT162b2	21JAN2021 (147)	12:47
4	BNT162b2	11FEB2021 (168)	13:10

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Appendicitis	appendicitis	04JAN2021 (130)		07JAN2021 (133)		4	3
2	MUSC	Arthralgia	Knee pain	08SEP2020 (12)		11SEP2020 (15)		4	2
3	MUSC	Joint swelling	Knee swelling	11SEP2020 (15)		11SEP2020 (15)		1	2
4	NERV	Headache	Headache	28AUG2020 (1)	14:35	28AUG2020 (1)		1	1
5	GENRL	Injection site pain	Injection site pain	28AUG2020 (1)	14:35	31AUG2020 (4)		4	2
6	EYE	Photophobia	Photophobia	28AUG2020 (1)	14:35	28AUG2020 (1)		1	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (07JAN2021)	NOT RELATED/OTHER: the event is related to the appendicitis	2	109	Y
2	N	N	Resolved (11SEP2020)	NOT RELATED/OTHER: twisted knee	1	12	N
3	N	N	Resolved (11SEP2020)	NOT RELATED/OTHER: twisted knee	1	15	N
4	N	N	Resolved (28AUG2020)	Study Treatment	1	1	N

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	N	N	Resolved (31AUG2020)	Study Treatment	1	1	N
6	N	N	Resolved (28AUG2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	05NOV2020	
Completed	REPEAT SCREENING 1	21JAN2021	
Completed	OPEN LABEL TREATMENT	11MAR2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1145 11451059, a 19-year-old white female with a pertinent medical history of cardiac murmur (in 2000); suicide attempt (in 2014); depression (since 2016); gallbladder disorder and cholecystectomy (both in 2019); fibromyalgia (since 2019); postural orthostatic tachycardia syndrome (POTS; since 21 Dec 2020); and chronic abdominal pain (since unknown date), received Dose 1 on 28 Aug 2020 and Dose 2 on 18 Sep 2020 (Day 22). The subject was diagnosed with appendicitis on 04 Jan 2021, 108 days after receiving Dose 2. Concomitant medications included ondansetron (since 2012) for nausea, ethinylestradiol/norethisterone acetate (since 2018) for contraception, mefenidramium metilsulfate (since 2019) for allergies, and baclofen (since 2020) for fibromyalgia. On 06 Jan 2021 (Day 132), the subject's mother notified the site that the subject was hospitalized on 04 Jan 2021 (Day 130) for appendicitis. On 03 Dec 2020 (Day 98), the subject was seen in the emergency department (ED) with symptoms of intermittent nausea, abdominal pain associated with constipation, and vomiting. Her laboratory test results showed a normal white blood cell count, and a computed tomography (CT) scan showed right lower quadrant mesenteric adenopathy (mesenteric adenitis). The gastrointestinal (GI) symptoms were related to gastroparesis; the GI physician diagnosed gastroparesis and prescribed linaclotide. The subject was discharged with a referral to the GI and cardiology divisions. Upper endoscopy and gastric emptying tests were scheduled in mid-January 2021. The subject developed diarrhea and stopped taking linaclotide. On 21 Dec 2020 (Day 116), the tilt test confirmed the diagnosis of POTS and the subject's abdominal pain worsened after the procedure. On 23 Dec 2020 (Day 118), she went back to ED because of abdominal pain and constipation. A CT imaging showed no evidence of acute obstruction or perforation. On 23 Dec 2020 (Day 118), a CT scan showed that the previously noted unremarkable mesenteric adenopathy (mesenteric adenitis) was resolved and her laboratory results were normal, except elevated neutrophils of 77.7% (normal range [NR]: 40%-70%) and decreased lymphocytes of 15.7% (NR: 24%-44%). The subject was prescribed a half dose of linaclotide and recommended to follow up with her GI physician the following week. On 04 Jan 2021 (Day 130), the subject experienced severe abdominal pain and went back to the ED. On examination, she had right lower quadrant pain and a positive Murphy's sign was noted. On the same day (Day 130), a CT scan was suggestive of early acute appendicitis and a mildly dilated appendix (9 mm) with mild periappendiceal inflammatory changes while the subject was standing. No abscess formation or perforations were noted. Laboratory tests showed no significant abnormalities and the subject remained afebrile. A COVID-19 test was negative. During hospitalization, the subject was treated with intravenous (IV) ceftriaxone 1 g/100 mL every 24 hours, IV metronidazole 500 mg/100 mL every 8 hours, IV ondansetron 4 mg/2 mL 1-time dose, oral (PO) acetaminophen 1000 mg every 6 hours as needed (PRN), PO tramadol 50 mg every 4 hours PRN, and PO polyethylene glycol 17 g PRN for constipation from 04 Jan 2021 (Day 130) to 05 Jan 2021 (Day 131). On 05 Jan 2021 (Day 131), the subject underwent laparoscopic appendectomy and was discharged from the hospital. On 06 Jan 2021 (Day 132), the subject required readmission to the hospital for monitoring and evaluation; she experienced nausea and vomiting that she was unable to control with ondansetron at home. She felt dizzy and weak. She reported having had a similar reaction in the past after a cholecystectomy in 2019. A repeat COVID-19 test was negative. During hospitalization, the subject was treated with PO acetaminophen 650 mg every 4 hours PRN, subcutaneous enoxaparin 40 mg every afternoon, ondansetron 4 mg every 6 hours PRN, PO sennosides 2 tablets PRN, and sodium chloride 0.9% infusion 100 mL/hour. It was reported that her symptoms were likely secondary to POTS syndrome. She was recommended to continue with IV saline infusion 2 times per week as an outpatient along with physical therapy (frequent

Narrative Comment
ambulation was also encouraged). The subject was referred to her GI physician again for further evaluation of GI symptoms. On 07 Jan 2021 (Day 133), the appendicitis resolved, and the subject was discharged on the same day. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 21 Jan 2021 (Day 147) and 11 Feb 2021 (Day 168), respectively, and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	31	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	62.6 kg	23.7 kg/m2	28AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	10:34
2	Placebo	18SEP2020 (22)	09:48

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	11FEB2021 (168)	13:14
4	BNT162b2	04MAR2021 (189)	12:58

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	appendicitis	11JAN2021 (137)		14JAN2021 (140)		4
2	NERV	Headache	headache	12FEB2021 (169)	08:00	13FEB2021 (170)	08:00	2
3	GENRL	Injection site pain	injection site pain	12FEB2021 (169)	08:00	13FEB2021 (170)	08:00	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/TCN	Y	Resolved (14JAN2021)	NOT RELATED/OTHER: infection	2	116	Y
2	2	TC	N	Resolved (13FEB2021)	Study Treatment	3	2	N
3	1	N	N	Resolved (13FEB2021)	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	19OCT2020	
Completed	REPEAT SCREENING 1	11FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1223 12231014, a 31-year-old white female with no reported medical history, received Dose 1 on 28 Aug 2020 and Dose 2 on 18 Sep 2020 (Day 22). The subject was diagnosed with appendicitis on 11 Jan 2021, 115 days after receiving Dose 2. The subject was on contraception with Mirena (levonorgestrel) intrauterine device (since 2018). On 12 Jan 2021 (Day 138), the subject presented to the emergency room (ER) with a complaint of a 1-day history of sharp, intermittent severe lower abdominal pain, which was associated with nausea, and 1 episode of syncope. She was noted to be hemodynamically stable. She had an elevated white blood cell count of 12,700 cells/µL (normal range: 4000-10,000 cells/µL). On the same day (Day 138), an abdominal ultrasound examination showed a noncompressible mildly prominent tip of the appendix indicative of early acute appendicitis; a transvaginal ultrasound examination was unremarkable; and a SARS-CoV-2 test was negative. The appendicitis was considered an important medical event by the investigator. The subject received ceftriaxone sodium and metronidazole for appendicitis; hydromorphone hydrochloride and morphine for appendicitis pain; and ondansetron for nausea. General surgery personnel were consulted. On 13 Jan 2021 (Day 139), a computed tomography (CT) scan of the abdomen/pelvis with intravenous and oral contrast was performed and the tip of the appendix appeared slightly dilated although not well visualized, and the base of the appendix was well visualized and was normal. Per the discharge summary, the subject's bladder was enlarged on the CT scan. She voided afterwards 800 mL with a pulmonary vascular resistance showing 300 mL. She had voided 5 hours prior to that. She then voided 400 mL a couple of hours later, and the postvoid residual was 134 mL. The subject's pain improved with treatment and, as the CT findings did not confirm appendicitis, a regular oral diet was pursued and she tolerated it well. She was educated on the signs of possible appendicitis, and the CT findings of her bladder were explained. On the same day (Day 139), she was discharged from the hospital and was instructed to follow up with her primary care physician as needed. The next day (14 Jan 2021), the subject again presented to the hospital ER with increased severe right lower quadrant pain. She also reported nausea. She was afebrile and hemodynamically stable. On physical examination, she was noted to have abdominal tenderness in the lower quadrant. She was seen by a surgeon and was scheduled for a laparoscopic appendectomy on 14 Jan 2021 (Day 140). She received morphine for appendicitis and ondansetron for nausea on 14 Jan 2021 (Day 140), and the appendicitis resolved on the same day. She also received ibuprofen for pain on 15 Jan 2021 (Day 141). Her pain improved with the treatment and she was discharged from the hospital on 15 Jan 2021 (Day 141) on oxycodone for pain, which she took on 16 Jan 2021 (Day 142). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 11 Feb 2021 (Day 168) and 04 Mar 2021 (Day 189), respectively, and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178.3 cm	102 kg	32.1 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
obesity	Obesity	2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	10:46
2	BNT162b2	10SEP2020 (23)	10:26

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INFEC	Appendicitis	Appendicitis	01OCT2020 (44)		03OCT2020 (46)		3

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC/TCN	Y	Resolved (03OCT2020)	NOT RELATED/OTHER: cause: alimentary	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	26OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261282, a 35-year-old white male with a pertinent medical history of obesity (since 2012), received Dose 1 on 19 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 23). The subject was diagnosed with appendicitis on 01 Oct 2020, 21 days after receiving Dose 2. On 01 Oct 2020 (Day 44), the subject experienced abdominal pain, nausea, and vomiting and he self-treated with ciprofloxacin 400 mg 1 tablet twice a day and ketoprofen 100 mg 1 tablet once daily for infection and pain prophylaxis. Despite treatment, the symptoms worsened and the subject was hospitalized. On admission, a computed tomography scan of the abdomen was performed; however, the results were unknown. On the same day (Day 44), the subject underwent surgery for appendicitis. On 03 Oct 2020 (Day 46), the appendicitis was considered resolved and the subject was discharged from the hospital. He reported that no SARS-CoV-2 test was performed while in the hospital. On 05 Oct 2020 (Day 48), a histopathology report showed acute gangrenous appendicitis with extensive overactive process in the mesoappendix and suppurative inflammatory changes in the surgical margin. The appendicitis was considered as a medically significant event. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	76	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	67.3 kg	24.7 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Systemic arterial hypertension	Hypertension	2010	Present
Inclusion body myositis	Inclusion body myositis	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	14:00

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	19SEP2020 (24)	12:50
3	BNT162b2	05MAR2021 (191)	10:50

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	Appendicitis	12JAN2021 (139)		21JAN2021 (148)		10

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/TCN	Y	Resolved (21JAN2021)	NOT RELATED/OTHER: Unknown	2	116	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	21OCT2020	
Completed	REPEAT SCREENING 1	05MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261477, a 76-year-old white male with a pertinent medical history of hypertension and inclusion body myositis (both since 2010), received Dose 1 on 27 Aug 2020 and Dose 2 on 19 Sep 2020 (Day 24). The subject was diagnosed with appendicitis on 12 Jan 2021, 115 days after receiving Dose 2. On 12 Jan 2021 (Day 139), the subject informed the site that he had abdominal pain and visited the hospital. On the same day (Day 139), he was hospitalized and underwent a laparoscopic appendectomy. He was treated with intravenous ceftriaxone and metronidazole (from 12 Jan 2021 to 16 Jan 2021); and metamizole 500 mg orally (PO) as needed, pantoprazole 40 mg PO once daily, and amoxicillin/clavulanic acid 875/125 mg twice a day (all from 17 Jan 2021 to 21 Jan 2021). On 13 Jan 2021 (Day 140), the pathology findings confirmed the diagnosis of acute ulcer-phlegmonous appendicitis and acute fibrinopurulent periappendicitis. The subject was discharged on 16 Jan 2021 (Day 143). The appendicitis was considered resolved on 21 Jan 2021 (Day 148). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first dose of BNT162b2 on 05 Mar 2021 (Day 191) and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2000	19	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	69.2 kg	23.9 kg/m2	15AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Pituitary microadenoma	Pituitary tumour benign	04APR2019	Present
Epigastralgia	Abdominal pain upper	APR2020	Present
Gastritis	Gastritis	01APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15AUG2020 (1)	11:10
2	BNT162b2	04SEP2020 (21)	10:45

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	acute appendicitis	18SEP2020 (35)	09:00	06OCT2020 (53)	15:00	19
2	INV	Electrocardiogram QT prolonged	QT interval prolongation	18SEP2020 (35)	14:00	18SEP2020 (35)	20:00	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (06OCT2020)	NOT RELATED/OTHER: unknown	2	15	Y
2	1	N	N	Resolved (18SEP2020)	NOT RELATED/OTHER: Unknown	2	15	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311281, a 19-year-old white female with a pertinent medical history of upper abdominal pain (since Apr 2020) and gastritis (since 01 Apr 2020), received Dose 1 on 15 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 21). The subject was diagnosed with appendicitis on 18 Sep 2020, 14 days after receiving Dose 2. On 18 Sep 2020 (Day 35), the subject experienced abdominal pain and nausea and she self-treated with pargeverine 1 mg and pantoprazole (dose unknown), but the symptoms persisted. After 3 hours of persistent symptoms, she visited the emergency room. Laboratory test results showed a white blood cell count of 14,980 cells/mL and neutrophils of 79% (normal ranges not reported), and an abdominal ultrasound examination showed an inflammatory process in the right lower quadrant. An electrocardiogram showed sinus rhythm and prolonged QT (QT interval corrected for heart rate [QTc] of 531 mm, which was reported as a nonserious adverse event), and a chest x-ray was unremarkable. The subject was diagnosed with acute appendicitis and hospitalized. She underwent an appendectomy and was treated with unspecified intravenous antibiotics. On 19 Sep 2020 (Day 36), she was discharged from the hospital on oral ciprofloxacin 500 mg twice a day and metronidazole 500 mg 3 times a day for 7 days. On 22 Sep 2020 (Day 39), the pathology report showed a resected cecal appendix with exacerbation of chronic appendicitis. The appendicitis resolved on 06 Oct 2020 (Day 53), and the subject was released from the surgeon's care on the same day. At an ambulatory follow-up visit with the surgeon on 07 Oct 2020 (Day 54), the subject was asymptomatic. A COVID-19 test was not performed because the subject did not have any COVID-19 symptoms. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1971	49	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
190 cm	98 kg	27.1 kg/m2	18AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	18AUG2020 (1)	19:42
2	BNT162b2	07SEP2020 (21)	10:50

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INFEC	Appendicitis	Acute appendicitis	06JAN2021 (142)	22:00	11FEB2021 (178)	19:00	37
2	CARD	Atrial fibrillation	Acute Paroxysmal Atrial Fibrillation with High Ventricular Response.	11JAN2021 (147)	12:00	15JAN2021 (151)	10:00	5
3	INFEC	Peritonitis	Peritonitis	06JAN2021 (142)	22:00	11FEB2021 (178)	19:00	37

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC/TCN	Y	Resolved (11FEB2021)	NOT RELATED/OTHER: unknown	2	122	Y
2	1	TC	N	Resolved (15JAN2021)	NOT RELATED/OTHER: Unknown	2	127	N
3	3	TC/TCN	Y	Resolved (11FEB2021)	NOT RELATED/OTHER: unknown	2	122	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312125, a 49-year-old white male with no reported medical history, received Dose 1 on 18 Aug 2020 and Dose 2 on 07 Sep 2020 (Day 21). The subject was diagnosed with appendicitis and peritonitis on 06 Jan 2021, 121 days after receiving Dose 2. On 06 Jan 2021 (Day 142), the subject complained of persistent abdominal pain in the right iliac fossa. On 07 Jan 2021 (Day 143), the subject was seen in the clinic and was treated with oral diclofenac 75 mg twice a day (BID) for abdominal pain since 07 Jan 2021 (Day 143). On the same day, the subject was evaluated at the emergency room and was diagnosed with renal colic and the treatment with diclofenac was continued. On 08 Jan 2021 (Day 144), the abdominal pain persisted, and the subject had vomited and was in poor general condition. On 09 Jan 2021 (Day 145), the subject was hospitalized for generalized abdominal pain, peritoneal reaction, leukocytosis, and fever. An abdominal ultrasound examination on the same day showed mild to moderate fluid collections in the right upper quadrant and left flank, and a nonadenomegalic lymph node in the right iliac fossa. An emergency abdominal laparoscopy was performed, which showed appendicular peritonitis in 4 quadrants; and the subject underwent a laparoscopic appendectomy along with a copious irrigation of the peritoneal cavity. The subject was in the intensive care unit for 6 days after surgery, and continuous positive airway pressure was required, where he presented an isolated episode of atrial fibrillation due to sepsis and was treated with amiodarone. On the same day (Day 145), laboratory tests showed a white blood cell (WBC) count of 4300/mm3, neutrophils of 86%, and neutrophil count of 3698/mm3 (normal ranges [NRs] not reported), blood sugar of 116 mg/dL (NR: 70-100 mg/dL), and creatinine of 20 mg/L (NR: 9-13 mg/L). The abdominal fluid culture showed Escherichia coli and nonfermenting gram-negative bacilli; tissue culture was positive for Escherichia coli and Pseudomonas aeruginosa. On 10 Jan 2021 (Day 146), laboratory tests showed a WBC count of 3500/mm3 with 85% neutrophils, hematocrit of 37%, hemoglobin of 11.7 g/dL, pH of 7.27, partial pressure of carbon dioxide (PCO2) of 37 mmHg, partial pressure of oxygen (PO2) of 91 mmHg, bicarbonate of 17 mEq/L, base excess of -9 mEq/L, and oxygen saturation of 96% (NRs not reported), blood sugar of 88 mg/dL (NR: 70-100 mg/dL), and creatinine of 13 mg/L (NR: 9-13 mg/L). On 13 Jan 2021 (Day 149), the laboratory tests included hematocrit of 35%, WBC count of 8100/mm3, C-reactive protein of 144 mg/L (NRs not reported), procalcitonin of 2.19 ng/mL (NR: less than 0.1 ng/mL), pH of 7.23, PCO2 of 36 mmHg, PO2 of 93 mmHg, bicarbonate of 15 mEq/L, base excess of -12 mEq/L, and oxygen saturation of 94% (NRs not reported). On 17 Jan 2021 (Day 153), the laboratory tests included hematocrit of 36%, WBC count of 10100/mm3, C-reactive protein of 75 mg/L (NRs not reported), alanine aminotransferase of 54 U/L (NR: 5-45 U/L), aspartate aminotransferase of 63 U/L (NR: 5-40 U/L), and alkaline phosphatase of 411 U/L (NR: 50-270 U/L). On 18 Jan 2021 (Day 154), the abdominal ultrasound examination showed a thin-walled gallbladder with biliary sludge and collection of 75 × 32 mm in the right hepatorenal space. On the same day, the subject was febrile and showed leukocytosis. On 19 Jan 2021 (Day 155), the laboratory tests showed hematocrit of 38%, hemoglobin of 12.4 g/dL, WBC count of 13700/mm3, neutrophils of 80%, and neutrophil count of 10,960/mm3 (NRs not reported). On an unknown date, an electrocardiogram showed sinus rhythm. On 20 Jan 2021 (Day 156), the treatment with amiodarone was discontinued and treatment with bisoprolol was started. On 21 Jan 2021 (Day 157), a percutaneous abdominal drainage was performed, and 30 mm of serous fluid was drained; the abdominal serous fluid culture was negative. The subject was treated with intravenous piperacillin/tazobactam 4.5 g 4 times a day for 12 days (dates unknown). A hepatorenal collection puncture was performed (date and details unknown). On 26 Jan 2021 (Day 162), an abdominal ultrasound examination showed scanty pericatheter fluid and the catheter was removed. On the same day (Day 162), the subject was discharged from the hospital. The discharge medications included amoxicillin/clavulanic acid 1 g BID. On 02 Feb 2021 (Day 169), the subject was feeling better and asymptomatic and continued with the antibiotic treatment. On 11 Feb 2021 (Day 178), the appendicitis and peritonitis resolved. The appendicitis and peritonitis were considered as medically significant. In the opinion of the investigator, there was no reasonable possibility that the appendicitis and peritonitis were related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	26	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	77 kg	27.9 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	13SEP2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	19:30
2	BNT162b2	10SEP2020 (23)	16:30

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	Acute Appendicitis	28DEC2020 (132)	15:00	12JAN2021 (147)	18:00	16

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (12JAN2021)	NOT RELATED/OTHER: unknown	2	110	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312420, a 26-year-old white female with a pertinent medical history of hypertension (since 13 Sep 2019), received Dose 1 on 19 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 23). The subject was diagnosed with appendicitis on 28 Dec 2020, 109 days after receiving Dose 2. Concomitant medication included losartan (since 13 Sep 2019) for arterial hypertension. On 29 Dec 2020 (Day 133), the subject informed the site that on 28 Dec 2020 (Day 132), she experienced nonspecific abdominal pain and went to the emergency room (ER). Laboratory test results showed leukocytes of 13.7 × 109/L with segmented neutrophils of 77.7% and lymphocytes of 15.2% (normal ranges not reported), and the urinalysis was unremarkable. An abdominal ultrasound examination and abdominal computed tomography scan were performed, with results not available. On 29 Dec 2020 (Day 133), the subject was discharged from the ER. Later that day, the abdominal pain persisted, and the subject was hospitalized because of acute appendicitis. A SARS-CoV-2 test was negative. On 30 Dec 2020 (Day 134), a laparoscopic appendectomy was performed without complications. The subject was treated with unspecified antibiotics and analgesics. On 31 Dec 2020 (Day 135), she was discharged from the hospital. As of 05 Jan 2021 (Day 140), she was feeling well. On 12 Jan 2021 (Day 147), the surgical stitches were removed and the appendicitis was considered resolved. On 13 Jan 2021 (Day 148), the subject was feeling well. The pathology result showed suppurative acute appendicitis. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1991	28	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	52 kg	19.8 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Neuroepithelial tumor surgery	Cancer surgery	15DEC1999	Past
Diplopia	Diplopia	15DEC1999	Present
Brachiocrural hemiparesis	Hemiparesis	15DEC1999	Present
chronic headache	Headache	01MAR2000	Present
Vesicular lithiasis	Calculus bladder	JAN2016	Past
Cholecystectomy	Cholecystectomy	05APR2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	09:34
2	Placebo	14SEP2020 (21)	09:50
3	BNT162b2	26JAN2021 (155)	14:45
4	BNT162b2	17FEB2021 (177)	15:27

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	Acute appendicitis	22OCT2020 (59)	09:00	06NOV2020 (74)	16:00	16

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/TCN	Y	Resolved (06NOV2020)	NOT RELATED/OTHER: unknown	2	39	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	13OCT2020	
Completed	REPEAT SCREENING 1	26JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313785, a 28-year-old white female with no pertinent medical history, received Dose 1 on 25 Aug 2020 and Dose 2 on 14 Sep 2020 (Day 21). The subject was diagnosed with appendicitis on 22 Oct 2020, 38 days after receiving Dose 2. Concomitant medications included caffeine/ergotamine, chlorpheniramine dipyrone, and metoclopramide (all since unknown dates) for chronic headache. During Visit 102, the subject informed the site that on 22 Oct 2020 (Day 59), she presented to the emergency room with abdominal pain and was hospitalized for further treatment. An abdominal ultrasound examination and a blood test were performed, but the results were not reported. On 23 Oct 2020 (Day 60), a SARS-CoV-2 test was negative. The subject underwent an appendectomy on 23 Oct 2020 (Day 60) without any complications during or after the procedure. On 24 Oct 2020 (Day 61), she was discharged on ketorolac 20 mg 3 times a day for 2 days and cefalexin 1000 mg twice a day for 7 days. On 26 Oct 2020 (Day 63), the histology report revealed the following: resected cecal appendix measuring 6.3 cm in length; serous was smooth and bright; wall measured 0.4 cm; pink mucous layer; filiform lumen with a diagnosis of acute appendicitis with serous and mesoappendix compromise. After a week, the subject had an appointment with the surgeon and the stitches were removed. On 06 Nov 2020 (Day 74), she had a telephone appointment; her condition stabilized, and the appendicitis was considered resolved. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 26 Jan 2021 (Day 155) and 17 Feb 2021 (Day 177), respectively, and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	57	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	112 kg	37 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	05OCT2015	Present
Asthma	Asthma	23JAN2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	10:02
2	BNT162b2	14SEP2020 (20)	19:20

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	Accute appendictis	06JAN2021 (134)	16:00	23JAN2021 (151)	12:30	18
2	METAB	Type 2 diabetes mellitus	TYPE 2 DIABETES	13JAN2021 (141)	08:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (23JAN2021)	NOT RELATED/OTHER: unknown	2	115	Y
2	1	TC/TCN	N	Yes	NOT RELATED/OTHER: Unknown	2	122	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	13OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12314091, a 57-year-old white male with a pertinent medical history of hypertension (since 05 Oct 2015) and asthma (since 23 Jan 2018), received Dose 1 on 26 Aug 2020 and Dose 2 on 14 Sep 2020 (Day 20). The subject was diagnosed with appendicitis on 06 Jan 2021, 114 days after receiving Dose 2. Concomitant medication included enalapril (since 05 Oct 2015) for arterial hypertension. On 10 Feb 2021 (Day 169), the site contacted the subject, who reported persistent right low quadrant pain starting from 06 Jan 2021 (Day 134); the pain worsened along with hypogastric abdominal pain on 12 Jan 2021 (Day 140). The subject presented to the emergency room on 13 Jan 2021 (Day 141) and underwent an abdominal ultrasound examination (results not available). Laboratory tests showed a white blood cell count of 23,210, neutrophils of 87%, blood alkaline phosphatase of 143, glucose of 333, sodium of 134, hematocrit of 44, hemoglobin of 15.7, international normalized ration of 1.17, and prothrombin time of 30 (units and normal range not reported). On 13 Jan 2021 (Day 141), the subject was hospitalized with a diagnosis of acute appendicitis and underwent a laparoscopic appendectomy. A surgical drain was placed in the Douglas cul-de-sac. During the surgical procedure, an appendicular plastron was identified, and a wash and vacuum was performed. The subject was treated with unspecified intravenous (IV) pain medications, metronidazole, and ciprofloxacin. He was also diagnosed with type 2 diabetes mellitus and treated with metformin. He was on a liquid diet with IV medication. A consultation was placed to manage hyperglycemia on the first postoperative day. On the second postoperative day, 10 units of insulin were indicated before breakfast and dinner with hemoglucotest control 2 hours after ingestion. On the third postoperative day, the IV ciprofloxacin and metronidazole were switched to oral administration. The subject tolerated the diet, he walked without difficulty, the surgical wound was clean and dry, and the surgical drain consisted of 100 mL of serosanguineous fluid. An abdominal ultrasound examination on an unspecified date showed a diffusely increased liver echogenicity compatible with moderate steatosis and findings consistent with appendicular plastron. On 15 Jan 2021 (Day 143), the pathology result revealed a diagnosis of acute appendicitis with periappendicitis phenomena and associated hemorrhagic areas. On 16 Jan 2021 (Day 144), the subject was discharged with a drain and prescribed ciprofloxacin 500 mg twice a day (BID), metronidazole 500 mg 3 times a day (TID), ketorolac 10 mg TID, and metformin 850 mg once daily (QD). The subject reported that ketorolac was taken TID for 1 day, BID until 21 Jan 2021 (Day 149), and QD on 22 Jan 2021 (Day 150), and then discontinued. On 23 Jan 2021 (Day 151), the drain was removed, the subject was asymptomatic, and his condition stabilized. A COVID-19 test was not performed. On 23 Jan 2021 (Day 151), the appendicitis was considered resolved. The subject completed the antibiotic treatment on 27 Jan 2021 (Day 155). The type 2 diabetes mellitus was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	91 kg	34.3 kg/m2	26AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	14:50

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	INFEC	Appendicitis	Acute Appendicitis	05SEP2020 (11)	22:00	09SEP2020 (15)	14:00	5	3
2	VASC	Orthostatic hypotension	orthostatic hypotension	11OCT2020 (47)	06:30	12OCT2020 (48)	13:00	2	1
3	EAR	Vertigo	Vertigo	07OCT2020 (43)		26NOV2020 (93)	21:00	51	2

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: unknown	1	11	Y
2	N	N	Resolved (12OCT2020)	NOT RELATED/OTHER: dietary habit change, lower intake.	1	47	N
3	N	N	Resolved (26NOV2020)	NOT RELATED/OTHER: Unknow	1	43	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Withdrawn	VACCINATION	26NOV2020	WITHDRAWAL BY SUBJECT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	26NOV2020	WITHDRAWAL BY SUBJECT

Narrative Comment
Subject C4591001 1231 12314216, a 57-year-old white female with no reported medical history, received Dose 1 on 26 Aug 2020. The subject was diagnosed with appendicitis on 05 Sep 2020, 10 days after receiving Dose 1. The subject stated that she had diarrhea and vomiting since 05 Sep 2020 (Day 11). On 06 Sep 2020 (Day 12), she experienced abdominal pain and presented to the emergency room and was hospitalized. Per the hospital discharge summary, the cause of the acute abdomen was “acute appendicitis,” which was surgically resolved. Discharge medications included amoxicillin/clavulanic acid 1 g twice a day for 7 days, metronidazole 500 mg 3 times a day (TID) for 5 days, and ibuprofen 400 mg TID for 3 days. A COVID-19 test was not performed, as the subject had no symptoms. The surgical pathology report was not available. The appendicitis was considered resolved on 09 Sep 2020 (Day 15). The subject requested withdrawal from the study on 26 Nov 2020. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator’s causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	70 kg	25.4 kg/m2	28AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	14:15
2	Placebo	18SEP2020 (22)	15:00
3	BNT162b2	08MAR2021 (193)	15:23

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	INFEC	Abdominal abscess	Intra-abdominal Abscess	29OCT2020 (63)	12:00	04DEC2020 (99)	12:15	37	3	TC/TCN	Y
2	INFEC	Appendicitis	Acute Appendicitis	16OCT2020 (50)	09:00	24OCT2020 (58)		9	3	TC/TCN	Y
3	INFEC	Postoperative wound infection	infection in surgical wound	30OCT2020 (64)	18:42	04DEC2020 (99)	12:15	36	2	TC/TCN	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (04DEC2020)	NOT RELATED/OTHER: surgical history of appendicitis on 19OCT2020	2	42	Y
2	Resolved (24OCT2020)	NOT RELATED/OTHER: Escherichia coli	2	29	Y
3	Resolved (04DEC2020)	NOT RELATED/OTHER: unknown	2	43	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	02DEC2020	
Completed	REPEAT SCREENING 1	08MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12314833, a 49-year-old white male with no reported medical history, received Dose 1 on 28 Aug 2020 and Dose 2 on 18 Sep 2020 (Day 22). The subject was diagnosed with appendicitis on 16 Oct 2020, 28 days after receiving Dose 2, and abdominal abscess on 29 Oct 2020, 41 days after receiving Dose 2. On 16 Oct 2020 (Day 50), the subject complained of diffuse abdominal pain and on 17 Oct 2020 (Day 51), he went to the hospital emergency room (ER) for evaluation. He was treated with intravenous (IV) saline and an IV analgesic medication. He was observed for 12 hours and was discharged. However, his abdominal pain persisted and, later, it localized in the right lower quadrant. The subject attended a different hospital ER and an abdominal computed tomography (CT) scan was done, but the results were not provided. On 19 Oct 2020 (Day 53), he underwent an appendectomy. On 23 Oct 2020 (Day 57), the appendectomy histopathology results revealed transmural suppurative acute appendicitis involving the peritoneal serosa and mesoappendix. On 24 Oct 2020 (Day 58), the appendicitis resolved, and the subject was discharged from the hospital.

Narrative Comment
The subject was asymptomatic, did not use pain medications, and remained on bed rest. On 29 Oct 2020 (Day 63), he reported that he was febrile with no other symptoms and the surgical scar did not show any signs of infection. On 30 Oct 2020 (Day 64), he remained febrile and noticed draining from the surgical wound; he was seen in the ER and was readmitted. On the same day, laboratory results showed a white blood cell (WBC) count of 19,170/mm^3, neutrophils of 87%, and platelets of 542,000/mm^3 (normal ranges [NRs] not reported); the remaining investigations were unremarkable, and blood culture (twice) and urine culture were negative. An enhanced CT scan of the thorax, abdomen, and pelvis showed intra-abdominal fluid collection in the cecal area (size 74.4 × 45.5 × 57.7 mm) and reactive ganglionic structures. The subject had a surgical appointment on 31 Oct 2020 (Day 65). He was treated with IV piperacillin/tazobactam. According to the subject, on 01 Nov 2020 (Day 66), he was found to have abdominal free fluid and underwent an exploratory laparotomy with mesenteric abscess drainage without complications. He remained afebrile and asymptomatic. As per the site, the intra-abdominal abscess was secondary to the appendicitis. On 02 Nov 2020 (Day 67), the antibiotic susceptibility test of the abscess culture showed broad-spectrum antibiotic-sensitive *Escherichia coli*. On 04 Nov 2020 (Day 69), an abdominal drain was removed. The abscess culture was pending, and an abdominal x-ray was done, but the results were not reported. The subject continued treatment with IV piperacillin/tazobactam until 05 Nov 2020 (Day 70) and then switched to oral antibiotics. A COVID-19 test was not performed because the events were not related to COVID-19 illness and the subject did not present any COVID-19 symptoms. On 05 Nov 2020 (Day 70), the subject remained hospitalized with mild abdominal pain but felt well overall. On the same day (Day 70), laboratory tests showed an erythrocyte sedimentation rate of 95 mm/hour, C-reactive protein of 180.70 mg/L, and procalcitonin of 0.27 ng/mL (NRs not reported). On 06 Nov 2020 (Day 71), the laboratory tests showed hemoglobin of 9.6 g/dL, hematocrit of 30.8%, WBC count of 9790/mm^3, neutrophils of 71.7%, and platelets of 62,7000/mm^3 (NRs not reported). On 06 Nov 2020 (Day 71), the subject was treated with IV ampicillin/sulbactam. On 07 Nov 2020 (Day 72), the subject remained hospitalized and an abdominal and pelvic CT scan showed new intra-abdominal collections (a surgical wound collection), and treatment with unspecified IV antibiotics was restarted again. An abdominal ultrasound (US) examination showed paravesical collection, which was not drained, as it was in close contact with the urinary bladder, small intestine, and iliac vessels. The subject was treated with ciprofloxacin, and wound lavage was done daily. The subject felt well with mild surgical scar pain, and he was on analgesics as needed (PRN). His C-reactive protein on Day 72 was 51.50 mg/L (NR not reported). On 09 Nov 2020 (Day 74), an abdominal US-guided drainage of 80 mL of purulent fluid was completed successfully. The culture of the surgical wound subcutaneous cellular tissue (SCT) showed *E coli* (ampicillin/sulbactam resistant, ciprofloxacin sensitive). On 10 Nov 2020 (Day 75), the subject noted that there was a persistent retrovesical collection that would require drainage. The subject had a urinary catheter placed. An abscess material culture was done, and *E coli* was isolated. The subject was treated with a 10-day course of IV ampicillin/sulbactam for the *E coli* (intra-abdominal abscess culture - *E. coli* sensitive to ampicillin). The subject continued treatment with IV ciprofloxacin to treat *E coli* sensitive to quinolones and for *E coli* resistant to ampicillin isolated in the SCT culture; and the local surgical wound was healing. No attempt to perform US-guided drainage of the retrovesical collection was done. According to the discharge summary, a paravesical collection was diagnosed, but because of its location, it was managed conservatively. On 13 Nov 2020 (Day 78), the subject reported that he was feeling well, was afebrile without pain, and was eating normally. As the subject remained asymptomatic and afebrile, he was discharged on 16 Nov 2020 (Day 81). Discharge medications included diclofenac PRN, and ciprofloxacin 500 mg twice a day until 21 Nov 2020 (Day 86). The subject was feeling well, with continued local wound healing. On 27 Nov 2020 (Day 92), he continued to feel well, was afebrile, and denied any pain. On 04 Dec 2020 (Day 99), he continued to feel well, was afebrile, and denied any pain, and the abdominal abscess was resolved. On the same day (Day 99), the subject consulted the surgeon, who confirmed that the subject had recovered and did not need further follow-up.

Narrative Comment
In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first dose of BNT162b2 on 08 Mar 2021 (Day 193) and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the appendicitis and abdominal abscess were related to the study intervention or clinical trial procedures, but rather the appendicitis was related to *E coli* infection and the abdominal abscess was related to the appendectomy performed on 19 Oct 2020. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	24	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	99.5 kg	33.2 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	2000	Present
Allergic rhinitis	Rhinitis allergic	2000	Present
Migraine	Migraine	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15OCT2020 (1)	18:19
2	Placebo	06NOV2020 (23)	10:23
3	BNT162b2	26JAN2021 (104)	11:47
4	BNT162b2	16FEB2021 (125)	10:00

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Appendicitis	APPENDICITIS	23NOV2020 (40)		25NOV2020 (42)		3	3
2	GENRL	Chills	Chills	26JAN2021 (104)	21:00	28JAN2021 (106)		3	1
3	GENRL	Chills	Chills	16FEB2021 (125)	21:00	17FEB2021 (126)		2	1
4	INFEC	Conjunctivitis	Conjunctivitis in the right eye	17OCT2020 (3)		24OCT2020 (10)		8	1
5	GENRL	Injection site pain	Injection site pain	26JAN2021 (104)	21:00	28JAN2021 (106)		3	1
6	GENRL	Pyrexia	Fever	26JAN2021 (104)	21:00	28JAN2021 (106)		3	1
7	GENRL	Pyrexia	Fever	16FEB2021 (125)	21:00	17FEB2021 (126)		2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (25NOV2020)	NOT RELATED/OTHER: Unknown	2	18	Y
2	N	N	Resolved (28JAN2021)	Study Treatment	3	1	N
3	N	N	Resolved (17FEB2021)	Study Treatment	4	1	N
4	TC	N	Resolved (24OCT2020)	NOT RELATED/OTHER: Bacterial infection	1	3	N

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	N	N	Resolved (28JAN2021)	Study Treatment	3	1	N
6	N	N	Resolved (28JAN2021)	Study Treatment	3	1	N
7	TC	N	Resolved (17FEB2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15OCT2020	
Completed	VACCINATION	09DEC2020	
Completed	REPEAT SCREENING 1	26JAN2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1241 12412218, a 24-year-old white female with a pertinent medical history of asthma and allergic rhinitis (both since 2000) and migraine (since 2016), received Dose 1 on 15 Oct 2020 and Dose 2 on 06 Nov 2020 (Day 23). The subject was diagnosed with appendicitis on 23 Nov 2020, 17 days after receiving Dose 2. Concomitant medications included mometasone furoate (since 2010) and budesonide/formoterol fumarate (since 2015) for asthma. On 23 Nov 2020 (Day 40), the subject was taken to the emergency room because of severe abdominal pain. On the same day, an abdominal computed tomography scan confirmed the appendicitis and, subsequently, the subject was hospitalized. On 24 Nov 2020 (Day 41), the subject underwent an appendectomy and was treated with oral metamizole sodium 1 g once (on 23 Nov 2020), and oral ciprofloxacin 500 mg every 12 hours and oral metronidazole 400 mg every 8 hours (both from 23 Nov 2020 to 01 Dec 2020). On 25 Nov 2020 (Day 42), the appendicitis resolved, and the subject was discharged from the hospital. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 26 Jan 2021 (Day 104) and 16 Feb 2021 (Day 125), respectively, and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	96.3 kg	34.5 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Former tobacco smoker	Ex-tobacco user	1965	Past
hypercholesteromia	Hypercholesterolaemia	2005	Present
hypertension	Hypertension	2005	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04SEP2020 (1)	15:41
2	Placebo	24SEP2020 (21)	13:32
3	BNT162b2	19JAN2021 (138)	12:36
4	BNT162b2	11FEB2021 (161)	15:13

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Aortic aneurysm	abdominal aortic aneurysm	07OCT2020 (34)	01:09	ONGOING			2
2	INFEC	Appendicitis	acute appendicitis	05OCT2020 (32)		07OCT2020 (34)		3	2
3	MUSC	Back pain	lower back soreness	20JAN2021 (139)	08:00	22JAN2021 (141)	08:00	3	1
4	MUSC	Back pain	slight backache	12FEB2021 (162)	08:00	13FEB2021 (163)	08:00	2	1
5	GENRL	Injection site pain	soreness at the injection site	20JAN2021 (139)	08:00	22JAN2021 (141)	08:00	3	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: incidential finding on CT scan	2	14	N
2	TC/TCN	Y	Resolved (07OCT2020)	NOT RELATED/OTHER: appendicitis	2	12	Y
3	TC	N	Resolved (22JAN2021)	Study Treatment	3	2	N
4	TC	N	Resolved (13FEB2021)	Study Treatment	4	2	N
5	TC	N	Resolved (22JAN2021)	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccination	INFLUENZA VACCINE	07OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	27OCT2020	
Completed	REPEAT SCREENING 1	19JAN2021	
Completed	OPEN LABEL TREATMENT	08MAR2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1260 12601069, a 71-year-old white male with a pertinent medical history of hypercholesterolemia and hypertension (both since 2005) and ex-smoker (1.5 packs per day; started in 1965 at the age of 16 years and quit at the age of 50 years), received Dose 1 on 04 Sep 2020 and Dose 2 on 24 Sep 2020 (Day 21). The subject was diagnosed with appendicitis on 05 Oct 2020, 11 days after receiving Dose 2. On 06 Oct 2020 (Day 33), the subject presented to the emergency room (ER) with lower quadrant abdominal pain (constant and nonradiating) that began on 05 Oct 2020 (Day 32). On examination, the subject was normotensive, afebrile, and mildly tachycardic (heart rate [beats/min] was in the 100s). On 06 Oct 2020 (Day 33), laboratory tests revealed an elevated white blood cell count of 18.2 × 103/mm3 (normal range [NR] not provided) and sodium level of 131 (unit and NR not provided). On 07 Oct 2020 (Day 34), the subject reported that he felt nauseous and lost his appetite, and denied any other pain. His bowel movement was normal. A computed tomography (CT) scan of the abdomen/pelvis showed acute appendicitis without any gross perforation or abscess; abdominal aortic aneurysm measuring 5.1 cm without rupture; and small gallstones. A SARS-CoV-2 test performed on 07 Oct 2020 (Day 34) was negative. On the same day (Day 34), the subject underwent a laparoscopic appendectomy without any complications. The appendix was gangrenous with pus. On 07 Oct 2020 (Day 34), the appendicitis was considered resolved, and the subject was discharged from the hospital on amoxicillin 875 mg/clavulanic acid 275 mg twice a day for 5 days as a prophylaxis. On 07 Oct 2020 (Day 34), the subject also received nonstudy influenza vaccination. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 19 Jan 2021 (Day 138) and 11 Feb 2021 (Day 161), respectively, and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	50	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
195.58 cm	87.45 kg	22.8 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tendonopathy (hip)	Tendon disorder	2015	Present
tendonopathy (hands)	Tendon disorder	2015	Present
tendonopathy (feet)	Tendon disorder	2015	Present
allergy to penicillin	Drug hypersensitivity	13FEB2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	08SEP2020 (1)	09:31
2	BNT162b2	02OCT2020 (25)	16:17

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Appendicitis	acute appendicitis	04DEC2020 (88)		08DEC2020 (92)	20:00	5	2
2	GENRL	Injection site pain	soreness at injection site	08SEP2020 (1)	16:00	10SEP2020 (3)	08:00	3	1
3	MUSC	Tendon disorder	worsening of tendopathy (hands)	18OCT2020 (41)		01NOV2020 (55)	18:00	15	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (08DEC2020)	NOT RELATED/OTHER: acute appendicitis	2	64	Y
2	N	N	Resolved (10SEP2020)	Study Treatment	1	1	N
3	TC/TCN	N	Resolved (01NOV2020)	NOT RELATED/OTHER: medical history of tendopathy	2	17	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	03NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1260 12601075, a 50-year-old white male with no pertinent medical history, received Dose 1 on 08 Sep 2020 and Dose 2 on 02 Oct 2020 (Day 25). The subject was diagnosed with acute appendicitis on 04 Dec 2020, 63 days after receiving Dose 2. On 04 Dec 2020 (Day 88), the subject experienced abdominal pain and fatigue. On 07 Dec 2020 (Day 91), he called his physician and reported that he had right lower quadrant abdominal pain, fatigue, abdominal distention, nausea, and fever (body temperature of 102°F). On the same day (Day 91), he visited his primary care physician. On 08 Dec 2020 (Day 92), a laboratory test (not specified) showed results that were consistent with acute appendicitis. The same day, the subject was admitted to the hospital under urgent care and an abdominal computed tomography scan showed acute appendicitis. He underwent an appendectomy, the acute appendicitis was considered resolved on 08 Dec 2020 (Day 92), and he was discharged from the hospital on 09 Dec 2020. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	American Indian or Alaska Native	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.2 cm	107.7 kg	37.2 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Intermittent Asthma	Asthma	23MAR2017	Present
Allergic Rhinitis	Rhinitis allergic	23MAR2017	Present
Anal Skin Tag	Anal skin tags	21AUG2018	Present
Acne Vulgaris	Acne	16AUG2019	Present
Intermittent Sinus Headache	Sinus headache	25OCT2019	Present
Cyclothymic Disorder	Cyclothymic disorder	17APR2020	Present
Genital Herpes Simplex	Genital herpes simplex	30JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	11:52
2	BNT162b2	30SEP2020 (27)	15:56

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	APPENDICITIS	20SEP2020 (17)	21:00	22SEP2020 (19)	10:19	3
2	INV	Blood cholesterol increased	Elevated Cholesterol	08OCT2020 (35)	18:41	ONGOING		
3	INV	Low density lipoprotein increased	Elevated Low-Density Lipoprotein	08OCT2020 (35)	18:41	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (22SEP2020)	NOT RELATED/OTHER: UNKNOWN	1	17	Y
2	1	TCN	N	Yes	NOT RELATED/OTHER: Unknown	2	9	N
3	1	TCN	N	Yes	NOT RELATED/OTHER: Unknown	2	9	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flulaval Quadrivalent 2020-2021 PF (Influenza Vaccine)	INFLUENZA VACCINE INACT SPLIT 4V	28OCT2020
Pfizer Biontech Covid 19 mRNA Vaccine	TOZINAMERAN	31DEC2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	28OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	13JAN2021	PROTOCOL DEVIATION

Narrative Comment
Subject C4591001 1270 12701069, a 31-year-old American Indian or Alaska Native female with no pertinent medical history, received Dose 1 on 04 Sep 2020 and Dose 2 on 30 Sep 2020 (Day 27). The subject was diagnosed with appendicitis on 20 Sep 2020, 16 days after receiving Dose 1. Concomitant medications included montelukast sodium (since 18 Sep 2018) for asthma and escitalopram oxalate (since 17 Apr 2020) for cyclothymic disorder. On 20 Sep 2020 (Day 17), the subject experienced acute, intermittent, crampy generalized abdominal pain, associated with vomiting and diarrhea. She denied any fever, chills, chest pain, shortness of breath, syncope, lightheadedness, numbness, weakness, dysuria, hematuria, edema, or sore throat. The following day (Day 18), she presented to the emergency room (ER) for further evaluation of her symptoms (abdominal pain, vomiting, and diarrhea) and was subsequently hospitalized. In the ER, a computed tomography scan of the abdomen and pelvis with contrast was consistent with mild acute appendicitis. Relevant laboratory tests performed on 21 Sep 2020 (Day 18) included blood potassium of 3.4 mEq/L and carbon dioxide level of 22 mEq/L (normal ranges not reported), and a SARS-CoV-2 test was negative. On 22 Sep 2020 (Day 19), the subject underwent an appendectomy and, on the same day, the appendicitis was considered resolved and the subject was discharged from the hospital in stable condition. The final pathology report revealed acute suppurative appendicitis that was negative for malignancy. On 28 Oct 2020 (Day 55), the subject also received a nonstudy influenza vaccination and on 31 Dec 2020 (Day 119), she received commercially available COVID-19 vaccine (tozinameran) outside of the study. She was withdrawn from the study on 13 Jan 2021 because of this protocol deviation. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	55.8 kg	21.8 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Dyslipidemia	Dyslipidaemia	04MAR2010	Present
Anxiety disorder	Anxiety disorder	07APR2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21SEP2020 (1)	17:40

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	13OCT2020 (23)	12:30
3	BNT162b2	23FEB2021 (156)	19:08

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Complicated appendicitis	Acute gangrenous appendicitis	12DEC2020 (83)	20:00	04JAN2021 (106)	15:00	24

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (04JAN2021)	NOT RELATED/OTHER: unknown	2	61	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Completed	VACCINATION	12NOV2020	
Completed	REPEAT SCREENING 1	23FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 4444 44441145, a 59-year-old white female with a pertinent medical history of dyslipidemia (since 04 Mar 2010), received Dose 1 on 21 Sep 2020 and Dose 2 on 13 Oct 2020 (Day 23). The subject was diagnosed with acute gangrenous appendicitis (complicated appendicitis) on 12 Dec 2020, 60 days after receiving Dose 2. Concomitant medications included atorvastatin (since 03 Apr 2010) for dyslipidemia and clonazepam (since 07 Apr 2015) for anxiety disorder. On 12 Dec 2020 (Day 83), the subject experienced diffuse, colicky abdominal pain, which radiated to the back with a pain intensity of 7/10, and was associated with nausea, bilious vomiting (6 episodes), asthenia, and myalgia. On 14 Dec 2020 (Day 85), the subject was contacted by the site after reporting COVID-19 illness symptoms; she reported having nausea and vomiting, with abdominal pain that improved with analgesics and antispasmodics (drug, route, and dose unknown) for the last 4 days. Later, the abdominal pain was localized to the right iliac fossa with a pain intensity of 1/10. A COVID-19 swab test performed at home on 15 Dec 2020 (Day 86) was negative. On the same day (Day 86), a computed tomography (CT) scan of the abdomen and pelvis showed an ascending laterocecal edematous, congestive appendix with parietal mucosa alteration with a maximum diameter of 16 mm in the distal third, which was associated with densitometric alteration of the periappendicular fat and reactive regional lymph nodes; abdominal ultrasound examination in the right iliac fossa showed an aperistaltic noncompressible intestinal loop, with an increased echogenicity of the surrounding fat and laminar free fluid. An additional blood test performed on 15 Dec 2020 (Day 86) was unremarkable. The subject was hospitalized on 16 Dec 2020 (Day 87), and the physical examination showed a painful abdomen in the right iliac fossa on deep palpation, with a positive McBurney sign, without signs of peritoneal irritation. An electrocardiogram showed sinus rhythm with a heart rate of 80 beats/min. The subject was evaluated by a surgeon and underwent laparoscopic appendectomy for acute gangrenous appendicitis. She was treated with intravenous amoxicillin/sulbactam (dose unknown) and had a stable postoperative period, with good pain management. The pathology report for the appendectomy is pending. A blood test performed on 17 Dec 2020 (Day 88) was unremarkable. The subject was discharged from the hospital on 17 Dec 2020 (Day 88) with oral amoxicillin/clavulanate 1 g 2 times a day for 9 days and oral ibuprofen 400 mg 4 times a day for 3 days. Per the discharge summary, the main diagnosis was acute gangrenous appendicitis. On 18 Dec 2020 (Day 89), the subject was feeling well and asymptomatic. On 22 Dec 2020 (Day 93), she was seen by the surgeon as scheduled, the stitches were removed, and the wound was healing well. The subject was advised to continue to rest and finish the course of antibiotics. On 23 Dec 2020 (Day 94), the subject was afebrile, and she was feeling well without abdominal pain. On 04 Jan 2021 (Day 106), she had a follow-up visit with the surgeon, who assessed that no further follow-up was required. The subject completed antibiotic treatment and the acute gangrenous appendicitis was considered resolved on 04 Jan 2021 (Day 106). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 23 Feb 2021 (Day 156) and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the acute gangrenous appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1987	33	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	143.18 kg	42.7 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypothyroid	Hypothyroidism	2009	Present
narcolepsy	Narcolepsy	2010	Present
obesity	Obesity	2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	10:03
2	Placebo	03SEP2020 (23)	09:47
3	BNT162b2	19JAN2021 (161)	10:38
4	BNT162b2	09FEB2021 (182)	09:05

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Exposure during pregnancy	Exposure During partner Pregnancy	17SEP2020 (37)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Yes	NOT RELATED/OTHER: Partner became Pregnant	2	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	07OCT2020	
Completed	REPEAT SCREENING 1	19JAN2021	
Completed	OPEN LABEL TREATMENT	11MAR2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1003 10031186, a 33-year-old white male with no pertinent medical history, received Dose 1 on 12 Aug 2020 and Dose 2 on 03 Sep 2020 (Day 23). The subject's partner had an exposure during pregnancy on 17 Sep 2020, 14 days after the subject received Dose 2. Concomitant medications included levothyroxine (since 2009) for hypothyroid; and methylphenidate and modafinil (since 2010), both for narcolepsy. The first day of the subject's partner's last menstrual period was 01 Sep 2020 (Day 21) and the estimated date of conception was 17 Sep 2020 (Day 37). The gestational age at the time of initial exposure was first trimester. At the time of a convalescent visit on 15 Jan 2021 (Day 157), the subject noted that the estimated date of delivery is 08 Jun 2021. The subject's partner was currently taking a prenatal multivitamin once daily. The subject's partner was 31 years old and had an obstetrical history of 1 previous pregnancy delivered by cesarean section, as the child was in breech position. At Visit 2, the subject reported that his partner was on birth control pills as a contraceptive method; however, at Visit 1 and Visit 3, the subject reported abstaining from sexual intercourse until his partner was started back on birth control pills. The subject was instructed in using a barrier method for contraception. He had no genetic/congenital disorders within his family lineage. He and his partner never smoked tobacco or used illicit drugs, and the subject's partner never drank alcohol, but the subject drank alcohol once a week during the pregnancy. No relevant tests were reported. It was reported that the subject's partner had not delivered the baby yet and no abnormalities were found in the pregnancy at the time of the last available report. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 19 Jan 2021 (Day 161) and 09 Feb 2021 (Day 182), respectively, and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	26	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152.4 cm	76.36 kg	32.8 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Intolerance Reglan	Drug intolerance	2016	Present
Migraine headaches	Migraine	30AUG2016	Present
Obesity	Obesity	2018	Present
Recurring tonsilitis	Tonsillitis	2018	Past
Major depressive disorder	Major depression	13JUL2018	Present
BRCA1 CANCER GENE CARRIER	Cancer gene carrier	NOV2018	Present
dorsopathies occipito-atlanto-axial region	Back disorder	16AUG2019	Present
Disorder of trigeminal nerve	Trigeminal nerve disorder	16AUG2019	Present
Intermittent muscle spasm neck and back	Muscle spasms	23AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	18:17
2	Placebo	04SEP2020 (22)	17:35
3	BNT162b2	18DEC2020 (127)	16:24
4	BNT162b2	08JAN2021 (148)	13:46

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Clostridium difficile infection	Clostridium Difficile Infection	30SEP2020 (48)		28FEB2021 (199)		152	2
2	INJ&P	Exposure during pregnancy	Exposure During Pregnancy	08FEB2021 (179)		ONGOING			
3	GENRL	Injection site pain	Injection Site Pain	18DEC2020 (127)	19:00	20DEC2020 (129)		3	1
4	INFEC	Pharyngitis streptococcal	Strep throat	08SEP2020 (26)		18SEP2020 (36)		11	2
5	INJ&P	Procedural pain	Post Surgical Pain	28DEC2020 (137)		12JAN2021 (152)		16	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (28FEB2021)	NOT RELATED/OTHER: Multiple antibiotics	2	27	N
2	N	N	Yes	NOT RELATED/OTHER: Stopped birth control	4	32	Y

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	N	N	Resolved (20DEC2020)	Study Treatment	3	1	N
4	TC	N	Resolved (18SEP2020)	NOT RELATED/OTHER: bacterial infection	2	5	N
5	TC	N	Resolved (12JAN2021)	NOT RELATED/OTHER: Tonsillectomy	3	11	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	02OCT2020	
Completed	REPEAT SCREENING 1	18DEC2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	08FEB2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1006 10061040, a 26-year-old white female with an obstetrical history of no prior births/nulliparous and a pertinent medical history of migraine (since 30 Aug 2016), obesity (since 2018), intermittent insomnia (since 27 Mar 2018), major depression (since 13 Jul 2018), and cancer gene carrier (BRCA 1 cancer gene; since Nov 2018), received Dose 1 on 14 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 22). Concomitant medications included eletriptan hydrobromide (since 13 Jun 2018), topiramate (since 09 Aug 2019), naratriptan hydrochloride (since 25 Oct 2019), and botulinum toxin type A (since 31 Jul 2020) for migraine headaches; fluoxetine hydrochloride (since 13 Jun 2018) for major depressive disorder; and trazodone (since 13 Jun 2018) for intermittent insomnia. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 18 Dec 2020 (Day 127) and 08 Jan 2021 (Day 148), respectively, and remains in the study. The subject had an exposure during pregnancy on 08 Feb 2021, 31 days after receiving the second dose of BNT162b2. On an unspecified date, the subject's pregnancy test was positive and the site was informed that the subject was 4 weeks pregnant. The first day of her last menstrual period was 25 Jan 2021 (Day 165) and the estimated date of conception was 08 Feb 2021 (Day 179). It was estimated that the subject stopped using contraception 1 week after the second dose of BNT162b2 and conception occurred approximately 4 weeks later. The estimated delivery date is reported as 01 Nov 2021. The subject and her 27-year-old partner did not smoke, drink alcohol, or use illicit drugs during this pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179.07 cm	109.55 kg	34.1 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DIABETES MELITUS TYPE I	Type 1 diabetes mellitus	1989	Present
ERYTHROMYCIN BASE INTOLERANCE	Drug intolerance	2002	Present
RECURRING COUGH	Cough	2014	Present
dyshidroctic eczema	Dyshidrotic eczema	2018	Present
CALCIFIC TENDINITIS RIGHT HAND	Tendonitis	03NOV2018	Present
ERECTILE DYSFUNCTION	Erectile dysfunction	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	14:13
2	Placebo	08SEP2020 (22)	11:27
3	BNT162b2	15FEB2021 (182)	10:11
4	BNT162b2	09MAR2021 (204)	14:57

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Exposure during pregnancy	Exposure During Partner Pregnancy	01JAN2021 (137)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Yes	NOT RELATED/OTHER: Stopped condoms	2	116	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine	INFLUENZA VACCINE	06OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	09OCT2020	
Completed	REPEAT SCREENING 1	15FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1006 10061052, a 36-year-old white male with a pertinent medical history of type 1 diabetes mellitus (since 1989), dyshidrotic eczema (since 2018), erectile dysfunction (since 2019), and hypertension (since 08 Nov 2019), received Dose 1 on 18 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 22). The subject had an exposure during his partner's pregnancy on 01 Jan 2021, 115 days after the subject received Dose 2. Concomitant medications included insulin aspart (since 2003) for diabetes mellitus type 1, betamethasone valerate (since 01 Mar 2019) for dyshidrotic eczema, sildenafil citrate (since 01 Mar 2019) for erectile dysfunction, lisinopril (since 08 Nov 2019) for hypertension, and vitamin (since 2020; not otherwise specified) as a supplement. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first dose of BNT162b2 on 15 Feb 2021 (Day 182). On that same day (Day 182), the subject informed the site that his partner, who had an obstetrical history of 1 previous pregnancy resulting in a live birth with no complications, was pregnant. The subject confirmed the use of contraception at the time of enrollment and through 28 days after the last dose of investigational product as per protocol requirement. His partner's first day of her last menstrual period was 14 Dec 2020 (Day 119) and the estimated date of conception was 01 Jan 2021 (Day 137). The estimated delivery date is reported as 20 Sep 2021. He and his partner did not smoke, drink alcohol, or use illicit drugs during this pregnancy. On 09 Mar 2021 (Day 204), the subject received the second dose of BNT162b2 and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	62.55 kg	20.3 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
EHLRS DAULOS SYNDROME	Ehlers-Danlos syndrome	1986	Present
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	1986	Present
OPSTURAL ORTHOSTATIC TACHYCHARDIA SYNDROME	Postural orthostatic tachycardia syndrome	1986	Present
DEVIATED SEPTUM	Nasal septum deviation	1987	Past
SEASONAL ALLERGIES	Seasonal allergy	1988	Present
MILD ASTHMA	Asthma	1990	Present
IODINATED CONTRAST MEDIA ALLERGY	Contrast media allergy	1990	Present
PENICILLIN G ALLERGY	Drug hypersensitivity	1990	Present
AMOXICILLIN ALLERGY	Drug hypersensitivity	1990	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
POST TRAUMATIC STRESS DISORDER	Post-traumatic stress disorder	1990	Present
ORAL COLD SORES	Oral herpes	1995	Present
ACNE (FACIAL)	Acne	1998	Present
ATTENTION DEFICIT DISORDER	Attention deficit hyperactivity disorder	1998	Present
MIGRAINES	Migraine	2003	Present
MUSCLE SPASMS (BACK AND SHOULDERS)	Muscle spasms	2003	Present
TEMPORPMANDIBULAR JOINT DYSFUNCTION	Temporomandibular joint syndrome	2003	Present
DEVIATED SEPTUM REPAIR	Nasal septal operation	2004	Past
NISSEN FUNDIPLICATION	Oesophagogastric fundoplasty	2009	Present
RECURRENT SINUSITIS	Sinusitis	2010	Present
DIFFUSE SPASTIC ESOPHAGUS	Oesophageal spasm	2015	Present
HEART MURMUR	Cardiac murmur	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	09:46
2	BNT162b2	18SEP2020 (26)	13:29

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Exposure during pregnancy	Exposure During Pregnancy	15NOV2020 (84)		ONGOING		
2	GENRL	Injection site pain	INJECTION SITE PAIN	19SEP2020 (27)	18:00	20SEP2020 (28)	18:00	2
3	GENRL	Pain	GENERALIZED ACHES	19SEP2020 (27)	18:00	20SEP2020 (28)	18:00	2
4	GENRL	Pyrexia	FEVER	19SEP2020 (27)	18:00	20SEP2020 (28)	18:00	2

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		N	N	Yes	NOT RELATED/OTHER: condom failure	2	59	Y
2	1	N	N	Resolved (20SEP2020)	Study Treatment	2	2	N
3	1	N	N	Resolved (20SEP2020)	Study Treatment	2	2	N
4	2	TC	N	Resolved (20SEP2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	16OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1006 10061094, a 35-year-old white female with a pertinent obstetrical history of 1 previous pregnancy resulting in 1 live birth (in 2019) and pertinent medical history of Ehlers-Danlos syndrome (since 1986), asthma (since 1990), muscle spasms and migraine (both since 2003), and cardiac murmur (since 2019), received Dose 1 on 24 Aug 2020 and Dose 2 on 18 Sep 2020 (Day 26). The subject had a positive urine pregnancy test on 01 Dec 2020 (Day 100), and a maternal exposure before pregnancy was reported on 15 Nov 2020, 58 days after receiving Dose 2. Concomitant medications included albuterol sulfate (since 1995) for mild asthma, naratriptan hydrochloride (since 22 Jun 1995) for migraines, tizanidine hydrochloride (since 11 Sep 2015) for muscle spasms, promethazine hydrochloride (since Jun 2020) for seasonal allergies, and rimegepant (since 13 Jul 2020) for migraines. The subject informed the site that on 01 Dec 2020 (Day 100), her home urine pregnancy test was positive. The contraception method used at the time of conception was confirmed to be a barrier method (condom). The first day of her last menstrual period was 01 Nov 2020 (Day 70), the estimated date of conception was 15 Nov 2020 (Day 84), and the estimated delivery date is reported as 08 Aug 2021. The subject and her 34-year-old partner did not smoke, drink alcohol, or use illicit drugs during this pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	39	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	79.36 kg	30 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2000	Present
Seasonal allergies	Seasonal allergy	2000	Present
Generalized anxiety disorder	Generalised anxiety disorder	2010	Present
Hypertension	Hypertension	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15SEP2020 (1)	11:36
2	BNT162b2	06OCT2020 (22)	09:10

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	23DEC2020 (100)		ONGOING			
2	GENRL	Injection site pain	Injection site pain	16SEP2020 (2)		17SEP2020 (3)		2	1
3	GENRL	Injection site pain	Injection site pain	07OCT2020 (23)		08OCT2020 (24)		2	1
4	GENRL	Pain	Body aches	07OCT2020 (23)		09OCT2020 (25)		3	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: positive pregnancy test	2	79	Y
2	N	N	Resolved (17SEP2020)	Study Treatment	1	2	N
3	N	N	Resolved (08OCT2020)	Study Treatment	2	2	N
4	N	N	Resolved (09OCT2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Quadrivalent flu vaccine prophylaxis intramuscular 0.5 ml once	INFLUENZA VACCINE	21OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15SEP2020	
Completed	VACCINATION	03NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1008 10081337, a 39-year-old white female with no pertinent medical history or obstetrical history (no previous pregnancies), received Dose 1 on 15 Sep 2020 and Dose 2 on 06 Oct 2020 (Day 22). The subject reported maternal exposure before pregnancy on 23 Dec 2020, 78 days after receiving Dose 2. Concomitant medications included citalopram (since 2010) for anxiety and amlodipine (since Feb 2020) for hypertension. On 26 Jan 2021 (Day 134), the subject informed the site that she had a positive urine human chorionic gonadotropin test on 25 Jan 2021 (Day 133). As per protocol requirement, she confirmed at the visit on 03 Nov 2020 (Day 50) the use of contraceptives (condom with spermicide). The first day of her last menstrual period was 23 Dec 2020 (Day 100) and the estimated date of conception was 09 Jan 2021 (Day 117). Her first obstetrician appointment was scheduled on 24 Feb 2021 (Day 163) and she had not undergone any ultrasound examination. The estimated delivery date is reported as 29 Sep 2021. The subject did not smoke, drink alcohol, or use illicit drugs during this pregnancy. The subject's 40-year-old male partner did not smoke or use illicit drugs; however, he drank alcohol (4 units per week) during this pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	25	Asian	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.6 cm	79.3 kg	30 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ATTENTION DEFICIT HYPERACTIVITY DISORDER	Attention deficit hyperactivity disorder	2010	Present
OBESITY	Obesity	2016	Present
BREAST AUGMENTATION	Mammoplasty	JUN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	09:40
2	Placebo	10SEP2020 (23)	14:50

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure During Pregnancy	10DEC2020 (114)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N	Yes	NOT RELATED/OTHER: PREGNANCY	2	92	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	14OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1013 10131229, a 25-year-old Asian female with a pertinent medical history of obesity (since 2016) and mammoplasty (in Jun 2020) and an obstetrical history of 1 previous pregnancy resulting in 1 live birth, received Dose 1 on 19 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 23). The subject had an exposure during pregnancy on 10 Dec 2020, 91 days after receiving Dose 2. Concomitant medication included desogestrel/ethinyl estradiol (since 2019) for birth control. On 21 Jan 2021 (Day 156), the subject informed the site that a home pregnancy test done on an unspecified date was positive and she had an appointment with her obstetrician/gynecologist to confirm the home test. The first day of her last menstrual period was 26 Nov 2020 (Day 100) and the estimated date of conception was 10 Dec 2020 (Day 114). The estimated delivery date is reported as 02 Sep 2021. The subject and her partner did not smoke, drink alcohol, or use illicit drugs during the pregnancy. The subject's partner did not take any drugs during the subject's pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178 cm	60.5 kg	19.1 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
WISDOM TEETH REMOVAL	Wisdom teeth removal	MAY2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	10:10
2	Placebo	10SEP2020 (22)	15:50

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	PREG	Abortion spontaneous	MISCARRIAGE	OCT2020 ()		OCT2020 ()			3	N
2	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	SEP2020 ()		OCT2020 ()				N

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (OCT2020)	NOT RELATED/OTHER: MISCARRIAGE	2		Y
2	N	Resolved (OCT2020)	NOT RELATED/OTHER: PREGNANCY WITH MISCARRIAGE			Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	14OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1013 10131255, a 30-year-old white female with no pertinent medical or obstetrical history, received Dose 1 on 20 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 22). The subject had an exposure during pregnancy in Sep 2020 and reported a spontaneous abortion in Oct 2020. During a follow-up call by the research assistant, the subject reported that she had become pregnant in Sep 2020. She used condoms with spermicides as a contraceptive method. The first day of her last menstrual period was in Aug 2020 and the estimated date of conception was in Sep 2020. The gestational age at the time of initial exposure was first trimester. The subject and her 32-year-old partner did not smoke tobacco, drink alcohol, or use illicit drugs during the pregnancy. On an unknown date in Oct 2020, the subject had a spontaneous abortion. In the opinion of the investigator, there was no reasonable possibility that the spontaneous abortion was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
190.5 cm	93.18 kg	25.6 kg/m2	13AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13AUG2020 (1)	13:34
2	Placebo	03SEP2020 (22)	13:18

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	28JAN2021 (169)	16:30
4	BNT162b2	18FEB2021 (190)	13:06

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Exposure during pregnancy	Exposure During Partner Pregnancy	25NOV2020 (105)		ONGOING			

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: Pregnancy occured unrelated to vaccine	2	84	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	01OCT2020	
Completed	REPEAT SCREENING 1	28JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1015 10151011, a 30-year-old white male with a pertinent medical history of generalized anxiety disorder (unknown date), received Dose 1 on 13 Aug 2020 and Dose 2 on 03 Sep 2020 (Day 22). The subject's partner had an exposure during pregnancy on 25 Nov 2020, 83 days after the subject received Dose 2. Concomitant medications included fluoxetine hydrochloride (since 25 Aug 2018) for generalized anxiety disorder. On 28 Jan 2021 (Day 169) when the subject received the first dose of BNT162b2, he informed the site that his partner, with no pertinent obstetrical history, was pregnant. On 26 Dec 2020 (Day 136), the subject's partner's pregnancy test was positive. The first day of the subject's partner's last menstrual period was 25 Nov 2020 (Day 105) and the estimated date of conception was 09 Dec 2020 (Day 119). The subject confirmed no use of condoms since the start of pregnancy or during receipt of BNT162b2 and also confirmed that his partner was taking oral contraceptive pills when she conceived (dates not reported). The subject and his partner did not smoke, drink alcohol, or use illicit drugs during the pregnancy. The estimated date of delivery is 01 Sep 2021. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 28 Jan 2021 (Day 169) and 18 Feb 2021 (Day 190), respectively, and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	32	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	53.18 kg	18.3 kg/m2	20AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	11:48
2	Placebo	10SEP2020 (22)	10:32

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	21DEC2020 (124)	13:06
4	BNT162b2	11JAN2021 (145)	11:01

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy	07JAN2021 (141)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N	Yes	NOT RELATED/OTHER: Unrelated	3	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	09OCT2020	
Completed	REPEAT SCREENING 1	21DEC2020	
Completed	OPEN LABEL TREATMENT	16FEB2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1015 10151071, a 32-year-old white female with no medical history or obstetric history (no previous pregnancies) reported, received Dose 1 on 20 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 21 Dec 2020 (Day 124) and 11 Jan 2021 (Day 145), respectively, and remains in the study. The subject had an exposure during pregnancy on 07 Jan 2021, 17 days after receiving the first dose of BNT162b2. On 16 Feb 2021 (Day 181) during a study visit call (Visit 103), the subject reported that she was pregnant. She confirmed contraception use (condoms) during both doses of BNT162b2. The pregnancy was not confirmed by her obstetrician-gynecologist. The first day of her last menstrual period was 07 Jan 2021 (Day 141) and the estimated date of conception was 19 Jan 2021 (Day 153). The estimated delivery date is reported as 14 Oct 2021. The subject did not smoke, drink alcohol, or use illicit drugs during the pregnancy. The subject's 36-year old partner did not take any medications, smoke, or use illicit drugs but drank alcohol twice a month during the pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1987	33	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	79.55 kg	24.4 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	1987	Present
Acne	Acne	2000	Present
ADHD	Attention deficit hyperactivity disorder	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	17:35
2	BNT162b2	15SEP2020 (22)	14:37

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PREG	Exposure during pregnancy	Exposure during pregnancy (partner)	22JAN2021 (151)		ONGOING		
2	METAB	Gout	Gout	01OCT2020 (38)	06:00	12OCT2020 (49)	08:00	12

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Yes	NOT RELATED/OTHER: Not realted	2	130	Y
2	1	TC	N	Resolved (12OCT2020)	Study Treatment	2	17	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	13OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1015 10151101, a 33-year-old white male with no pertinent medical history, received Dose 1 on 25 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 22). The subject's partner had an exposure during pregnancy on 22 Jan 2021, 129 days after the subject received Dose 2. Concomitant medications included tretinoin (since 2000) and cefadroxil (from 2000 to Dec 2020), both for acne, and lisdexamfetamine mesylate (since 2010) for attention deficit hyperactivity disorder. The subject's partner's pregnancy was confirmed by a physician on 05 Mar 2021 (Day 193). It was reported that his partner had stopped using contraception from the end of December 2020 (more than 28 days after the last vaccination and hence permitted per protocol). The female partner was also vaccinated against COVID-19 (not part of the study); however, the date and brand were not reported. The first day of the subject's partner's last menstrual period was 10 Jan 2021 (Day 139) with an estimated date of conception of 22 Jan 2021 (Day 151). The subject and his partner denied smoking, alcohol use, or use of illicit drugs during the pregnancy. His partner had no previous pregnancy history.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1991	29	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	110.91 kg	41.9 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Attention Deficit Hyperactivity Disorder	Attention deficit hyperactivity disorder	NOV2015	Present
Restless Leg syndrome	Restless legs syndrome	NOV2015	Present
Factor 5 Leiden Mutation	Factor V Leiden mutation	FEB2019	Present
Obesity	Obesity	MAY2019	Present
Migraines	Migraine	JAN2020	Present
Anxiety	Anxiety	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	12:12
2	Placebo	02SEP2020 (22)	14:57
3	BNT162b2	23DEC2020 (134)	10:44
4	BNT162b2	13JAN2021 (155)	09:24

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Cellulitis	cellulitis of face	31JAN2021 (173)		10FEB2021 (183)		11	1
2	INJ&P	Exposure during pregnancy	exposure during pregnancy	03FEB2021 (176)		ONGOING			

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (10FEB2021)	NOT RELATED/OTHER: bacterial skin infection	4	19	N
2	N	N	Yes	NOT RELATED/OTHER: pregnancy	4	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	30SEP2020	
Completed	REPEAT SCREENING 1	23DEC2020	
Completed	OPEN LABEL TREATMENT	10FEB2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1016 10161103, a 29-year-old white female with an obstetrical history of 1 previous pregnancy complicated by preeclampsia with a healthy live birth, and a pertinent medical history of attention deficit hyperactivity disorder (ADHD) and restless legs syndrome (both since Nov 2015), factor V Leiden mutation (since Feb 2019), obesity (since May 2019), migraine (since Jan 2020), and anxiety (since Jun 2020), received Dose 1 on 12 Aug 2020 and Dose 2 on 02 Sep 2020 (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 23 Dec 2020 (Day 134) and 13 Jan 2021 (Day 155), respectively, and remains in the study. The subject reported being pregnant (exposure during pregnancy) on 03 Feb 2021, 21 days after receiving the second dose of BNT162b2. Concomitant medications included amfetamine aspartate/amfetamine sulfate/dexamfetamine saccharate/dexamfetamine sulfate (since Nov 2015) for ADHD, clonazepam (since Nov 2015) for restless legs syndrome, acetylsalicylic acid (since Feb 2019) for factor V Leiden mutation, liraglutide (since May 2019) for obesity, topiramate (since Jan 2020) for migraines, and duloxetine hydrochloride (since Jun 2020) for anxiety. During a routine gynecologist appointment to change her intrauterine device (IUD) on 23 Feb 2021 (Day 196), the subject learned that she was pregnant. The first day of her last menstrual period was 19 Dec 2020 (Day 130); she stated that she had infrequent menses because of the IUD, and an estimated date of conception was 03 Feb 2021 (Day 176). The gestational age at the time of initial exposure was first trimester. The estimated delivery date is reported as 26 Oct 2021. The subject did not smoke, drink alcohol, or use illicit drugs during the pregnancy. The subject's 33-year-old partner did not use illicit drugs but smoked 1 pack per day and drank 6 beers per day during the subject's pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1993	26	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	86.09 kg	32.5 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	MAR2003	Present
spontaneous abortion	Abortion spontaneous	MAR2020	Past
dilation and cirettage	Uterine dilation and curettage	MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	09SEP2020 (1)	12:32
2	BNT162b2	28SEP2020 (20)	10:50

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	exposure during pregnancy	29NOV2020 (82)			

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N		NOT RELATED/OTHER: pregnancy	2	63	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Hepatitis B Vaccine	HEPATITIS B VACCINE	15DEC2020
MMR Vaccine	MEASLES VACCINE;MUMPS VACCINE;RUBELLA VACCINE	15DEC2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	27OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1016 10161265, a 26-year-old white female with a pertinent obstetrical history of 1 previous pregnancy that resulted in miscarriage (spontaneous abortion) requiring uterine dilation and curettage at 10 weeks (in Mar 2020), received Dose 1 on 09 Sep 2020 and Dose 2 on 28 Sep 2020 (Day 20). The subject had a reported exposure during pregnancy on 29 Nov 2020, 62 days after receiving Dose 2. On 11 Dec 2020 (Day 94), the subject's urine pregnancy test was positive. The first day of her last menstrual period was 10 Nov 2020 (Day 63), the estimated date of conception was 29 Nov 2020 (Day 82), and the estimated delivery date is 15 Aug 2021. The subject's 28-year-old male partner had a family history of trisomy 19 (partner's (b) (6)). The subject did not smoke, drink alcohol, or use illicit drugs during this pregnancy, and her partner did not take any medications during this pregnancy. The prenatal ultrasound scan performed on 19 Jan 2021 (Day 133) was normal.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	36	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	86.09 kg	32.5 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Penicillin allergy	Drug hypersensitivity	1984	Present
Generalized Anxiety	Generalised anxiety disorder	APR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10AUG2020 (1)	12:22
2	Placebo	01SEP2020 (23)	13:19

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Exposure during pregnancy	Exposure during Pregnancy	24NOV2020 (107)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Yes	NOT RELATED/OTHER: Unprotected sexual activity	2	85	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Moderna Covid 19 Vaccine	COVID-19 VACCINE MRNA (MRNA 1273)	05MAR2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10AUG2020	
Completed	VACCINATION	06OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1018 10181111, a 36-year-old white female with a pertinent medical history of generalized anxiety disorder (since Apr 2019) and no previous pregnancies, received Dose 1 on 10 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 23). The subject had a reported exposure during pregnancy on 24 Nov 2020, 84 days after receiving Dose 2. Concomitant medication included sertraline hydrochloride (since Mar 2020) for anxiety. On 09 Jan 2021 (Day 153), before Visit 101, the subject's serum pregnancy test (human chorionic gonadotropin) showing 129,975 mIU/mL [normal range: less than 5 (nonpregnant) and less than 10 mIU/mL (postmenopausal)] was positive. The estimated date of conception was 24 Nov 2020 (Day 107). On 11 Jan 2021 (Day 155), the subject visited her gynecologist and an abdominal ultrasound scan confirmed that she was pregnant, with the gestational age estimated to be 9 weeks. She also reported condom use and felt her pregnancy was due to contraceptive failure. The estimated delivery date is reported as 17 Sep 2021. The subject received ascorbic acid (since 27 Nov 2020) as a supplement. She drank alcohol 1 unit per month prior to her pregnancy, and the subject's 35-year old partner drank alcohol 2 to 3 units weekly, but he did not take any drugs (over-the-counter or prescription) during the pregnancy. The subject and her partner did not smoke or use illicit drugs during the pregnancy. The subject also received nonstudy COVID-19 mRNA vaccine (mRNA 1273) on 05 Mar 2021.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.99 cm	68.09 kg	22.4 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic Rhinitis	Rhinitis allergic	2004	Present
Iron-Deficiency Anemia	Iron deficiency anaemia	2006	Present
Myopia	Myopia	2008	Present

Reason(s) for Narrative: Pregnancy
Unique Subject ID: C4591001 1019 10191002; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 10AUG2020; Date of Last Dose: 31AUG2020

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	10AUG2020 (1)	09:13
2	BNT162b2	31AUG2020 (22)	08:15

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Exposure during pregnancy	Exposure During Pregnancy	26SEP2020 (48)		ONGOING		

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		N	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	27	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10AUG2020	
Completed	VACCINATION	29SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1019 10191002, a 31-year-old white female with a pertinent obstetrical history of 2 previous pregnancies resulting in 2 live births and a pertinent medical history of iron-deficiency anemia (since 2006), received Dose 1 on 10 Aug 2020 and Dose 2 on 31 Aug 2020 (Day 22). The subject had a reported exposure during pregnancy on 26 Sep 2020, 26 days after receiving Dose 2. Concomitant medications included iron (since 2019) as a supplement and norethisterone (19 Aug 2020 to 17 Oct 2020) for contraception. On 02 Dec 2020 (Day 115), the subject contacted the site after her obstetrician/gynecologist appointment and reported a positive pregnancy test on 27 Oct 2020 (Day 79). The first day of her last menstrual period was 26 Sep 2020 (Day 48) and the estimated date of conception was 10 Oct 2020 (Day 62). The gestational age at the time of initial exposure was first trimester. Per the subject, she was 9 weeks pregnant (b) (6) with an estimated date of delivery of 03 Jul 2021. The subject's 31-year-old male partner/husband who was also part of the study received his first dose on 12 Aug 2020 and the second dose on 02 Sep 2020. The subject and her husband did not smoke, drink alcohol, or use illicit drugs during this pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	61	Black or African American	Not reported	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.2 cm	69.4 kg	24 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYSTERECTOMY	Hysterectomy	1980	Past
UTERINE FIBROIDS	Uterine leiomyoma	1980	Past
ARTHRITIS	Arthritis	2000	Present
hypertension	Hypertension	2010	Present
HYPERLIPIDEMIA	Hyperlipidaemia	2015	Present
LEFT TOTAL HIP REPLACEMENT	Hip arthroplasty	JAN2019	Past
ARTERIAL THROMBOSIS	Arterial thrombosis	FEB2020	Past
CONGESTIVE HEART FAILURE	Cardiac failure congestive	FEB2020	Present
HYPOKALEMIA	Hypokalaemia	FEB2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	12:07
2	BNT162b2	23SEP2020 (20)	10:45

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	08FEB2021 (158)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	N	N	Yes	NOT RELATED/OTHER: PREGNANCY	2	139	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
After the data cutoff date of 13 Mar 2021 (with database snapshot taken on 25 Mar 2021), it was determined that Subject C4591001 1037 10371141 was not pregnant and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	24	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.6 cm	68 kg	24.2 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ASTHMA	Asthma	JAN2001	Present
SEASONAL ALLERGIES	Seasonal allergy	JAN2001	Present
MIGRAINE HEADACHES	Migraine	JAN2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15SEP2020 (1)	09:21
2	Placebo	05OCT2020 (21)	15:45
3	BNT162b2	18DEC2020 (95)	13:10
4	BNT162b2	11JAN2021 (119)	16:30

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	08FEB2021 (147)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	N	N	Yes	NOT RELATED/OTHER: PREGNANCY	4	29	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINE	INFLUENZA VACCINE	19OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15SEP2020	
Completed	VACCINATION	04NOV2020	
Completed	REPEAT SCREENING 1	18DEC2020	
Completed	OPEN LABEL TREATMENT	08FEB2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1037 10371214, a 24-year-old white female with no pertinent medical history, received Dose 1 on 15 Sep 2020 and Dose 2 on 05 Oct 2020 (Day 21). Concomitant medications included ethinyl estradiol/norgestimate (from Mar 2009 to 2021) for birth control, loratadine (since Jan 2010) for seasonal allergies; acetylsalicylic acid/caffeine (since Jan 2010) for migraine headaches; and fluticasone propionate/salmeterol xinafoate (since Jan 2018) and salbutamol sulfate (since May 2020) for asthma. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 18 Dec 2020 (Day 95) and 11 Jan 2021 (Day 119), respectively, and remains in the study. The subject had an exposure before pregnancy on 08 Feb 2021, 28 days after receiving the second dose of BNT162b2. After the data cutoff date of 13 Mar 2021 (with database snapshot taken on 25 Mar 2021), the subject reported that she was pregnant and had her pregnancy test done in the previous week (date unspecified). The first date of her last menstrual period was 08 Feb 2021 (Day 147) and the estimated date of conception was 19 Feb 2021 (Day 158). The subject denied smoking, alcohol use, or use of illicit drugs during the pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	29	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	106.45 kg	36.7 kg/m2	19AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	10:09
2	BNT162b2	09SEP2020 (22)	08:52

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Exposure during pregnancy	Exposure during Pregnancy	19AUG2020 (1)		ONGOING		

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		N	N	Yes	NOT RELATED/OTHER: Birth Control Failure	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Withdrawn	VACCINATION	19OCT2020	OTHER
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1042 10421129, a 29-year-old black or African American female with a pertinent obstetrical history of 3 previous pregnancies that resulted in 1 miscarriage and 2 live births (1 live child and 1 death of a child due to delivery at 24 weeks), received Dose 1 on 19 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 22). The subject had an exposure during pregnancy on 19 Aug 2020, on the day of Dose 1 administration. Concomitant medication included medroxyprogesterone acetate (from Nov 2019 to Jun 2020) for birth control. The first day of her last menstrual period was 22 Jul 2020. Her estimated date of conception was 24 Jul 2020 and the gestational age at the time of initial exposure was 4 weeks. The subject and her 32-year-old partner never smoked, drank alcohol, or used illicit drugs during this pregnancy. She contacted the site to request unblinding and reported to the site that she was 7 months pregnant. It was reported that this pregnancy is a dichorionic diamniotic twin pregnancy. The estimated date of delivery is 28 Apr 2021.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	29	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	71.82 kg	24.7 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Eczema	Eczema	1991	Present
Seasonal Allergies	Seasonal allergy	1992	Present
Asthma	Asthma	1993	Present
Food Allergy (Milk)	Milk allergy	1998	Present
Insomnia	Insomnia	2001	Present
Anxiety	Anxiety	2005	Present
Peptic Ulcer	Peptic ulcer	2009	Present
Attention Deficit Disorder	Attention deficit hyperactivity disorder	2012	Present
Migraines	Migraine	2012	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bipolar Disorder Type II	Bipolar II disorder	2015	Present
Medication Allergy (Trileptal)	Drug hypersensitivity	2016	Present
Knee Pain [L]	Arthralgia	2018	Present
Osteonecrosis of the Knee [L]	Osteonecrosis	2018	Past
Core Decompression [L] Knee	Knee operation	19FEB2019	Past
Blood Clots (Thrombus)	Thrombosis	APR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	11:16
2	Placebo	29SEP2020 (20)	16:48
3	BNT162b2	18JAN2021 (131)	11:30
4	BNT162b2	10FEB2021 (154)	16:22

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure During Pregnancy	20JAN2021 (133)		ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1			N	N	Yes	NOT RELATED/OTHER: n/a	3	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	27OCT2020	
Completed	REPEAT SCREENING 1	18JAN2021	
Completed	OPEN LABEL TREATMENT	11MAR2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1042 10421217, a 29-year-old white female with a pertinent medical history of asthma (since 1993), anxiety (since 2005), attention deficit hyperactivity disorder (since 2012), bipolar II disorder (since 2015), and thrombosis (since Apr 2019), and a pertinent obstetrical history of 3 previous pregnancies, including 1 full-term birth on 31 May 2012, a miscarriage in 2014, and an elective abortion in Aug 2020, received Dose 1 on 10 Sep 2020 and Dose 2 on 29 Sep 2020 (Day 20). Concomitant medications included gabapentin (since 2018) and diazepam (since 20 Oct 2020) for anxiety, montelukast sodium (since 2018) for asthma, lamotrigine (since Jul 2019) for bipolar II disorder, and amfetamine aspartate/amfetamine sulfate/dexamfetamine saccharate/dexamfetamine sulfate (since Apr 2020) for attention deficit hyperactivity disorder. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 18 Jan 2021 (Day 131) and 10 Feb 2021 (Day 154), respectively, and remains in the study. The subject had an exposure during pregnancy on 20 Jan 2021, 2 days after receiving the first dose of BNT162b2. On 11 Mar 2021 (Day 183), the subject was contacted for Visit 103 and reported that she went to the emergency room (ER). On 12 Mar 2021 (Day 184), per the ER records, the subject had a positive pregnancy test, with mild vaginal bleeding and no mention of miscarriage. She was discharged in good condition and was instructed to follow up with an obstetrician-gynecologist; however, she had not yet followed up at the time of the last available report. The first day of her last menstrual period was 01 Jan 2021 (Day 114) and, per the subject, the date of conception was 20 Jan 2021. The subject smoked (e-cigarettes daily) and her 37-year old partner smoked; however, they did not drink alcohol or use illicit drugs during this pregnancy. The estimated date of delivery is 08 Oct 2021.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	24	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	139.55 kg	58 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillectomy	Tonsillectomy	2001	Past
Tonsillitis	Tonsillitis	2001	Past
Obsessive Compulsive Disorder	Obsessive-compulsive disorder	2015	Present
Hair Loss	Alopecia	2017	Present
Cholecystectomy	Cholecystectomy	2019	Past
Inflamed Gallbladder	Cholecystitis	2019	Past
Pancreatitis	Pancreatitis	2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27AUG2020 (1)	13:30
2	BNT162b2	18SEP2020 (23)	12:20

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Pregnancy Exposure	09JAN2021 (136)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N	Yes	NOT RELATED/OTHER: unknown	2	114	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	16OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1046 10461118, a 24-year-old white female with an obstetrical history of 3 previous pregnancies with 3 live births, received Dose 1 on 27 Aug 2020 and Dose 2 on 18 Sep 2020 (Day 23). The subject had a maternal exposure before pregnancy on 09 Jan 2021, 113 days after receiving Dose 2. Concomitant medications included fluoxetine hydrochloride (since 2015) for obsessive compulsive disorder, folic acid (since 2017) for hair loss, and drospirenone/ethinyl estradiol (since 2020) for birth control. On 11 Mar 2021 (Day 197), the subject reported that she was 10 weeks pregnant. The first date of her last menstrual period was in Dec 2020. The subject and her partner denied smoking, alcohol use, or use of illicit drugs during the pregnancy. The subject reported that she had been taking drospirenone/ethinyl estradiol as instructed.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1991	29	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	109.09 kg	32.5 kg/m2	14OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
c section	Caesarean section	2009	Past
c section	Caesarean section	2010	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14OCT2020 (1)	10:42
2	Placebo	02NOV2020 (20)	09:05

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy	DEC2020 ()		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N	Yes	NOT RELATED/OTHER: pregnancy	2		Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14OCT2020	
Completed	VACCINATION	30NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1047 10471318, a 29-year-old black or African American female with a pertinent medical history of obesity and substance abuse (tetrahydrocannabinol and cocaine use) and an obstetrical history of 3 previous pregnancies with 2 live births via cesarean sections (in 2009 and 2010) and 1 spontaneous miscarriage, received Dose 1 on 14 Oct 2020 and Dose 2 on 02 Nov 2020 (Day 20). The subject had an exposure during pregnancy on 23 Nov 2020 (Day 41). The subject reported that she was pregnant at the unblinding contact visit on 05 Feb 2021 (Day 115). The date of her last menstrual period was 04 Nov 2020 (Day 22) and the gestational period was thought to be 12 weeks. It was reported that the subject's pregnancy test had been negative at Visit 2. The subject did not smoke or use illicit drugs (she stated would not use/was not using currently) but drank alcohol occasionally during the pregnancy. The subject's 40-year-old partner did not smoke, drink alcohol, or use illicit or any drugs during the subject's pregnancy. An ultrasound scan indicated that the estimated date of conception was 23 Nov 2020 (Day 41) and the expected date of delivery is 30 Aug 2021.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	24	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	75.91 kg	25.4 kg/m2	04SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	10:11
2	BNT162b2	25SEP2020 (22)	08:43

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy	20SEP2020 (17)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Yes	NOT RELATED/OTHER: failed contraception	1	17	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Withdrawn	VACCINATION	12NOV2020	OTHER
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1048 10481088, a 24-year-old white female with no pertinent medical or obstetrical history, received Dose 1 on 04 Sep 2020 and Dose 2 on 25 Sep 2020 (Day 22). The subject had a reported exposure during pregnancy on 20 Sep 2020, 16 days after receiving Dose 1. The subject took a home pregnancy test on 01 Nov 2020 (Day 59), which was positive. The first day of her last menstrual period was 20 Sep 2020 (Day 17). The estimated date of conception was 04 Oct 2020 (Day 31). The estimated date of delivery is reported as 27 Jun 2021. The subject did not smoke, drink alcohol, or use illicit drugs during this pregnancy. Her 29-year-old partner did not smoke or use illicit drugs or any drugs, but drank alcohol, during the subject's pregnancy. After the data cutoff date of 13 Mar 2021 (with database snapshot taken on 25 Mar 2021), the subject attended Visit 4 (on 17 Mar 2021) and protocol-required samples were taken; therefore, the subject is still continuing in the study for safety, efficacy, and immunogenicity.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	30	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.2 cm	80.4 kg	27.4 kg/m2	20AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	13:33
2	BNT162b2	08SEP2020 (20)	12:00

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Exposure during pregnancy	Exposure during Partner pregnancy	04FEB2021 (169)		ONGOING		
2	GENRL	Fatigue	Fatigue	20AUG2020 (1)	15:30	21AUG2020 (2)	08:00	2
3	GENRL	Fatigue	Fatigue	08SEP2020 (20)	14:00	09SEP2020 (21)	07:00	2
4	GENRL	Feeling hot	Warm feeling of neck and head	20AUG2020 (1)	14:05	21AUG2020 (2)	09:00	2
5	GENRL	Pyrexia	Low grade fever	08SEP2020 (20)	14:00	09SEP2020 (21)	07:00	2

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		N	N	Yes	NOT RELATED/OTHER: sexual intercourse	2	150	Y
2	1	N	N	Resolved (21AUG2020)	Study Treatment	1	1	N
3	1	N	N	Resolved (09SEP2020)	Study Treatment	2	1	N
4	1	TC	N	Resolved (21AUG2020)	Study Treatment	1	1	N
5	1	TC	N	Resolved (09SEP2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu Vaccine	INFLUENZA VACCINE	09OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	08OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1055 10551084, a 30-year-old Asian male with no pertinent medical history, received Dose 1 on 20 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 20). The subject's partner had an exposure before pregnancy on 04 Feb 2021, 149 days after the subject received Dose 2. Concomitant medication included fish oil (since 2019) as a supplement. The subject reported that his partner was pregnant on 04 Feb 2021 (Day 169). The first day of his partner's last menstrual period was 21 Jan 2021 (Day 155) and the estimated date of conception was 04 Feb 2021 (Day 169). The subject did not smoke, drink alcohol, or use illicit drugs during his partner's pregnancy. The pregnancy was reported to be normal (no further details were available).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	47	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174.5 cm	70 kg	23 kg/m2	24AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	11:38
2	BNT162b2	15SEP2020 (23)	14:13

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Exposure during pregnancy	Exposure during partner pregnancy	03FEB2021 (164)		ONGOING		
2	NERV	Headache	Headache	16SEP2020 (24)	08:00	16SEP2020 (24)	10:00	1
3	GENRL	Injection site pain	Injection Site Pain	24AUG2020 (1)	17:00	26AUG2020 (3)	08:00	3
4	GENRL	Injection site pain	Injection site pain	15SEP2020 (23)	17:00	17SEP2020 (25)	17:00	3

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		N	N	Yes	NOT RELATED/OTHER: sexual intercourse	2	142	Y
2	1	N	N	Resolved (16SEP2020)	Study Treatment	2	2	N
3	1	N	N	Resolved (26AUG2020)	Study Treatment	1	1	N
4	1	N	N	Resolved (17SEP2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu vaccine	INFLUENZA VACCINE	14OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	13OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1055 10551092, a 47-year-old white male with no pertinent medical history, received Dose 1 on 24 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 23). The subject had an exposure during his partner's pregnancy on 03 Feb 2021, 141 days after the subject received Dose 2. Concomitant medications included multivitamins (since 1982) as a supplement, fish oil (since 2010) as a supplement, and lysine (since 2018) as a supplement and as cold sore prophylaxis. The subject reported that his partner was pregnant on 03 Feb 2021 (Day 164). The first day of his partner's last menstrual period was 20 Jan 2021 (Day 150) and the estimated date of conception was 03 Feb 2021 (Day 164). The subject did not smoke or use illicit drugs but drank alcohol at 1 unit per week during his partner's pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1987	32	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	112.27 kg	38.7 kg/m2	02SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	14:00
2	Placebo	25SEP2020 (24)	12:04

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure During Pregnancy	19OCT2020 (48)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N	Yes	NOT RELATED/OTHER: N/A	2	25	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	27OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1085 10851246, a 32-year-old white female with a pertinent obstetrical history of 6 previous pregnancies with 4 live births, 1 molar pregnancy, and 1 spontaneous miscarriage, received Dose 1 on 02 Sep 2020 and Dose 2 on 25 Sep 2020 (Day 24). The subject's pregnancy test was positive on 16 Nov 2020 (Day 76) and she had an exposure during pregnancy on 19 Oct 2020, 24 days after receiving Dose 2. Concomitant medications included drospirenone/ethinylestradiol Betadex clathrate (from 2018 to Oct 2020) and ethinylestradiol/norethisterone acetate (from Oct 2020 to 16 Oct 2020) for hormonal birth control. On 18 Nov 2020 (Day 78), the subject reported that she was on birth control pills that were not covered by her insurance and switched to a different brand. The subject reported no missed pills or delay in starting the new pack. The first day of her last menstrual period was 19 Oct 2020 (Day 48), but she decided to take a home pregnancy test after being sick for several mornings. Her pregnancy test was positive on 16 Nov 2020 (Day 76). Per the subject, a transvaginal ultrasound scan performed on 18 Nov 2020 (Day 78) confirmed a pregnancy of 6 weeks 5 days' gestation, with an estimated date of conception of 02 Oct 2020 (Day 31). The subject's continued menstrual cycle resulted in the discrepant dates. The subject and her partner were nonsmokers, did not drink alcohol, and did not use illicit drugs during the pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	22	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.77 cm	67.91 kg	21.9 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
right shoulder injury	Limb injury	2014	Past
right shoulder surgery	Shoulder operation	2014	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	12:32
2	BNT162b2	15SEP2020 (22)	14:25

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Exposure during pregnancy	Exposure During Partner Pregnancy	25DEC2020 (123)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Yes	NOT RELATED/OTHER: unsafe sexual intercourse	2	102	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	13OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1089 10891181, a 22-year-old black or African American male with no pertinent medical history, received Dose 1 on 25 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 22). The subject's partner had an exposure during pregnancy on 25 Dec 2020, 101 days after the subject received Dose 2. The subject smoked (1-2 cigarettes per day) but did not drink alcohol or use illicit drugs during his partner's pregnancy (Subject C4591001 1089 10891273).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2000	19	Black or African American	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	62.91 kg	22.3 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin drug allergy	Drug hypersensitivity	2002	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	09SEP2020 (1)	14:49
2	BNT162b2	02OCT2020 (24)	15:51

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Exposure during pregnancy	Exposure during Pregnancy	25DEC2020 (108)		ONGOING		

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		N	N	Yes	NOT RELATED/OTHER: subject of childbearing potential	2	85	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	30OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1089 10891273, a 19-year-old black or African American female with no pertinent medical history or previous pregnancies, received Dose 1 on 09 Sep 2020 and Dose 2 on 02 Oct 2020 (Day 24). The subject had an exposure during pregnancy on 25 Dec 2020, 84 days after receiving Dose 2. The subject abstained from sex as per protocol requirements from 09 Sep 2020 (Day 1; Visit 1) to 30 Oct 2020 (Day 52; Visit 3). On 18 Feb 2021 (Day 163), she informed the site that she was pregnant, and that the delivery date would be in Sep 2021. The first day of her last menstrual period was 25 Nov 2020 (Day 78) and the estimated date of conception was 25 Dec 2020 (Day 108). The subject did not smoke, drink alcohol, or use illicit drugs during this pregnancy. Her 22-year-old partner was also in the study (Subject C4591001 1089 10891181). Her partner smoked (1-2 cigarettes per day), but he did not drink alcohol or use illicit drugs during the subject's pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	93.36 kg	36.4 kg/m2	07OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
obesity	Obesity	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07OCT2020 (1)	10:47
2	BNT162b2	28OCT2020 (22)	14:58

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Exposure during pregnancy	Exposure During Pregnancy	16JAN2021 (102)		ONGOING		

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		N	N	Yes	NOT RELATED/OTHER: unplanned pregnancy	2	81	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07OCT2020	
Completed	VACCINATION	03DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1092 10921208, a 36-year-old white female with a pertinent medical history of obesity (since 2018) and an obstetrical history of 3 previous pregnancies resulting in 3 live vaginal births (all were full-term and no abnormalities were reported), received Dose 1 on 07 Oct 2020 and Dose 2 on 28 Oct 2020 (Day 22). The subject had an exposure during pregnancy on 16 Jan 2021, 80 days after receiving Dose 2. Concomitant medication included ethinylestradiol/ferrous fumarate/norethisterone acetate (from 01 Sep 2020 to 25 Jan 2021) for birth control. On an unspecified day, the subject called the site to report that she had a positive pregnancy test. The first day of her last menstrual period was 30 Dec 2020 (Day 85), the estimated date of conception was 16 Jan 2021 (Day 102), and the estimated delivery date is 07 Oct 2021. Of note, the subject was on ethinylestradiol/ferrous fumarate/norethisterone acetate for birth control at the time of conception. The subject and her partner did not smoke, drink alcohol, or use illicit drugs during this pregnancy. Her partner did not take any drugs during this pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.75 cm	88.65 kg	32.7 kg/m2	20OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
pepperoni allergy	Food allergy	1989	Present
anxiety	Anxiety	2016	Present
depression	Depression	2016	Present
high cholesterol	Blood cholesterol increased	2018	Present
thoracic bulging disc	Intervertebral disc protrusion	2018	Present
lumbar bulging disc	Intervertebral disc protrusion	2018	Present
type two diabetes mellitus	Type 2 diabetes mellitus	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20OCT2020 (1)	15:30
2	Placebo	12NOV2020 (24)	09:50

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	PREG	Abortion spontaneous	spontaneous abortion	20FEB2021 (124)		20FEB2021 (124)		1	3	N	Y
2	INFEC	Coxsackie viral infection	infection of coxsackievirus	06DEC2020 (48)		15DEC2020 (57)	11:58	10	2	N	N
3	INJ&P	Exposure during pregnancy	exposure during pregnancy	19DEC2020 (61)		ONGOING				N	N
4	INFEC	Genital herpes	genital herpes	09NOV2020 (21)		ONGOING			2	TC	N
5	NERV	Headache	headache	21OCT2020 (2)		23OCT2020 (4)		3	1	TC	N
6	RESP	Sinus congestion	sinus congestion	21OCT2020 (2)		23OCT2020 (4)		3	1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (20FEB2021)	NOT RELATED/OTHER: unknown, but subject has a history or pregnancy complications	2	101	Y

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	Resolved (15DEC2020)	NOT RELATED/OTHER: other viral infection	2	25	N
3	Yes	NOT RELATED/OTHER: Intercourse	2	38	Y
4	Yes	NOT RELATED/OTHER: genital sexually transmitted disease not related to IP	1	21	N
5	Resolved (23OCT2020)	Study Treatment	1	2	N
6	Resolved (23OCT2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20OCT2020	
Completed	VACCINATION	10DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1101 11011115, a 31-year-old white female with a pertinent medical history of anxiety and depression (both since 2016), type 2 diabetes mellitus, and blood cholesterol increased (both since 2018), and an obstetrical history of 3 previous pregnancies resulting in 1 stillbirth, 1 miscarriage, and 1 live birth, received Dose 1 on 20 Oct 2020 and Dose 2 on 12 Nov 2020 (Day 24). The subject had an exposure during pregnancy on 19 Dec 2020, 37 days after receiving Dose 2, and reported a spontaneous abortion on 20 Feb 2021, 100 days after receiving Dose 2.

The subject was diagnosed with genital herpes since 09 Nov 2020 (Day 21) and a coxsackie viral infection from 06 Dec 2020 (Day 48) to 15 Dec 2020 (Day 57).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. The site contacted her on 01 Feb 2021 (Day 105) to inform her that she had originally received placebo. During this call, the subject notified the site that she was approximately 6 weeks 2 days pregnant. The first day of her last menstrual period was 13 Dec 2020 (Day 55) and the estimated date of conception was 19 Dec 2020 (Day 61). The subject smoked (1 pack of cigarettes/day and reduced to 3-4 cigarettes/day); however, she did not drink alcohol or use illicit drugs during the pregnancy. On 23 Feb 2021 (Day 127), she notified the site that she had an emergency room visit because of a spontaneous abortion on 20 Feb 2021 (Day 124).

In the opinion of the investigator, there was no reasonable possibility that the spontaneous abortion was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179.83 cm	75.36 kg	23.3 kg/m2	29AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29AUG2020 (1)	12:16
2	BNT162b2	18SEP2020 (21)	09:59

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	exposure during pregnancy	25FEB2021 (181)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N	Yes	NOT RELATED/OTHER: unknown	2	161	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1110 11101164, a 34-year-old white female with no reported medical history or previous pregnancy, received Dose 1 on 29 Aug 2020 and Dose 2 on 18 Sep 2020 (Day 21). The subject had an exposure before pregnancy with an estimated date of conception of 25 Feb 2021, 160 days after receiving Dose 2. After the data cutoff date of 13 Mar 2021 (with database snapshot taken on 25 Mar 2021), the subject informed the site (on 23 Mar 2021, during Visit 4) about her positive home urine pregnancy test (date not specified). The first day of her last menstrual period was 15 Feb 2021 (Day 171). The subject denied any complications. She did not smoke, drink alcohol, or use illicit drugs during this pregnancy. Her 33-year-old partner was also in the study (Subject C4591001 1110 11101165). Her partner received Dose 1 on 29 Aug 2020 and Dose 2 on 18 Sep 2020 (Day 21), and then received the first dose of BNT162b2 on 12 Mar 2021 (Day 196). Her partner did not take any drugs but drank alcohol 2 to 3 times per week during this pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1987	33	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	81.41 kg	25 kg/m2	29AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	29AUG2020 (1)	12:23
2	Placebo	18SEP2020 (21)	09:42
3	BNT162b2	12MAR2021 (196)	09:50

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	INJ&P	Exposure during pregnancy	exposure during pregnancy	25FEB2021 (181)		ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1			N	N	Yes	NOT RELATED/OTHER: unknown	2	161	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	19OCT2020	
Completed	REPEAT SCREENING 1	12MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1110 11101165, a 33-year-old white male with no reported medical history, received Dose 1 on 29 Aug 2020 and Dose 2 on 18 Sep 2020 (Day 21). The subject's partner had an exposure during pregnancy on 25 Feb 2021, 160 days after receiving Dose 2. The subject did not take any drugs but drank alcohol 2 to 3 times per week during his partner's pregnancy (Subject C4591001 1110 11101164). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first dose of BNT162b2 on 12 Mar 2021 (Day 196) and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	26	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	49.86 kg	18.8 kg/m2	09OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	2011	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	09OCT2020 (1)	15:15
2	BNT162b2	28OCT2020 (20)	11:35

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Exposure during pregnancy	exposure during pregnancy	25NOV2020 (48)		ONGOING		

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		N	N	Yes	NOT RELATED/OTHER: exposure during pregnancy	2	29	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09OCT2020	
Completed	VACCINATION	24NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1122 11221051, a 26-year-old white female with a pertinent medical history of seasonal allergy (since 2011), received Dose 1 on 09 Oct 2020 and Dose 2 on 28 Oct 2020 (Day 20). The subject had an exposure during pregnancy on 25 Nov 2020, 28 days after receiving Dose 2. Concomitant medication included fluticasone propionate (since Jul 2020) for allergies. On 11 Feb 2021 (Day 126), the subject informed the site that she was approximately 11 weeks pregnant and also stated that she had found out that she was pregnant in Jan 2021. The first day of her last menstrual period was 25 Nov 2020 (Day 48) and the estimated date of conception was 09 Dec 2020 (Day 62). On 18 Feb 2021 (Day 133), the subject reported that she underwent an ultrasound on 17 Feb 2021 (Day 132), which revealed a gestational age of 12 weeks 1 day and an estimated delivery date of 01 Sep 2021 (Day 328). She did not smoke, drink alcohol, or use illicit drugs during the pregnancy. Her partner did not smoke or use illicit drugs, but he drank alcohol (1 beer weekly) during this pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	21	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156.4 cm	83.9 kg	34.3 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	DEC2018	Present
Attention deficit hyperactive disorder	Attention deficit hyperactivity disorder	DEC2018	Present
Depression	Depression	DEC2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27AUG2020 (1)	16:09
2	BNT162b2	15SEP2020 (20)	16:19

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	exposure during pregnancy	22OCT2020 (57)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N	Yes	NOT RELATED/OTHER: unknown	2	38	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	13OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1123 11231204, a 21-year-old white female with a pertinent medical history of anxiety, depression, and attention deficit hyperactivity disorder (all since Dec 2018) and an obstetrical history of 1 previous pregnancy with 1 live birth, received Dose 1 on 27 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 20). The subject had an exposure during pregnancy on 22 Oct 2020, 37 days after receiving Dose 2. Concomitant medications included lisdexamfetamine mesilate (from Dec 2018 to 07 Nov 2020) for attention deficit hyperactivity disorder, cariprazine hydrochloride (from Dec 2018 to 07 Nov 2020) for depression, and hydroxyzine (since Dec 2018) for anxiety. On 02 Sep 2020 (Day 7), the subject's intrauterine device (IUD) was removed successfully. On 15 Sep 2020 (Day 20), she received Dose 2 and at this visit, she denied contraception changes and did not report the IUD removal; a pregnancy test performed per protocol was negative. On 07 Nov 2020 (Day 73), the pregnancy was confirmed at an obstetrician/gynecologist appointment. The first day of her last menstrual period was 04 Sep 2020 (Day 9) and the estimated date of conception was 22 Oct 2020 (Day 57). An ultrasound examination performed on 30 Nov 2020 (Day 96) showed a gestational age of 7 weeks 3 days. On 07 Dec 2020 (Day 103), an ultrasound examination showed a gestational age of 8 weeks 3 days. On 14 Jan 2021 (Day 141), the subject informed the site that she was pregnant. The subject and her partner did not smoke, drink alcohol, or use illicit drugs during this pregnancy. Her partner did not take any over-the-counter or prescribed drugs during this pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	24	Black or African American	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	100 kg	36.6 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1996	Present
Obese	Obesity	2000	Present
Asthma	Asthma	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14SEP2020 (1)	11:10
2	Placebo	07OCT2020 (24)	10:49

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Exposure during pregnancy	Exposure during Pregnancy	NOV2020 ()		ONGOING		
2	SKIN	Night sweats	Increased diaphoresis during sleep	25OCT2020 (42)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Yes	NOT RELATED/OTHER: pregnancy	2		Y
2	1	N	N	Yes	NOT RELATED/OTHER: Unknown-possibly endocrinologic	2	19	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	04NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1124 11241223, a 24-year-old black or African American female with no pertinent medical history or previous pregnancies, received Dose 1 on 14 Sep 2020 and Dose 2 on 07 Oct 2020 (Day 24). The subject had an exposure during pregnancy with an estimated date of conception on an unspecified date in Nov 2020. Concomitant medication included salbutamol sulfate (since 2018) for asthma. The subject reported that she was pregnant at the unblinding contact from the site on an unspecified date. The first day of her last menstrual period was 25 Oct 2020 (Day 42). She never smoked, drank alcohol, or used illicit drugs. Her 25-year-old partner smoked and used illicit drugs 2 times a day but never drank alcohol during this pregnancy. The subject had a prenatal screening test on 20 Jan 2021 (Day 129) and an ultrasound scan on 25 Jan 2021 (Day 134), and the results were unknown.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1999	21	Black or African American	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159 cm	68.9 kg	27.3 kg/m2	19AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	16:52

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Exposure during pregnancy	Exposure During Pregnacy	20AUG2020 (2)		26SEP2020 (39)		38

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		TC	N	Resolved (26SEP2020)	NOT RELATED/OTHER: Pregnacy	1	2	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Withdrawn	VACCINATION	30SEP2020	WITHDRAWAL BY SUBJECT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	30SEP2020	WITHDRAWAL BY SUBJECT

Narrative Comment
Subject C4591001 1133 11331207, a 21-year-old black or African American female with a pertinent obstetrical history of 1 previous pregnancy with 1 live birth, received Dose 1 on 19 Aug 2020. The subject had an exposure during pregnancy on 20 Aug 2020, 1 day after receiving Dose 1. On 20 Aug 2020 (Day 2), the subject underwent laboratory tests that included a qualitative urine pregnancy (human chorionic gonadotropin) test, which was positive, and a quantitative urine human chorionic gonadotropin test, which showed an elevated β-human chorionic gonadotropin level of 195.0 (unit and normal range not provided). The subject was asked to visit the site to discuss the risks and confirm the pregnancy, as she had had a negative pregnancy test 12 hours earlier and reported using contraception and had no missed periods/menses. On 25 Aug 2020 (Day 7), because of a personal emergency, the subject was unable to visit the site as scheduled. The first day of her last menstrual period was 19 Jul 2020. The subject and her partner did not smoke, drink alcohol, or use illicit drugs during this pregnancy. On 02 Sep 2020 (Day 15), the subject visited a clinic and started the process of elective/induced abortion and received mifepristone 200 mg, with the first dose on the same day (Day 15) and the second dose on 03 Sep 2020 (Day 16). After the treatment, she was feeling well and was interested in continuing in the study. On 16 Sep 2020 (Day 29), during a follow-up appointment for an ultrasound scan, it was confirmed that her pregnancy had ended. The outcome of the pregnancy was reported as completely resolved on 26 Sep 2020 (Day 39). The subject requested withdrawal from the study on 30 Sep 2020.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	56.82 kg	21.5 kg/m2	27OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
bilateral inguinal hernia	Inguinal hernia	1998	Past
bilateral inguinal hernia repair	Inguinal hernia repair	1998	Past
shellfish allergy	Food allergy	2012	Present
iodine allergy	Iodine allergy	2012	Present
C-section	Caesarean section	19APR2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27OCT2020 (1)	14:28
2	BNT162b2	19NOV2020 (24)	09:41

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	01DEC2020 (36)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	N	N	Yes	NOT RELATED/OTHER: Pregnancy	2	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27OCT2020	
Completed	VACCINATION	18DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1136 11361082, a 31-year-old white female with a pertinent medical history of bilateral inguinal hernia and bilateral inguinal hernia repair (both in 1998) and food allergy (shellfish) and iodine allergy (both since 2012), and an obstetrical history of 1 previous pregnancy with 1 live birth via cesarean section (on 19 Apr 2019), received Dose 1 on 27 Oct 2020 and Dose 2 on 19 Nov 2020 (Day 24). The subject had an exposure during pregnancy on 01 Dec 2020, 12 days after receiving Dose 2. On 19 Nov 2020 (Day 24), the same day as Dose 2, the subject's urine pregnancy (human chorionic gonadotropin [hCG]) test at home was negative. On 13 Jan 2021 (Day 79), her urine pregnancy (hCG) test at home was positive. On 14 Jan 2021 (Day 80), she visited the clinic for an illness visit with the complaint of nausea and vomiting for 24 hours. A repeat urine pregnancy test performed at the office on 14 Jan 2021 (Day 80) was positive. The first date of her last menstrual period was 01 Dec 2020 (Day 36) and the estimated date of delivery is 05 Sep 2021. The subject did not smoke, drink alcohol, or use illicit drugs during her pregnancy.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1989	31	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
175.26 cm	110.23 kg	35.8 kg/m2	27AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	27AUG2020 (1)	11:30
2	Placebo	18SEP2020 (23)	07:37

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	PREG	Abortion spontaneous	spontaneous abortion	21JAN2021 (148)		21JAN2021 (148)		1	3	N	Y
2	INJ&P	Exposure during pregnancy	Exposure during pregnancy	2021 ()		ONGOING			3	N	N
3	REPRO	Vaginal haemorrhage	Vaginal Bleeding	21JAN2021 (148)		22JAN2021 (149)		2	2	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (21JAN2021)	NOT RELATED/OTHER: loss of fetus	2	126	Y
2	Yes	NOT RELATED/OTHER: Vaginal Bleeding, No diagnosis from physician of spontaneous abortion.	2		Y
3	Resolved (22JAN2021)	NOT RELATED/OTHER: Vaginal bleeding due to a spontaneous abortion	2	126	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1146 11461133, a 31-year-old white female with no obstetrical history, received Dose 1 on 27 Aug 2020 and Dose 2 on 18 Sep 2020 (Day 23). The subject reported vaginal bleeding and a spontaneous abortion on 21 Jan 2021, 125 days after receiving Dose 2, and had an exposure during pregnancy on an unknown date in 2021. After the data cutoff date of 13 Mar 2021 (with snapshot taken on 25 Mar 2021), it was determined that the subject had an adverse event of exposure during pregnancy on 26 Dec 2020 (which resulted in the spontaneous abortion) in addition to the adverse event of exposure during pregnancy on an unknown date in 2021. Concomitant medication included ethinylestradiol norgestimate (unknown date to 11 Feb 2020) for contraception. On 21 Jan 2021 (Day 148), the subject called the site and reported that she had vaginal bleeding following a positive urine pregnancy test on 12 Jan 2021 (Day 139). The first day of her last menstrual period was 14 Dec 2020 (Day 110) and the estimated date of conception was 26 Dec 2020 (Day 122). Lack of contraception was confirmed at the time of the pregnancy when the subject confirmed that she had stopped using birth control on 11 Feb 2020 and did not use condoms. She had no previous pregnancies. She was an alcohol user during the pregnancy (last consumed on 03 Jan 2021). Her 35-year-old partner was a current smoker and alcohol user (daily), but he did not use illicit drugs during this pregnancy. Her partner was also in the study and received the first dose of blinded study intervention on 04 Sep 2020 and the second dose on 23 Sep 2020, and he did not have any serious adverse events. On 21 Jan 2021 (Day 148), the outcome of the pregnancy was spontaneous abortion/miscarriage at 5 weeks. On 22 Jan 2021 (Day 149), the vaginal bleeding resolved. On 01 Mar 2021 (Day 187), the subject informed the site of a new positive urine pregnancy test (date was not specified). The subject was called to follow up regarding details about the second pregnancy; however, she was unreachable. In the opinion of the investigator, there was no reasonable possibility that the spontaneous abortion and vaginal haemorrhage were related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.7 cm	104.3 kg	35 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
menarche female	Menarche	1996	Present
intermittent lumbosacral disc herniation	Intervertebral disc protrusion	2006	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03AUG2020 (1)	15:11
2	Placebo	24AUG2020 (22)	10:25

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	GASTR	Diarrhoea	Diarrhea	12MAR2021 (222)		13MAR2021 (223)		2	1	N
2	INJ&P	Exposure during pregnancy	Exposure during pregnancy	NOV2020 ()		ONGOING				N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Resolved (13MAR2021)	NOT RELATED/OTHER: Non-study COVID-19 vaccine (Pfizer)	2	201	N
2	N	Yes	NOT RELATED/OTHER: Pregnancy	2		Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
non-study COVID-19 vaccine (Pfizer)	TOZINAMERAN	18FEB2021
Non-study COVID-19 vaccine (Pfizer)	TOZINAMERAN	11MAR2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	21SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1147 11471007, a 36-year-old white female with a pertinent history of menarche (since 1996) and intervertebral disc protrusion (since 2006), and an obstetrical history of 3 previous pregnancies resulting in 1 live birth via cesarean section, 1 miscarriage, and 1 elective termination (unknown dates), received Dose 1 on 03 Aug 2020 and Dose 2 on 24 Aug 2020 (Day 22). The subject had an exposure during pregnancy on an unspecified date in Nov 2020. In accordance with the protocol allowance, the subject was unblinded on 11 Feb 2021 (Day 193) to determine whether she was eligible for receipt for BNT162b2. It was confirmed that she had originally received placebo. On 17 Feb 2021 (Day 199), she visited the clinic for Visit 101. During the eligibility confirmation, she was found to be pregnant. She met exclusion criteria and was therefore no longer eligible for the vaccine transition option. However, she received commercially available COVID-19 vaccine (tozinameran) Dose 1 on 18 Feb 2021 (Day 200) and Dose 2 on 11 Mar 2021 (Day 221). The first day of her last menstrual period and the estimated date of conception were on unknown dates in Nov 2020. The subject and her partner did not smoke, drink alcohol, or use illicit drugs during this pregnancy. Her partner did not use any drugs (over-the-counter or prescription) during this pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	57.27 kg	19.7 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Ceclor allergy	Drug hypersensitivity	1989	Present
Seasonal Allergies	Seasonal allergy	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28AUG2020 (1)	09:15
2	BNT162b2	18SEP2020 (22)	08:40

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Exposure during pregnancy	Exposure during Pregnancy	11NOV2020 (76)		ONGOING		
2	NERV	Headache	Headache	19SEP2020 (23)		20SEP2020 (24)		2
3	GENRL	Injection site pain	Pain at injection site	19SEP2020 (23)		20SEP2020 (24)		2
4	GENRL	Injection site pain	arm soreness (left arm, injection site)	28AUG2020 (1)	19:00	29AUG2020 (2)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Yes	NOT RELATED/OTHER: pregnancy	2	55	Y
2	1	N	N	Resolved (20SEP2020)	Study Treatment	2	2	N
3	1	N	N	Resolved (20SEP2020)	Study Treatment	2	2	N
4	1	N	N	Resolved (29AUG2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu Vaccine	INFLUENZA VACCINE	16OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	16OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1150 11501069, a 31-year-old white female with a pertinent medical history of drug hypersensitivity (since 1989) and seasonal allergy (since 2000), and an obstetrical history of 1 previous pregnancy resulting in 1 live birth (in Oct 2018), received Dose 1 on 28 Aug 2020 and Dose 2 on 18 Sep 2020 (Day 22). The subject had an exposure during pregnancy on 11 Nov 2020, 54 days after receiving Dose 2. Concomitant medications included fexofenadine hydrochloride (since Aug 2020) for allergies and influenza vaccine (on 16 Oct 2020). On 18 Jan 2021 (Day 144), the subject notified the site that she was pregnant. She was healthy and had no other problems. The first day of her last menstrual period was 11 Nov 2020 (Day 76). She did not smoke, drink alcohol, or use illicit drugs during her pregnancy. Her partner drank alcohol (on weekends) but he did not smoke or use illicit drugs during this pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.09 cm	70.45 kg	23.7 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergies	Seasonal allergy	AUG2015	Present
Irritable Bowel Syndrome	Irritable bowel syndrome	MAY2017	Present
Heartburn	Dyspepsia	JUL2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	18:23
2	Placebo	01OCT2020 (31)	16:49
3	BNT162b2	04MAR2021 (185)	09:16

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PREG	Abortion spontaneous	Spontaneous Miscarriage	19FEB2021 (172)		19FEB2021 (172)		1	2
2	GENRL	Chills	Chills	19SEP2020 (19)		23SEP2020 (23)		5	1
3	RESP	Cough	Cough	19SEP2020 (19)		23SEP2020 (23)		5	1
4	INJ&P	Exposure during pregnancy	Exposure during pregnancy	04OCT2020 (34)		19FEB2021 (172)		139	
5	NERV	Headache	Headache	19SEP2020 (19)		23SEP2020 (23)		5	1
6	RESP	Oropharyngeal pain	Sore Throat	19SEP2020 (19)		23SEP2020 (23)		5	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (19FEB2021)	NOT RELATED/OTHER: Other-Unknown	2	142	Y
2	N	N	Resolved (23SEP2020)	NOT RELATED/OTHER: Viral Illness	1	19	N
3	N	N	Resolved (23SEP2020)	NOT RELATED/OTHER: Viral Illness	1	19	N
4	N	N	Resolved (19FEB2021)	NOT RELATED/OTHER: pregnancy	2	4	Y
5	N	N	Resolved (23SEP2020)	NOT RELATED/OTHER: Viral Illness	1	19	N
6	N	N	Resolved (23SEP2020)	NOT RELATED/OTHER: Viral Illness	1	19	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	02NOV2020	
Completed	REPEAT SCREENING 1	04MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1150 11501084, a 34-year-old white female with a pertinent medical history of seasonal allergy (since Aug 2015) and an obstetrical history of 2 previous pregnancies resulting in 2 live births with no complications, received Dose 1 on 01 Sep 2020 and Dose 2 on 01 Oct 2020 (Day 31). The subject had an exposure during pregnancy on 04 Oct 2020, 3 days after receiving Dose 2, and reported spontaneous abortion on 19 Feb 2021, 141 days after receiving Dose 2. Concomitant medication included budesonide (since Aug 2015) for seasonal allergies. The subject notified the study site that she was pregnant and there were no issues with the pregnancy. The first day of her last menstrual period was 04 Oct 2020 (Day 34). The gestational age at the time of exposure was first trimester. She did not smoke, drink alcohol, or use illicit drugs during her pregnancy. Her 35-year-old partner did not smoke or use illicit drugs but drank alcohol once per week during the pregnancy. On 19 Feb 2021 (Day 172), the subject notified the site that she had a miscarriage (spontaneous abortion) because of an unknown cause. She was doing well with no complications. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 04 Mar 2021 (Day 185) and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the spontaneous abortion was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	29	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	98.36 kg	37.1 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	2001	Past
appendicitis	Appendicitis	2001	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	13AUG2020 (1)	13:09
2	BNT162b2	01SEP2020 (20)	12:03

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy	15FEB2021 (187)		ONGOING	
2	GASTR	Nausea	Nausea	13FEB2021 (185)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	N	N	Yes	NOT RELATED/OTHER: intercourse	2	168	Y
2		2	TC	N	Yes	NOT RELATED/OTHER: pregnancy	2	166	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	30SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1152 11521053, a 29-year-old white female with an obstetrical history of 1 previous pregnancy (primiparous), received Dose 1 on 13 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 20). The subject's pregnancy test was positive on 15 Feb 2021 (Day 187) and an exposure during pregnancy was reported on the same day, 167 days after receiving Dose 2. Concomitant medications included ethinylestradiol/levonorgestrel (from 04 Jun 2020 to 14 Feb 2021) for birth control. The subject experienced nausea on 13 Feb 2021 (Day 185) and tested positive with a home pregnancy test on 15 Feb 2021 (Day 187). She called the site to get information on unblinding criteria and reported that she was pregnant. She started treatment with ondansetron for nausea on 17 Feb 2021 (Day 189). The first day of her last menstrual period was 02 Nov 2020 (Day 82) and the estimated date of conception was unknown, as the subject had irregular menstrual cycles since the start of ethinylestradiol/levonorgestrel contraception. She did not smoke, drink alcohol, or use illicit drugs during this pregnancy. Her appointment with her obstetrician was scheduled on 23 Feb 2021 (Day 195). The nausea was reported to be related to the pregnancy and was ongoing at the time of the last available report.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	28	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
153.67 cm	86.55 kg	36.6 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
diarrhea, occasional (spicy food induced)	Diarrhoea	2017	Present
hypercholesterolemia	Hypercholesterolaemia	2018	Past
smoker's cough	Cough	MAR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16SEP2020 (1)	15:50
2	BNT162b2	09OCT2020 (24)	13:31

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Diarrhoea	Diarrhea	12OCT2020 (27)		12OCT2020 (27)		1	2
2	INJ&P	Exposure during pregnancy	Exposure during pregnancy	26DEC2020 (102)		ONGOING			3
3	GENRL	Fatigue	Fatigue	09OCT2020 (24)	18:00	11OCT2020 (26)		3	2
4	NERV	Headache	Headache	10OCT2020 (25)		12OCT2020 (27)		3	2
5	GENRL	Pain	Body Aches	10OCT2020 (25)		11OCT2020 (26)		2	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (12OCT2020)	Study Treatment	2	4	N
2	N	N	Yes	NOT RELATED/OTHER: Did not use birth control	2	79	Y
3	TC	N	Resolved (11OCT2020)	Study Treatment	2	1	N
4	TC	N	Resolved (12OCT2020)	Study Treatment	2	2	N
5	TC	N	Resolved (11OCT2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	16SEP2020	
Completed	VACCINATION	20NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1152 11521450, a 28-year-old white female with a pertinent medical history of hypercholesterolemia (in 2018), cough (smoker's cough since Mar 2019), and tobacco use (10 cigarettes per day for 10 years), and no obstetrical history, received Dose 1 on 16 Sep 2020 and Dose 2 on 09 Oct 2020 (Day 24). The subject had an exposure during pregnancy on 26 Dec 2020, 78 days after receiving Dose 2. . On 08 Feb 2021 (Day 146), the subject consulted her primary care physician, as her menstrual cycle was about a week late and a urine pregnancy test (urine human chorionic gonadotropin) done on the same day was positive. The subject was about 3 weeks into her pregnancy and was scheduled for blood and sonogram tests. It was reported that she had failed to use a birth control method (condom and spermicide). The first day of the last menstrual period was 12 Dec 2020 (Day 88) and the estimated date of conception was 26 Dec 2020 (Day 102). The subject smoked but did not drink alcohol or use illicit drugs during her pregnancy. She agreed to be contacted by the study site for further information.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2000	20	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	74.8 kg	29.2 kg/m2	01AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	2013	Present
iron deficiency	Iron deficiency	2015	Present
lumbar pain	Back pain	2016	Present
anxiety	Anxiety	2019	Present
heartburn	Dyspepsia	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01AUG2020 (1)	16:15
2	Placebo	19NOV2020 (111)	10:37

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure during Pregnancy	17JAN2021 (170)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	N	N	Yes	NOT RELATED/OTHER: relations	2	60	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01AUG2020	
Completed	VACCINATION	17DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1161 11611016, a 20-year-old white female with a pertinent medical history of seasonal allergy (since 2013), iron deficiency (since 2015), and anxiety (since 2019), and no obstetrical history, received Dose 1 on 01 Aug 2020 and Dose 2 on 19 Nov 2020 (Day 111). The subject had an exposure during pregnancy on 17 Jan 2021, 59 days after receiving Dose 2. Concomitant medication included bupropion (since 2020) for anxiety. The first day of her last menstrual period was 17 Jan 2021 (Day 170) and the estimated date of delivery is 24 Oct 2021 (Day 450). She had a doctor consultation scheduled on 09 Mar 2021 (Day 221). It was reported that the subject's 21-year-old male partner was also part of the study and had a medical history of seizures due to brain tumor. Her partner's concomitant medications included zonisamide and lamotrigine tablet, both at 100 mg once daily (since 2018) for seizures. The subject and her partner did not smoke, drink alcohol, or use illicit drugs during this pregnancy. Since she became pregnant, her partner had stopped using an electronic smoking device.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	37	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177 cm	111.5 kg	35.6 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Exploratory Abdominal Surgery	Abdominal exploration	2016	Past
Gun shot wound	Gun shot wound	MAY2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	13:19
2	BNT162b2	09SEP2020 (24)	16:33

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy	SEP2020 ()		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N	Yes	NOT RELATED/OTHER: Pregnancy			Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	13OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1162 11621128, a 37-year-old black or African American male with no pertinent medical history, received Dose 1 on 17 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 24). The subject's partner had an exposure during pregnancy in Sep 2020. The first day of his partner's last menstrual period was 21 Aug 2020 (Day 5) and the estimated date of conception was 04 Sep 2020 (Day 19). This was his partner's first pregnancy and she was expecting twins. The subject did not smoke or use illicit drugs but drank alcohol twice a week and his partner did not smoke, drink alcohol, or use illicit drugs during the pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	42	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.3 cm	102.5 kg	37.5 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
C-section	Caesarean section	15APR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15SEP2020 (1)	15:44
2	Placebo	05OCT2020 (21)	13:59

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	18DEC2020 (95)		ONGOING			

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: EXPOSURE DURING PREGNANCY	2	75	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15SEP2020	
Completed	VACCINATION	02NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1166 11661078, a 42-year-old white female with a pertinent obstetrical history of (b) (6) (b) (6), received Dose 1 on 15 Sep 2020 and Dose 2 on 05 Oct 2020 (Day 21). The subject had an exposure during pregnancy on 18 Dec 2020, 74 days after receiving Dose 2. Concomitant medications included ethinylestradiol/ferrous fumarate/norethisterone acetate from 15 Apr 2020 as oral contraceptive, fluticasone propionate (since an unknown date; recent dose on 04 Oct 2020) for seasonal allergies, and buprenorphine hydrochloride (since an unknown date; recent dose on 13 Jan 2021). On 18 Dec 2020 (Day 95), the subject had a low-grade fever, nonproductive cough, body aches, chills, diarrhea, fatigue, headache, loss of taste and smell, runny nose, nasal congestion, sore throat, nausea, and vomiting. She denied home nasal swab testing and reported that she had lost the nasal swab kits provided by the investigator. She also stated that she was pregnant as confirmed by a home urine human chorionic gonadotropin (hCG) pregnancy test. She stated that she had performed the test 5 times and each time the test was positive. She was treated with paracetamol for cold and flu on 18 Dec 2020 (Day 95), with little relief, and she did not take any more after she had a positive home urine hCG test. She denied exposure to positive COVID-19 contacts. On 18 Dec 2020 (Day 95), the subject was advised to schedule a telehealth appointment with her primary care physician for COVID-19 testing and to quarantine. The first day of the subject's last menstrual period was 20 Nov 2020 (Day 67). She was on a protocol-approved contraceptive at the time of study vaccinations. She and her 42-year-old partner did not smoke, drink alcohol, or use illicit drugs during this pregnancy. Her partner neither had medical prescriptions nor used over-the-counter drugs during the pregnancy. The subject was also advised to consult her obstetrician-gynecologist for a laboratory-confirmed hCG test, and she had her appointment scheduled on 13 Jan 2021.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	78.18 kg	24.7 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
anxiety	Anxiety	MAR2020	Present
left shoulder pain	Arthralgia	MAR2020	Present
left torn labrum	Cartilage injury	MAR2020	Past
left labrum repair	Chondroplasty	18MAY2020	Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	01SEP2020 (1)	10:08
2	BNT162b2	14OCT2020 (44)	10:09

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	MUSC	Bone pain	sternum pain	15OCT2020 (45)		ONGOING		
2	GENRL	Chills	Chills	02SEP2020 (2)		02SEP2020 (2)		1
3	INJ&P	Exposure during pregnancy	partner exposure during pregnancy	02OCT2020 (32)		ONGOING		
4	NERV	Headache	headache	02SEP2020 (2)		02SEP2020 (2)		1
5	GENRL	Injection site pain	injection site soreness	02SEP2020 (2)		02SEP2020 (2)		1
6	MUSC	Myalgia	myalgias	02SEP2020 (2)		02SEP2020 (2)		1

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Yes	NOT RELATED/OTHER: unknown	2	2	N
2	1	N	N	Resolved (02SEP2020)	Study Treatment	1	2	N
3		N	N	Yes	NOT RELATED/OTHER: fratnerization	1	32	Y
4	1	N	N	Resolved (02SEP2020)	Study Treatment	1	2	N
5	1	N	N	Resolved (02SEP2020)	Study Treatment	1	2	N
6	1	N	N	Resolved (02SEP2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	11NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1178 11781061, a 38-year-old white male with no pertinent medical history, received Dose 1 on 01 Sep 2020 and Dose 2 on 14 Oct 2020 (Day 44). The subject's partner had an exposure during pregnancy on 02 Oct 2020, 31 days after the subject received Dose 1. Concomitant medications included escitalopram oxalate for anxiety and meloxicam for left shoulder pain (both ongoing since an unknown date) and paracetamol (since 15 Oct 2020) for intermittent headache. On 02 Nov 2020 (Day 63), the subject informed the site that his partner was pregnant. The estimated date of conception was 02 Oct 2020 (Day 32) and the gestational age at the time of exposure was first trimester. The estimated delivery date was reported as Jun 2021. The subject did not smoke during his partner's pregnancy. He reported that the pregnancy was continuing without any complications.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1991	29	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	65 kg	22 kg/m2	29OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillectomy	Tonsillectomy	20DEC2001	Past
Miscarriage	Abortion spontaneous	06SEP2014	Past
Salpingitis	Salpingitis	01OCT2014	Past
Laparoscopic abscess resection at salpinx bilat.	Abscess drainage	07OCT2014	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	29OCT2020 (1)	14:10
2	Placebo	19NOV2020 (22)	16:00

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy	02NOV2020 (5)	18:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N	Yes	NOT RELATED/OTHER: pregnancy	1	5	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29OCT2020	
Completed	VACCINATION	17DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	16FEB2021	WITHDRAWAL BY SUBJECT

Narrative Comment
Subject C4591001 1185 11851055, a 29-year-old white female with a pertinent obstetrical history of 3 previous pregnancies resulting in 2 live births and 1 spontaneous abortion (on 06 Sep 2014) and a pertinent medical history of bilateral salpingitis (on 01 Oct 2014) and laparoscopic abscess resection at bilateral salpinx (on 07 Oct 2014), received Dose 1 on 29 Oct 2020 and Dose 2 on 19 Nov 2020 (Day 22). The subject had an exposure during pregnancy on 02 Nov 2020, 4 days after receiving Dose 1. On an unspecified date, the subject's urine pregnancy test was positive, and she reported an unplanned pregnancy despite contraception methods. On 08 Dec 2020 (Day 41), a pregnancy test showed elevated blood human chorionic gonadotropin, which confirmed the pregnancy. The first day of her last menstrual period was 02 Nov 2020 (Day 5). She did not smoke, drink alcohol, or use illicit drugs during the pregnancy. Her 33-year-old partner did not smoke or use any drugs, including illicit drugs, but he drank alcohol once a week during the pregnancy. A gynecologist consultation was scheduled on 11 Dec 2020 (Day 44). On 09 Feb 2021 (Day 104), the subject reported new circumstances with her ongoing twin pregnancy: a fetus without detectable heart sounds and a healthy fetus with no abnormalities were detected. The subject requested withdrawal from the study on 16 Feb 2021.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	80.45 kg	28.6 kg/m2	21OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Stress fracture (Sacrum area)	Stress fracture	2011	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21OCT2020 (1)	16:19
2	Placebo	13NOV2020 (24)	15:41

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Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	SURG	Abortion induced	Medication abortion	09NOV2020 (20)		09NOV2020 (20)		1
2	INJ&P	Exposure during pregnancy	Drug Exposure During Pregnancy	21OCT2020 (1)		09NOV2020 (20)		20

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC/TCN	N	Resolved (09NOV2020)	NOT RELATED/OTHER: pregnancy	1	20	N
2	2	TC/TCN	N	Resolved (09NOV2020)	NOT RELATED/OTHER: Pregnancy	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Moderna COVID-19 Vaccine	COVID-19 VACCINE MRNA (MRNA 1273)	04FEB2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21OCT2020	
Completed	VACCINATION	16DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	08MAR2021	PROTOCOL DEVIATION

Narrative Comment
Subject C4591001 1204 12041280, a 41-year-old white female with no pertinent medical history, received Dose 1 on 21 Oct 2020 and Dose 2 on 13 Nov 2020 (Day 24). The subject had an exposure during pregnancy on 21 Oct 2020, on the day of Dose 1. On 21 Oct 2020 (Day 1), during the subject's enrollment in the study, her urine pregnancy test was negative. At that time, she had agreed to use contraception. A sonogram on an unspecified date suggested that she had become pregnant, with an estimated date of conception of 01 Oct 2020 (Day -20). It was unclear whether the urine pregnancy test had resulted in a false-negative reading given its limits of detection or whether the follow-up pelvic sonogram was accurate in predicting the conception date. The gestational age at the time of initial exposure was first trimester. The initial sonogram performed on 09 Nov 2020 (Day 20) reported an intrauterine pregnancy with a gestational age of 5 weeks 4 days. On 13 Nov 2020 (Day 24), the subject informed the site that she had had a medical abortion on 09 Nov 2020 (Day 20). A sonogram performed on 13 Nov 2020 (Day 24) confirmed completion of the medical abortion. After the medical abortion was completed, the subject had no complications and returned to her baseline state of health. On 04 Feb 2021 (Day 107), she received COVID-19 mRNA vaccine (mRNA 1273). In accordance with the protocol allowance, the subject agreed to be unblinded on 11 Feb 2021 (Day 114) to determine whether she was eligible for receipt of BNT162b2, and it was confirmed that she had originally received placebo. Given the sensitive nature of the event, the subject was unwilling to provide many details that were requested on the exposure during pregnancy supplemental form. The subject was withdrawn from the study on 08 Mar 2021 because of the protocol deviation.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	26	American Indian or Alaska Native	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.75 cm	90.73 kg	35.9 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
chlamydia infection	Chlamydial infection	17JUN2011	Past
Admission for labor and delivery	Delivery	2014	Past
chlamydia infection	Chlamydial infection	13MAR2020	Past
uncomplicated kidney stones	Nephrolithiasis	13AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16OCT2020 (1)	13:35
2	BNT162b2	06NOV2020 (22)	12:12

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Diarrhoea	diarrhea	17OCT2020 (2)	07:30	19OCT2020 (4)	07:30	3	1
2	INJ&P	Exposure during pregnancy	Exposure during Pregnancy	23OCT2020 (8)		16DEC2020 (62)		55	3
3	NERV	Headache	Headache	07NOV2020 (23)	06:00	07NOV2020 (23)	23:59	1	2
4	GENRL	Injection site pain	Soreness at Injection site (left deltoid)	07NOV2020 (23)	06:00	09NOV2020 (25)	14:00	3	2
5	GASTR	Vomiting	Vomiting	07NOV2020 (23)	06:00	07NOV2020 (23)	23:59	1	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (19OCT2020)	Study Treatment	1	2	N
2	TCN	N	Resolved (16DEC2020)	NOT RELATED/OTHER: unprotected heterosexual intercourse	1	8	Y
3	N	N	Resolved (07NOV2020)	Study Treatment	2	2	N
4	N	N	Resolved (09NOV2020)	Study Treatment	2	2	N
5	N	N	Resolved (07NOV2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	16OCT2020	
Completed	VACCINATION	04DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1220 12201020, a 26-year-old American Indian or Alaska Native female with a pertinent obstetrical history of 3 previous pregnancies with 3 full-term live births and a medical history of chlamydial infections (on 17 Jun 2011 and 13 Mar 2020), received Dose 1 on 16 Oct 2020 and Dose 2 on 06 Nov 2020 (Day 22). The subject had an exposure during pregnancy on 23 Oct 2020, 7 days after receiving Dose 1. At both the Dose 1 and Dose 2 visits, the subject tested negative for urine human chorionic gonadotropin and appropriate pregnancy prevention counseling was performed. On 02 Dec 2020 (Day 48), her home urine pregnancy test was positive. She reported that she had had unprotected intercourse approximately 2 weeks after receiving her second dose. The first day of her last menstrual period was 23 Oct 2020 (Day 8) and the estimated date of conception was 20 Nov 2020 (Day 36). The gestational age at the time of initial exposure was first trimester. The subject did not smoke or use illicit drugs but drank alcohol occasionally during this pregnancy. She had not been seen by a medical provider for confirmation of pregnancy testing and had an appointment scheduled on 16 Dec 2020 (Day 62) to discuss termination, as the subject did not desire to continue the pregnancy at this time.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177 cm	66.2 kg	21.1 kg/m2	28AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	15:09
2	Placebo	18SEP2020 (22)	15:27

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	17FEB2021 (174)	15:30
4	BNT162b2	10MAR2021 (195)	14:14

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy	07NOV2020 (72)		ONGOING			1	N	N
2	GENRL	Injection site pain	injection site pain	17FEB2021 (174)	17:00	19FEB2021 (176)	09:00	3	1	N	N
3	RESP	Throat irritation	scratcy throat	28SEP2020 (32)		02OCT2020 (36)		5	1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: Wife became pregnant, not related to investigational product	2	51	Y
2	Resolved (19FEB2021)	Study Treatment	3	1	N
3	Resolved (02OCT2020)	NOT RELATED/OTHER: related to sick contacts	2	11	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	19NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	19OCT2020	
Completed	REPEAT SCREENING 1	17FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1223 12231024, a 35-year-old white male with no reported medical history, received Dose 1 on 28 Aug 2020 and Dose 2 on 18 Sep 2020 (Day 22). The subject's partner had an exposure during pregnancy on 07 Nov 2020, 50 days after the subject received Dose 2. On 21 Nov 2020 (Day 86), his partner's home pregnancy test was positive. The first day of his partner's last menstrual period was 24 Oct 2020 (Day 58) and the estimated date of conception was 07 Nov 2020 (Day 72). According to the subject, his partner was doing well and she had an ultrasound examination on 09 Dec 2020 (Day 104), which showed a retroverted/retroflexed (RV/RF) uterus and an early intrauterine pregnancy with a gestational sac, yolk sac, amniotic fluid, and fetus. The fetal heart rate was 122 beats/min (within normal limits for early gestational age) and the cervix was long and closed. The ovaries were normal with a left ovary corpus luteum of 2.3 cm. The subject's partner had a history of 3 prior pregnancies and had had a miscarriage in 2015; and gestational hypertension with 2 prior pregnancies at 37 weeks, gastroesophageal reflux disease, and eosinophilic esophagitis. His partner did not smoke, drink alcohol, or use illicit drugs during the pregnancy. The subject's family history included prostate cancer ((b) (6)) and colon cancer (b) (6) . The subject did not smoke or use illicit drugs during the pregnancy, but he had 3 to 4 drinks of alcohol per week. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 17 Feb 2021 (Day 174) and 10 Mar 2021 (Day 195), respectively, and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.8 cm	52.5 kg	20.1 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
iron deficiency anemia	Iron deficiency anaemia	30JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	10:54
2	BNT162b2	08SEP2020 (23)	11:30

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy	10DEC2020 (116)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			TC	N	Yes	NOT RELATED/OTHER: Pregnancy	2	94	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	08OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261210, a 30-year-old white female with a pertinent medical history of iron-deficiency anemia (since 30 Jul 2020) and no obstetrical (no previous pregnancy) history, received Dose 1 on 17 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 23). The subject had an exposure during pregnancy on 10 Dec 2020, 93 days after receiving Dose 2. On 18 Jan 2021 (Day 155), the subject notified the site about her pregnancy and forwarded her beta-human chorionic gonadotropin (β-hCG) test reports to the site. Per the reports, the β-hCG levels on 14 Jan 2021 (Day 151) and 16 Jan 2021 (Day 153) were 7.597 IU/L and 12.679 IU/L, respectively, and the results did not indicate pregnancy. On 28 Jan 2021 (Day 165), during a convalescent visit at the site, the subject reported that her pregnancy was being monitored by a gynecologist and she had started taking folic acid 5 mg once a day (since 26 Jan 2021) as a vitamin supplement, meclizine hydrochloride 1 capsule if necessary (since 26 Jan 2021) for nausea, and ascorbic acid/calcium pantothenate/cyanocobalamin/ferrous sulfate/folic acid/nicotinamide/pyridoxine hydrochloride/riboflavin/thiamine hydrochloride 1 tablet twice a day (since 01 Feb 2021). On 29 Jan 2021 (Day 166), during a routine examination, an obstetrical ultrasound examination showed pregnancy of 7 weeks 1 day. Per the subject, the first day of her last menstrual period was 05 Dec 2020 (Day 111), the estimated date of conception was 10 Dec 2020 (Day 116), and the estimated delivery date is 11 Sep 2021. Her 38-year-old partner was also part of this study (dosing information not reported). She and her partner smoked (once a week) and drank alcohol (1 serving once a week), with no use of illicit drugs. The subject's partner did not have any relevant medical history reported and was not taking any other drugs during this pregnancy. On 10 Mar 2021 (Day 206), an ultrasonography scan showed normal fetal anatomy. Upon follow-up, it was reported that the subject continued to have nausea related to the pregnancy and denied any complications during the pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.3 cm	105.9 kg	32.6 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
obesity	Obesity	2006	Present
bariatric surgery	Metabolic surgery	2012	Past
systemic arterial hypertension	Hypertension	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	11:43
2	Placebo	11SEP2020 (23)	10:59
3	BNT162b2	19FEB2021 (184)	10:15
4	BNT162b2	12MAR2021 (205)	09:35

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Exposure during pregnancy	Exposure During Pregnancy	06OCT2020 (48)		ONGOING		
2	GENRL	Injection site pain	Pain at injection site	19FEB2021 (184)	20:00	20FEB2021 (185)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Yes	NOT RELATED/OTHER: Pregnancy	2	26	Y
2	1	N	N	Resolved (20FEB2021)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	13OCT2020	
Completed	REPEAT SCREENING 1	19FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261313, a 41-year-old white male with a pertinent medical history of obesity (since 2006; bariatric surgery in 2012), hypertension (since 2015), and subfertility (since 2015; the second pregnancy of the subject's partner was due to artificial insemination), received Dose 1 on 20 Aug 2020 and Dose 2 on 11 Sep 2020 (Day 23). The subject's partner had an exposure during pregnancy on 06 Oct 2020, 25 days after the subject received Dose 2. Concomitant medication included amlodipine (since 2015) for systemic arterial hypertension. On 18 Jan 2021 (Day 152), the subject had a COVID-19 illness visit at the site and reported that his partner was 4 months pregnant. The subject was instructed to bring his partner to the site for evaluation with pregnancy tests for follow-up and for signing the consent form. His partner had 2 previous pregnancies resulting in 2 live births (with no maternal or neonatal complications). He confirmed that they were not using condoms regularly because of previous difficulties of becoming pregnant. However, the need to use condoms in the study was reinforced and the subject agreed. The first day of his partner's last menstrual period was 22 Sep 2020 (Day 34), with the estimated date of conception being 06 Oct 2020 (Day 48) and the expected date of delivery being 29 Jun 2021. The subject and his partner did not smoke, drink alcohol, or use illicit drugs during this pregnancy. The subject denied occupational or environmental risk factors and family history of genetic diseases/congenital anomalies or consanguinity among family members. On 11 Dec 2020 (Day 114), the subject's partner underwent an ultrasound scan, which revealed pregnancy with a gestational age of 12 weeks 1 day and a subchorionic hematoma measuring 14.9 mm × 6. 8 mm × 21.1 mm in size. His partner was on complete rest and was treated with oral progesterone 1 tablet once daily (QD), and the hematoma resolved. She was also treated with 5 mg folic acid QD (from the 5th to the 12th week of gestation) and multivitamin and iron supplement at 1 tablet orally QD and vitamin D 1000 IU QD (since the 12th week of gestation). On 18 Jan 2021 (Day 152), a SARS-CoV-2 test was performed, and the result obtained on 20 Jan 2021 (Day 154) was positive. The subject and his partner were reoriented about the need for social isolation for 14 days and were asked to visit the center after the quarantine. The subject's partner's pregnancy was going well without any complications. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 19 Feb 2021 (Day 184) and 12 Mar 2021 (Day 205), respectively, and remains in the study.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1983	37	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
185.3 cm	95.4 kg	27.8 kg/m2	14SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	14SEP2020 (1)	13:36
2	Placebo	05OCT2020 (22)	13:06

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	05FEB2021 (145)	12:58
4	BNT162b2	26FEB2021 (166)	10:55

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Exposure during pregnancy	Exposure During Pregnancy	01FEB2021 (141)		ONGOING			
2	GENRL	Injection site pain	Pain at injection site	05FEB2021 (145)	17:58	06FEB2021 (146)		2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: Partner pregnancy	2	120	Y
2	TC	N	Resolved (06FEB2021)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	03NOV2020	
Completed	REPEAT SCREENING 1	05FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261713, a 37-year-old white male with no reported medical history, received Dose 1 on 14 Sep 2020 and Dose 2 on 05 Oct 2020 (Day 22). The subject's partner had an exposure during pregnancy on 01 Feb 2021, 119 days after the subject received Dose 2. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 05 Feb 2021 (Day 145) and 26 Feb 2021 (Day 166), respectively, and remains in the study. The subject informed the site that his wife was pregnant and sent his wife's serum human chorionic gonadotropin pregnancy test results performed on 08 Mar 2021 (Day 176), which confirmed the pregnancy. The estimated date of pregnancy was reported as 01 Feb 2021 (Day 141). The subject reported that his wife did not know the date of her last menstrual period. The subject confirmed that he used condoms regularly and that the pregnancy was not expected. The subject reported that his partner's pregnancy was going well, without any complications, and it was being followed up by a gynecologist/obstetrician.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	31	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182 cm	161 kg	48.6 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
obesity	Obesity	01JUN2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13AUG2020 (1)	15:15
3	BNT162b2	22FEB2021 (194)	14:39

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy (female partner)	07NOV2020 (87)	16:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N	Yes	NOT RELATED/OTHER: unknown	1	87	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Withdrawn	VACCINATION	19AUG2020	NO LONGER MEETS ELIGIBILITY CRITERIA
Completed	REPEAT SCREENING 1	22FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1231 12311147, a 31-year-old white male with a pertinent medical history of obesity (since 01 Jun 2000), received Dose 1 on 13 Aug 2020. The subject's partner had an exposure during pregnancy on 07 Nov 2020, 86 days after the subject received Dose 1.

On 19 Aug 2020 (Day 7), the subject tested positive for COVID-19 and was discontinued from the study intervention on the same day (Day 7), since he no longer met the eligibility criteria.

On 21 Dec 2020 (Day 131), the subject stated that his partner had a positive serum pregnancy test (β-human chorionic gonadotropin) on 18 Dec 2020 (Day 128). The contraception method used was a barrier method (condom). The first day of his partner's last menstrual period was 05 Nov 2020 (Day 85) and the estimated date of conception was 07 Nov 2020 (Day 87). His 29-year-old partner had no previous pregnancies and no obstetrical history. The subject's partner did not smoke, drink alcohol, or use illicit drugs during this pregnancy. The subject smoked (5 cigarettes per day) and drank alcohol (social on weekends), with no use of illicit drugs during this pregnancy. On 19 Jan 2021 (Day 160), a transvaginal ultrasound examination showed a single embryo with a gestational age of 10 weeks 3 days ± 1 week with an anterior placenta; cardiac activity and movements were present. On 27 Jan 2021 (Day 168), a repeat transvaginal ultrasound examination showed a gestational sac implanted in the fundus of the uterus, a gestational age of 12 weeks 3 days, and cardiac activity with a fetal heart rate of 158 beats/min. The amniotic fluid was normal; nasal bone was present and nuchal translucency was 0.92 mm; ductus venosus and uterine arteries seen via Doppler echocardiography were unremarkable. On 29 Jan 2021 (Day 170), the subject reported that his partner was feeling well and was asymptomatic. On 04 Feb 2021 (Day 176), the subject's partner's blood test results were unremarkable, except for rubella-specific immunoglobulin G (IgG) (28.1 IU/mL; normal range [NR]: positive at more than 10 IU/mL) and anticytomegalovirus IgG (more than 250 IU/mL; NR: positive at more than 15 IU/mL); the blood group was O and the RH factor was positive.

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first dose of BNT162b2 on 22 Feb 2021 (Day 194) and remains in the study.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	24	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	82.15 kg	32.9 kg/m2	15AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bulimia	Bulimia nervosa	01APR2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15AUG2020 (1)	16:58
2	Placebo	04SEP2020 (21)	17:25

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Exposure during pregnancy	Drug Exposed Pregnancy	07NOV2020 (85)	20:00	ONGOING		
2	INFEC	Urinary tract infection	Complicated Urinary Tract Infection	04JAN2021 (143)	08:00	18JAN2021 (157)	19:00	15

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Yes	NOT RELATED/OTHER: unknown	2	65	Y
2	3	TC	Y	Resolved (18JAN2021)	NOT RELATED/OTHER: unknown	2	123	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311387, a 24-year-old white female with a pertinent medical history of bulimia nervosa (from 01 Apr 2015 to 10 Dec 2015) and tobacco smoking (from an unspecified date to 02 Dec 2020), and no previous pregnancies, received Dose 1 on 15 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 21). The subject had a reported exposure during pregnancy on 07 Nov 2020, 64 days after receiving Dose 2, and urinary tract infection on 04 Jan 2021, 122 days after receiving Dose 2. On 08 Dec 2020 (Day 116), the subject's urine pregnancy test was positive. The first day of her last menstrual period was 01 Nov 2020 (Day 79) and the estimated date of conception was 07 Nov 2020 (Day 85). It was reported that the contraceptive method used was a barrier method (condom). The subject did not smoke, drink alcohol, or use illicit drugs during this pregnancy. Her 32-year old partner smoked (5 cigarettes per day) and drank alcohol (beers) during social weekends, but he did not take any drugs (over-the-counter or prescription) or use illicit drugs during this pregnancy. A transvaginal ultrasound examination on 09 Dec 2020 (Day 117) showed a small image, probably a gestational sac (to be confirmed) and a gestational age of less than 5 weeks. On 21 Dec 2020 (Day 129), a transvaginal ultrasound examination was performed, which showed a uterus increased in size as the result of a normoinserted gestational sac measuring 25 mm with positive embryo cardiac activity and movements, and the gestational age was 6 weeks 2 days. On 23 Dec 2020 (Day 131), the subject reported that she was feeling well when contacted via telephone. On 04 Jan 2021 (Day 143), her urine culture was positive for Escherichia coli and she was diagnosed with a urinary tract infection, which was considered an important medical event by the investigator. The subject did not have any symptoms of urinary tract infection and she denied having fever. Her blood test results were unremarkable, her blood group was O, and the RH factor was positive; a Venereal Disease Research Laboratory (VRDL) test was negative; hepatitis B virus surface antigen was 0.23 (nonreactive [not reactive <1]; units not reported); human immunodeficiency virus test was negative; Chagas disease (American trypanosomiasis) test was negative; toxoplasmosis immunoglobulin G (IgG) test was nonreactive; toxoplasmosis immunoglobulin M (IgM) test was negative; and antirubella antibody test was 6.2 IU/mL (indeterminate: 5-9.9 IU/mL). The subject was treated with oral amoxicillin/sulbactam (875/125 mg) twice a day (BID) for 7 days (from 11 Jan 2021 to 18 Jan 2021). On 18 Jan 2021 (Day 157), the urinary tract infection resolved. On 21 Jan 2021 (Day 160), the subject reported feeling well. On 04 Feb 2021 (Day 174), a transvaginal ultrasound examination showed a single fetus, with positive movements, heart rate of 157 beats/min, gestational age of 13 weeks ± 5 days with adequate amniotic fluid, and presence of nasal bone. On 08 Feb 2021 (Day 178), the subject was feeling well but had morning sickness. She was seen by her obstetrician/gynecologist, who prescribed pyridoxine 10 mg and doxylamine 10 mg BID, with improvement of the symptoms. The subject denied urinary symptoms and it was reported that her next obstetrician/gynecologist appointment was scheduled on 21 Feb 2021 (Day 191). In the opinion of the investigator, there was no reasonable possibility that the urinary tract infection was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	55.3 kg	18.7 kg/m2	15AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depressive Syndrome due to Relative Passing Away	Adjustment disorder with depressed mood	06JUN2008	Past
Smoking	Tobacco user	01MAY2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15AUG2020 (1)	19:55
2	Placebo	07SEP2020 (24)	19:40

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure during Pregnancy	09NOV2020 (87)	08:30	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N	Yes	NOT RELATED/OTHER: unknown	2	64	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15AUG2020	
Completed	VACCINATION	06OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311448, a 31-year-old white female with a pertinent medical history of tobacco use (from 01 May 2014 at a frequency of 7 cigarettes per day and discontinued during this pregnancy) and an obstetrical history of 1 previous pregnancy resulting in 1 live birth via spontaneous vaginal delivery on 27 Jul 2012, received Dose 1 on 15 Aug 2020 and Dose 2 on 07 Sep 2020 (Day 24). The subject had an exposure during pregnancy on 09 Nov 2020, 63 days after receiving Dose 2. On 14 Dec 2020 (Day 122), the subject's urine pregnancy test was positive. The first day of her last menstrual period was 06 Nov 2020 (Day 84) and the estimated date of conception was 09 Nov 2020 (Day 87). The subject did not smoke, drink alcohol, or use illicit drugs during this pregnancy. Her 40-year-old husband smoked (6 cigarettes per day) but he did not drink alcohol or use illicit drugs during this pregnancy. On 07 Jan 2021 (Day 146), the subject reported that she was feeling well and asymptomatic. On 11 Jan 2021 (Day 150), a transvaginal ultrasound examination revealed a normoinserted gestational sac, maximum embryonic length measuring 22.7 mm, positive cardiac activity, and a gestational age of 9 weeks ± 1 week. On 07 Feb 2021 (Day 177), the subject was contacted, and she reported that she was seen by her obstetrician/gynecologist. The subject's next obstetrician/gynecologist appointment was scheduled on 12 Feb 2021 (Day 182).

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1978	42	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
168 cm	97.2 kg	34.4 kg/m2	16AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	16AUG2020 (1)	16:45
2	BNT162b2	04SEP2020 (20)	13:40

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Benign hydatidiform mole	Molar pregnancy in partner	JAN2021 ()		JAN2021 ()		
2	INJ&P	Exposure during pregnancy	Drug exposed pregnancy (female partner)	20NOV2020 (97)	18:00	JAN2021 ()		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Resolved (JAN2021)	NOT RELATED/OTHER: it is unknown	2		Y
2		N	N	Resolved (JAN2021)	NOT RELATED/OTHER: unknown	2	78	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311635, a 42-year-old white male with no reported medical history, received Dose 1 on 16 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 20). The subject's partner had a reported exposure during pregnancy on 20 Nov 2020, 77 days after the subject received Dose 2, and a benign hydatidiform mole in Jan 2021. The subject's partner, with no obstetrical history, did not provide the date of her last menstrual period or estimated date of conception. She did not sign the pregnant partner information disclosure form. The subject did not smoke, drink alcohol, or use illicit drugs during his partner's pregnancy. The contraceptive method was a barrier method (condom). The subject's partner was diagnosed with benign hydatidiform mole in Jan 2021. The subject's partner's benign hydatidiform mole resolved on an unspecified date in Jan 2021. In the opinion of the investigator, there was no reasonable possibility that the benign hydatidiform mole was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1988	31	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
161 cm	63.7 kg	24.6 kg/m2	17AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	17AUG2020 (1)	17:40
2	Placebo	07SEP2020 (22)	15:49

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PREG	Abortion spontaneous	Complete miscarriage	27FEB2021 (195)	20:00	10MAR2021 (206)	14:00	12
2	INJ&P	Exposure during pregnancy	Exposure during pregnancy	05JAN2021 (142)	08:00	05MAR2021 (201)	17:00	60

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (10MAR2021)	NOT RELATED/OTHER: it is unknown	2	174	Y
2		N	N	Resolved (05MAR2021)	NOT RELATED/OTHER: it is unknown	2	121	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	05OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311812, a 31-year-old white female with no previous pregnancies, received Dose 1 on 17 Aug 2020 and Dose 2 on 07 Sep 2020 (Day 22). The subject had an exposure during pregnancy on 05 Jan 2021, 120 days after receiving Dose 2, and reported spontaneous abortion on 27 Feb 2021, 173 days after receiving Dose 2. On 07 Feb 2021 (Day 175), the subject's urine pregnancy test was positive, but she did not consult her obstetrician/gynecologist at that time and there were no adverse events with her pregnancy. It was reported that her partner used a condom as a contraceptive method. The first day of her last menstrual period was 05 Jan 2021 (Day 142) and the estimated date of conception was unknown at the time of this report. The subject did not smoke, drink alcohol, or use illicit drugs during this pregnancy. Her partner smoked (3 cigarettes per day), but he did not drink alcohol, take any over-the-counter or prescription drugs, or use illicit drugs during this pregnancy. On 27 Feb 2021 (Day 195), the subject started complaining of moderate vaginal bleeding. On 05 Mar 2021 (Day 201), a transvaginal ultrasound scan revealed a homogeneous endometrium measuring 18 mm with no evidence of gestational sac, and confirmed spontaneous abortion. On 08 Mar 2021 (Day 204), the subject was seen by her obstetrician/gynecologist, who prescribed intravaginal misoprostol 200 µg. On the same day (Day 204), the subject continued to have vaginal bleeding without abdominal pain. On 10 Mar 2021 (Day 206), the subject was feeling well and asymptomatic and recovered from the spontaneous abortion on the same day. In the opinion of the investigator, there was no reasonable possibility that the spontaneous abortion was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	40	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	62.2 kg	22.6 kg/m2	19AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	10:23
2	BNT162b2	07SEP2020 (20)	16:25

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PREG	Abortion spontaneous	Spontaneous abortion	26NOV2020 (100)	22:00	29NOV2020 (103)	23:00	4	2
2	INJ&P	Exposure during pregnancy	exposure during pregnancy	29SEP2020 (42)	20:00	29NOV2020 (103)	23:00	62	

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (29NOV2020)	NOT RELATED/OTHER: unknown	2	81	Y
2	N	N	Resolved (29NOV2020)	NOT RELATED/OTHER: unplanned pregnancy	2	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	05OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312205, a 40-year-old white female with an obstetrical history of 1 previous pregnancy resulting in a live birth via vaginal delivery, received Dose 1 on 19 Aug 2020 and Dose 2 on 07 Sep 2020 (Day 20). The subject had a reported exposure during pregnancy on 29 Sep 2020, 22 days after receiving Dose 2 and spontaneous abortion on 26 Nov 2020, 80 days after receiving Dose 2. On 05 Nov 2020 (Day 79), the subject's urine pregnancy test was positive. The first day of her last menstrual period was 29 Sep 2020 (Day 42) and the estimated date of conception was 29 Sep 2020 (Day 42). The gestational age at the time of initial exposure was first trimester. On 07 Nov 2020 (Day 81), a transvaginal ultrasound examination showed a gestational sac measuring 9 mm; gestational age was less than 4 weeks and an embryo was not visualized. The subject smoked (20 cigarettes per day), drank alcohol weekly, but did not use illicit drugs during this pregnancy. Her 44-year-old partner smoked (15 cigarettes per day), drank alcohol weekly, but did not use illicit drugs during this pregnancy. On 14 Nov 2020 (Day 88), a transvaginal ultrasound examination showed the presence of a normoinserted gestational sac and a 6.5-mm embryo, which corresponded to 6 weeks 3 days of gestation ± 5 days; visible cardiac kinetics, however, were not perceptible at the time of examination by this method. On 26 Nov 2020 (Day 100), the subject consulted her gynecologist and a transvaginal ultrasound examination was done, but the results were not reported. On 27 Nov 2020 (Day 101), the obstetric ultrasound examination showed an embryo without cardiac activity, which confirmed embryo intrauterine death. The blood tests were unremarkable on an unspecified date. On 28 Nov 2020 (Day 102), the subject reported that she had a spontaneous abortion. She had been having vaginal bleeding in the last 48 hours as of 29 Nov 2020 (Day 103) with retained products of conception, without pain or any other symptoms. She was admitted to the hospital for medical management from 29 Nov 2020 (Day 103) until 30 Nov 2020 (Day 104) to help complete expulsion of the retained intrauterine conception products because of an incomplete spontaneous abortion. She was prescribed misoprostol and had a manual vacuum aspiration. The discharge medications included ibuprofen 400 mg and paracetamol 500 mg as needed. The subject remained asymptomatic without vaginal bleeding or pain. A COVID-19 test was not performed because the subject did not present any symptoms related to COVID-19 illness. On 29 Nov 2020 (Day 103), the subject recovered from the spontaneous abortion. In the opinion of the investigator, there was no reasonable possibility that the spontaneous abortion was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	44	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	73 kg	27.8 kg/m2	19AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	18:22
2	BNT162b2	08SEP2020 (21)	16:05

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy	24DEC2020 (128)	20:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N	Yes	NOT RELATED/OTHER: it is unknown	2	108	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	06OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312378, a 44-year-old white female with a pertinent obstetrical history of 6 previous pregnancies resulting in 4 live births via spontaneous vaginal deliveries and 2 miscarriages (spontaneous abortions), received Dose 1 on 19 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 21). The subject had an exposure during pregnancy on 24 Dec 2020, 107 days after receiving Dose 2. Concomitant medications included ethinylestradiol and drospirenone (both from 18 Sep 2020 to 10 Dec 2020) for oral contraception. On 20 Jan 2021 (Day 155) and 21 Jan 2021 (Day 156), the subject's urine pregnancy tests were positive. The first day of her last menstrual period was 18 Dec 2020 (Day 122) and the estimated date of conception was 24 Dec 2020 (Day 128). She did not smoke or use illicit drugs, but she drank alcohol (2 times [beer]) during this pregnancy. Her 39-year-old partner did not take any drugs, smoke, or drink alcohol, but he used illicit drugs (marijuana daily) during this pregnancy. On an unknown date, the subject's serum pregnancy test (β-human chorionic gonadotropin) was positive. Upon follow-up on 01 Feb 2021 (Day 167), the subject was feeling well and asymptomatic; she was seen by her obstetrician/gynecologist the same day. On 04 Feb 2021 (Day 170), a transvaginal ultrasound examination showed an increase in uterus size. The gestational sac was 10.9 mm (approximate gestational age of 6 weeks ± 1 week) and an embryo was not visualized. Therefore, a new ultrasound examination was suggested in 1 to 2 weeks to reevaluate. On 09 Feb 2021 (Day 175), at the time of the telephone contact, the subject reported mild vaginal bleeding without any other symptoms, and she was seen by her obstetrician/gynecologist, who ordered a new transvaginal ultrasound examination in 7 days. On 18 Feb 2021 (Day 184), a transvaginal ultrasound examination showed anteversion and anteflexion of the uterus with a vital embryo with a gestational age of 8 weeks and heart rate of 146 beats/min; movements were present. On 02 Mar 2021 (Day 196), the subject was feeling well and asymptomatic. On 16 Mar 2021 (Day 210), a transvaginal ultrasound examination showed a single embryo with a gestational age of 11 weeks 3 days ± 10 days, normal amniotic fluid, positive cardiac activity, a heart rate of 160 beats/min, and nuchal translucency of 1.1 mm; nasal bone and movements were present. Normal abdominal wall, skull, and brain development according to gestational age were noted. Two uterine intramural myomas measuring 16 × 13 mm and 13 × 10 mm were noted on the anterior surface. On 19 Mar 2021 (Day 213), the subject was feeling well and asymptomatic.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1983	37	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
173 cm	66.5 kg	22.2 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
spontaneous abortion	Abortion spontaneous	2011	Past
spontaneous abortion	Abortion spontaneous	2011	Past
Spontaneous abortion	Abortion spontaneous	01NOV2014	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	12:25
2	Placebo	11SEP2020 (23)	11:39

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy	30NOV2020 (103)	08:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N	Yes	NOT RELATED/OTHER: it is unknown	2	81	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	14OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312529, a 37-year-old white female with a pertinent obstetrical history of 2 spontaneous abortions (twice in 2011) and 1 spontaneous abortion (on 01 Nov 2014), received Dose 1 on 20 Aug 2020 and Dose 2 on 11 Sep 2020 (Day 23). The subject had an exposure during pregnancy on 30 Nov 2020, 80 days after receiving Dose 2. The subject had a positive serum β-human chorionic gonadotropin test on 13 Jan 2021 (Day 147). She was not using contraception. The first day of her last menstrual period was unknown and the estimated date of conception was 30 Nov 2020 (Day 103). She did not smoke, drink alcohol, or use illicit drugs during this pregnancy. Her 33-year-old partner did not smoke or use illicit drugs, but he drank alcohol occasionally (beers) during this pregnancy. Her partner had no risk factors, including environmental or occupational exposures, and did not take any over-the-counter or prescription drugs. On 23 Jan 2021 (Day 157), the subject was feeling well and asymptomatic. On 17 Feb 2021 (Day 182), a transvaginal ultrasound examination showed an anteverted and anteflexed uterus and normoinserted gestational sac; embryo was visualized measuring 46.5 mm with a gestational age of 11 weeks 2 days; amniotic fluid was adequate; cardiac activity was positive; nuchal translucency was 0.8 mm; nasal bone was present; and ductus venosus was within normal characteristics. On 17 Feb 2021 (Day 182), Doppler echocardiography of the uterine arteries was unremarkable. On 27 Feb 2021 (Day 192), the subject stated that she was feeling well and asymptomatic. A transvaginal ultrasound examination was performed on an unknown date. During the ultrasound examination, the subject was asked about her last menstrual period, and she could not recall the exact date. Her next obstetrician/gynecologist appointment was scheduled in 3 weeks.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1993	27	American Indian or Alaska Native	Hispanic/Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
162 cm	70 kg	26.7 kg/m2	25AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	25AUG2020 (1)	12:28
2	Placebo	13SEP2020 (20)	19:36

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Exposure during pregnancy	Exposure to Investigation product during pregnancy	12SEP2020 (19)	13:38	ONGOING			
2	NERV	Headache	headache	14SEP2020 (21)	10:00	22SEP2020 (29)	17:00	9	3
3	INFEC	Urinary tract infection	Supected Complicated Urinary Tract Infection	31JAN2021 (160)	09:30	17FEB2021 (177)	21:00	18	3
4	GENRL	Injection site pain	Injection site pain	25AUG2020 (1)	12:30	25AUG2020 (1)	14:00	1	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: unplanned pregnancy	1	19	Y
2	TC	N	Resolved (22SEP2020)	NOT RELATED/OTHER: Unknown	2	2	N
3	TC	Y	Resolved (17FEB2021)	NOT RELATED/OTHER: unknown	2	141	Y
4	N	N	Resolved (25AUG2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	13OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313879, a 27-year-old American Indian or Alaska Native female with a pertinent obstetrical history of 3 previous pregnancies resulting in 2 spontaneous vaginal deliveries (2 children) and 1 miscarriage, received Dose 1 on 25 Aug 2020 and Dose 2 on 13 Sep 2020 (Day 20). The subject had an exposure during pregnancy on 12 Sep 2020, 18 days after receiving Dose 1, and a urinary tract infection on 31 Jan 2021, 140 days after receiving Dose 2. The subject's urine pregnancy test was positive on 13 Oct 2020 (Day 50). The first day of her last menstrual period was 10 Sep 2020 (Day 17) and the estimated date of conception was 12 Sep 2020 (Day 19). The expected date of delivery is 17 Jun 2021. The subject and her partner did not smoke, drink alcohol, or use illicit drugs, and the subject's partner did not use over-the-counter drugs or prescription drugs during the subject's pregnancy. On 25 Nov 2020 (Day 93), a transvaginal ultrasound scan showed a gestational sac measuring 36 mm with a gestational age of 10 weeks 4 days ± 7 days, positive embryo heart rate and embryo movements, adequate amniotic fluid, and low anterior chorion. On 01 Dec 2020 (Day 99), a transvaginal ultrasound scan and abdominal scan showed a gestational age of 11 weeks 3 days, and low anterior placenta. On 23 Dec 2020 (Day 121), the subject reported that she was feeling well. On 29 Dec 2020 (Day 127), bloodwork showed an elevated white blood cell count of 15,000/mm^3 (normal range [NR]: 4000-10,500/mm^3), decreased hemoglobin of 11.4 g/dL (NR: 12-15 g/dL) and mean corpuscular volume of 83.4 fl (NR: 85-95 fl), and normal hematocrit of 36.4% (NR: 36%-45%) and neutrophils at 74.8% (NR not reported). The rest of the results were unremarkable; her blood group was O and Rh factor was

Narrative Comment
positive. Immunoserology tests showed elevated toxoplasmosis immunoglobulin G (IgG) of 1541 U/mL (upper limit of normal: 30 U/mL); and Chagas disease (American trypanosomiasis) test, toxoplasmosis immunoglobulin M (IgM) test, human immunodeficiency virus test, Venereal Disease Research Laboratory (VDRL) test, and hepatitis B virus surface antigen test were all negative. On 05 Jan 2021 (Day 134), the subject visited her obstetrician/gynecologist, as she had hypertension with a blood pressure (BP) reading of 130/80 mmHg (systolic arterial hypertension), and she was advised to monitor her daily BP for a week. The subject also experienced odynophagia, headache, and nasal congestion. On 06 Jan 2021 (Day 135), a SARS-CoV-2 test was negative, and the subject's BP was 110/80 mmHg. On 07 Jan 2021 (Day 136), the subject's nasal congestion persisted, and her BP was normal at 120/70 mmHg. Her daily BP readings were as follows: 110/80 mmHg on 08 Jan 2021 (Day 137); 100/60 mmHg on 09 Jan 2021 (Day 138); 120/80 mmHg on 10 Jan 2021 (Day 139); and 130/80 mmHg on 11 Jan 2021 (Day 140). On 12 Jan 2021 (Day 141), a Doppler fetal echocardiography was performed, but the result was unknown, and the subject's BP was 120/80 mmHg. A transvaginal ultrasound scan showed a gestational age of 18 weeks 2 days and weight of 243 g ± 35 g; fetal biometry showed a fetal biparietal diameter of 4.13 cm, head circumference of 14.6 cm, abdominal circumference of 13.5 cm, and femoral diaphysis length of 2.67 cm; positive cardiac activity; adequate amniotic fluid; and anterior placenta. On 13 Jan 2021 (Day 142), her BP reading was 120/70 mmHg, and on 14 Jan 2021 (Day 143), it was 120/80 mmHg. On 14 Jan 2021 (Day 143), a Pap smear cytology was negative for inflammation. The subject's BP was monitored daily, and her highest value as of 25 Jan 2021 (Day 154) was 130/80 mmHg. As of 28 Jan 2021 (Day 157), the subject was feeling well and asymptomatic. On 31 Jan 2021 (Day 160), she complained of dysuria, pollakiuria, and increased vaginal discharge, malodorous and yellow/green in color. Vaginitis and complicated urinary tract infection were suspected. The physician prescribed cephalexin 500 mg 4 times a day (QID) for 7 days and metronidazole 500 mg once daily (QD) for 4 days. The obstetrician-gynecologist appointment was scheduled for 08 Feb 2021 (Day 168). On 09 Feb 2021 (Day 169), the subject reported that she presented to her obstetrician/gynecologist with an episode of vomiting, headache, and epistaxis associated with a systolic BP recording of 140 mmHg at home (on an unknown date). The subject was advised by her obstetrician to control her daily BP strictly, and reinforced that she had to visit the emergency room (ER) if her BP was more than 140/90 mmHg. On the same day (Day 169), a vaginal discharge culture result was pending and a urine culture was contaminated, and she had to repeat the sample in 7 days. A serious adverse event of suspected complicated urinary tract infection was reported with an onset date of 31 Jan 2021 (Day 160) and was considered an important medical event. The subinvestigator contacted the subject for follow-up on 15 Feb 2021 (Day 175), and the subject stated that she was feeling well and asymptomatic and completed her antibiotic treatment with cephalexin 500 mg QID and metronidazole 500 mg QD. On 17 Feb 2021 (Day 177), the suspected complicated urinary tract infection resolved. On 27 Feb 2021 (Day 187), a urine culture was negative. The subject's daily BP readings were as follows: 110/70 mmHg on 26 Feb 2021 (Day 186); 120/70 mmHg on 27 Feb 2021 (Day 187); 130/80 mmHg on 28 Feb 2021 (Day 188); 130/80 mmHg on 01 Mar 2021 (Day 189); 150/80 mmHg and 120/70 mmHg on 07 Mar 2021 (Day 195); and 110/70 mmHg on 08 Mar 2021 (Day 196). On 07 Mar 2021 (Day 195), the subject reported that her BP reading was 150/80 mmHg and she experienced epistaxis. The subject visited the ER (details unknown) and she was not given any medication as per the subject. A fetal monitoring was performed (date and result unknown). On 08 Mar 2021 (Day 196), a transvaginal ultrasound scan showed a gestational age of 25 weeks 5 days and a weight of 849 g ± 124 g; fetal biometry showed a fetal biparietal diameter of 6.39 cm, head circumference of 27.3 cm, abdominal circumference of 21 cm, femoral diaphysis length of 4.8 cm, normal amniotic fluid with positive cardiac activity, and placenta in the uterine fundus. On 09 Mar 2021 (Day 197), the subject visited her obstetrician/gynecologist and on examination, her BP reading was 120/70 mmHg and the uterine height was 27 cm, fetal heart rate was 150 beats/min, and fetal movement was positive. In the opinion of the investigator, there was no reasonable possibility that the urinary tract infection was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1980	40	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
147 cm	59 kg	27.3 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anemia	Anaemia	15AUG2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	18:10
2	Placebo	15SEP2020 (22)	15:20

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	20FEB2021 (180)	11:20
4	BNT162b2	12MAR2021 (200)	17:53

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PREG	Abortion spontaneous complete	Complete spontaneous abortion	24JAN2021 (153)	11:00	08FEB2021 (168)		16
2	INJ&P	Exposure during pregnancy	Drug exposed pregnancy	25DEC2020 (123)	11:00	28JAN2021 (157)	13:00	35

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (08FEB2021)	NOT RELATED/OTHER: unknown	2	132	Y
2		N	N	Resolved (28JAN2021)	NOT RELATED/OTHER: unknown	2	102	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	20FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313998, a 40-year-old white female with a pertinent medical history of anemia (since 15 Aug 2015) and no obstetrical history, received Dose 1 on 25 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 22). The subject had an exposure during pregnancy on 25 Dec 2020, 101 days after receiving Dose 2, and reported complete spontaneous abortion on 24 Jan 2021, 131 days after receiving Dose 2. Concomitant medications included folic acid/iron and cholecalciferol (both since 15 Aug 2015) for anemia. On 25 Jan 2021 (Day 154), the subject visited the hospital to complete her eligibility assessment to receive BNT162b2, as she had been found to be eligible for revaccination as per protocol on 16 Jan 2021; a urine pregnancy test taken on the same day was positive. The contraceptive method used was a barrier method (use of a condom by her partner). She was feeling well and asymptomatic. The first day of her last menstrual period was 25 Dec 2020 (Day 123) and the estimated date of conception was unknown. She smoked 3 cigarettes a day but did not drink alcohol or use illicit drugs during the pregnancy. Her 34-year-old partner did not smoke, drink alcohol, or use illicit drugs during the pregnancy. On 28 Jan 2021 (Day 157), the subject visited an obstetrician/gynecologist for painful vaginal bleeding. On examination, her oxygen saturation was 98%, heart rate was 80 beats/min, and blood pressure was 90/60 mmHg. She denied pelvic pain at the time of the examination, while the examination showed mild vaginal bleeding and a closed uterine neck. A serum β-human chorionic gonadotropin (β-hCG) was 5043 MIU/mL (positive) and a transvaginal ultrasound scan showed anteversion and anteflexion of the uterus (93.9 mm, 56.7 mm, 65.5 mm) and endometrium without any evidence of a gestational sac. A β-hCG test was performed on an unknown date and the result was pending. On 29 Jan 2021 (Day 158), the subject visited her gynecologist for treatment, who prescribed intravaginal misoprostol (dose unknown), after which she began to expel decidua and had more vaginal bleeding. On 01 Feb 2021 (Day 161), the subject had mild vaginal bleeding. On 08 Feb 2021 (Day 168), an obstetrician/gynecologist appointment was scheduled, and a transvaginal ultrasound scan showed anteversion and anteflexion of the uterus (73 mm, 33 mm, 47 mm), homogeneous echo structure, and endometrium of 4.8 mm. The subject was feeling well and asymptomatic. The complete spontaneous abortion was considered as resolved on 08 Feb 2021 (Day 168). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 20 Feb 2021 (Day 180) and 12 Mar 2021 (Day 200), respectively, and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the complete spontaneous abortion was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1980	39	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156 cm	90 kg	37 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hepatitis A	Hepatitis A	01JUL1987	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	19:20

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	13SEP2020 (20)	10:45
3	BNT162b2	04MAR2021 (192)	11:16

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Exposure during pregnancy	exposure during pregnancy	31AUG2020 (7)	17:30	09NOV2020 (77)		71	

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (09NOV2020)	NOT RELATED/OTHER: unplanned pregnancy	1	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	13OCT2020	
Completed	REPEAT SCREENING 1	04MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12314059, a 39-year-old white female with a pertinent obstetrical history of 7 pregnancies resulting in 6 live births via spontaneous vaginal deliveries and 1 miscarriage, received Dose 1 on 25 Aug 2020 and Dose 2 on 13 Sep 2020 (Day 20). The subject had an exposure during pregnancy on 31 Aug 2020, 6 days after receiving Dose 1. On 13 Oct 2020 (Day 50), during Visit 3, the subject reported that she had a positive urine pregnancy test on 26 Sep 2020 (Day 33). The first date of her last menstrual period was 22 Aug 2020. The estimated date of conception was 31 Aug 2020 (Day 7) per ultrasound scan performed on an unknown date. The gestational age at the time of initial exposure was 3 weeks (first trimester). On 28 Sep 2020 (Day 35), a transvaginal ultrasound scan showed a gestational sac located in the uterus measuring 14 × 13 × 13 mm and a gestational age of 4 weeks, but the embryo was not visualized. A repeat transvaginal ultrasound scan on 29 Sep 2020 (Day 36) was consistent with the previous scan. The subject did not smoke, drink alcohol, or use illicit drugs during this pregnancy; however, her 42-year-old partner smoked (10 per day) but did not drink alcohol or use illicit drugs or any other drugs (over-the-counter or prescription) during the pregnancy. The subject was feeling well and she visited her obstetrician on 13 Oct 2020 (Day 50). The subject reported that she had a voluntary termination of pregnancy with misoprostol 200 µg. The outcome of the pregnancy was reported as induced abortion on 09 Nov 2020 (Day 77). On 17 Nov 2020 (Day 85), a transvaginal ultrasound scan showed a normal-sized anteverted and anteflexed uterus and heterogeneous endometrium of 16 mm. The subject remained asymptomatic. On 03 Dec 2020 (Day 101), a transvaginal ultrasound scan showed a normal-sized anteverted and anteflexed uterus and endometrium of 9 mm. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 04 Mar 2021 (Day 192) and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	41	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	59 kg	23.6 kg/m2	26AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	11:40

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	PREG	Abortion incomplete	incomplete abortion	11FEB2021 (170)	09:00	13FEB2021 (172)	19:00	3
2	INJ&P	Exposure during pregnancy	Drug Exposed Pregnancy	07DEC2020 (104)	08:00	13FEB2021 (172)		69

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC/TCN	Y	Resolved (13FEB2021)	NOT RELATED/OTHER: it is unknown	1	170	Y
2		N	N	Resolved (13FEB2021)	NOT RELATED/OTHER: unknown	1	104	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Withdrawn	VACCINATION	14SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12314134, a 41-year-old white female with a pertinent obstetrical history of 2 previous pregnancies with 2 spontaneous vaginal deliveries (2 children), received Dose 1 on 26 Aug 2020. The subject had an exposure during pregnancy on 07 Dec 2020, 103 days after receiving Dose 1. The subject had an incomplete abortion on 11 Feb 2021, 169 days after receiving Dose 1. The subject tested positive for COVID-19 on 28 Aug 2020 (Day 3). She was discontinued from the study intervention on 14 Sep 2020 since she no longer met the eligibility criteria. On 12 Jan 2021 (Day 140), the subject's urine pregnancy test was positive. The first day of her last menstrual period and the estimated date of conception were reported as 07 Dec 2020 (Day 104). The contraception method used was a barrier method (condom). She and her 52-year-old partner did not smoke tobacco, drink alcohol, or use illicit drugs. An obstetrician/gynecologist appointment was scheduled in 2 weeks; however, the subject reported that she had not consulted the obstetrician/gynecologist yet, and the investigator strongly recommended an appointment as soon as possible. On 22 Jan 2021 (Day 150), a transvaginal ultrasound scan showed uterine myomatosis: posterior subserous myoma of 37 mm, in the lower third 2 intramural myomas of 11 mm and 9.6 mm, and 1 myoma 16 mm in fundus; normoinserted gestational sac measuring 6.7 mm, gestational age of 6 weeks 4 days ± 7 days, with positive heart rate and adequate amniotic fluid. On 29 Jan 2021 (Day 157), the subject was feeling well and asymptomatic. On 11 Feb 2021 (Day 170), she had a voluntary interruption of her pregnancy with intravaginal misoprostol 400 µg and had an induced abortion. Later, she complained of abdominal pain and moderate vaginal bleeding. On 12 Feb 2021 (Day 171), she presented to the emergency room because of abdominal pain and moderate vaginal bleeding. She was admitted to the hospital on the same day (Day 171) with a diagnosis of an incomplete abortion and was discharged on 13 Feb 2021 (Day 172). On 10 Mar 2021 (Day 197), she emailed the discharge summary to the site, which stated that on 13 Feb 2021 (Day 172), she was admitted to the gynecology department of another hospital because of the incomplete abortion; a uterine dilation and curettage was performed and a blood test was performed (unknown date and result). The discharge date was reported as 13 Feb 2021 (Day 172). After the data cutoff date of 13 Mar 2021, it was reported that in accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 23 Mar 2021 (Day 210) and remains in the study. In the opinion of the investigator, there was no reasonable possibility that the incomplete abortion was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156 cm	68.4 kg	28.1 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Superficial venous insufficiency	Peripheral venous disease	01MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	17:55
2	Placebo	16SEP2020 (22)	16:15

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	exposure during pregnancy	10DEC2020 (107)	21:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N	Yes	NOT RELATED/OTHER: unknown	2	86	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	29OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1231 12314308, a 31-year-old white female with a pertinent medical history of peripheral venous disease (since 01 Mar 2020) and no obstetrical history, received Dose 1 on 26 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 22). The subject had an exposure during pregnancy on 10 Dec 2020, 85 days after receiving Dose 2. Concomitant medication included bioflavonoids (from 03 Jan 2020 to 22 Jan 2021; not otherwise specified) for superficial venous insufficiency.

On 22 Jan 2021 (Day 150), the subject's urine pregnancy test was positive. A repeat urine pregnancy test done on the same day (Day 150) was also positive. The first day of her last menstrual period was 09 Dec 2020 (Day 106) and the estimated date of conception was 10 Dec 2020 (Day 107). She did not smoke, drink alcohol, or use illicit drugs; however, her 28-year-old partner drank alcohol weekly but did not smoke or use illicit drugs during this pregnancy. Her partner received bisoprolol once daily for an unspecified indication during this pregnancy. Her partner's family history of congenital abnormality/genetic diseases, (b) (6), included congenital cardiopathy. On 29 Jan 2021 (Day 157), the subject had an obstetrician/gynecologist visit, and an ultrasound scan and blood test were requested. The subject was contacted for follow-up, and she was feeling well and asymptomatic. On 01 Feb 2021 (Day 160), she visited her obstetrician/gynecologist and the bloodwork was unremarkable: her blood group was O and the Rh factor was positive; serum beta-human chorionic gonadotropin was 93,642.9 mIU/mL (normal range [NR]: >25 mIU/mL); immunoserology results including human immunodeficiency virus test, Venereal Disease Research Laboratory (VDRL) test, hepatitis B virus surface antigen, Chagas disease (American trypanosomiasis) test, toxoplasmosis immunoglobulin M (IgM) and immunoglobulin G (IgG) tests, and hepatitis C virus test were all negative; rubella-specific IgG was 14.4 IU/mL (positive; NR: >10 IU/mL) and antimeasles IgG was 1/32 (positive; negative cutoff value: 1/8). A transvaginal ultrasound scan showed anteversion and anteflexion of the uterus, normoinserted gestational sac, and a single embryo of 8.1 mm with positive cardiac activity and a gestational age of 7 weeks 4 days. It was reported that an obstetrician/gynecologist appointment was scheduled in 1 week.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1980	39	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152 cm	49 kg	21.2 kg/m2	27AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	09:47
2	Placebo	17SEP2020 (22)	09:33

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Drug Exposed Pregnancy	25OCT2020 (60)	18:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N	Yes	NOT RELATED/OTHER: unknown	2	39	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12314372, a 39-year-old white female with no obstetrical history, received Dose 1 on 27 Aug 2020 and Dose 2 on 17 Sep 2020 (Day 22). The subject had an exposure during pregnancy on 25 Oct 2020, 38 days after receiving Dose 2. Concomitant medication included drospirenone/ethinylestradiol (since an unspecified date) as an oral contraception. On 23 Nov 2020 (Day 89), the subject's urine pregnancy test was positive. The first day of her last menstrual period was unknown and the estimated date of conception was 25 Oct 2020 (Day 60). She did not smoke, drink, or use illicit drugs; however, her 46-year-old partner smoked 5 cigarettes per day, but he did not drink or use illicit drugs during this pregnancy. On 01 Dec 2020 (Day 97), a transvaginal ultrasound scan showed an increased size of the uterus at the expense of a normoinserted gestational sac that contained an embryo with positive cardiac activity; a gestational age of 5 weeks ± 5 days; and presence of a yolk sac. On 21 Dec 2020 (Day 117), the subject was feeling well. An obstetrician/gynecologist appointment was scheduled for 23 Dec 2020 (Day 119). The subject visited her obstetrician/gynecologist on an unknown date. On 29 Dec 2020 (Day 125), the subject's urine culture was negative, bloodwork was unremarkable, and her blood group was A and Rh factor was negative. On 13 Jan 2021 (Day 140), a transvaginal ultrasound scan showed a single fetus with a heart rate of 161 beats/min; gestational age of 13 weeks 2 days; adequate amniotic fluid; and posterior placenta. A fetal biometry revealed a fetal biparietal diameter of 21 mm, and nuchal translucency was 2.3 mm. The fetal anatomy showed the presence of nasal bone, and both hands and feet were visible. A myoma of 14.8 mm on the posterior wall of the uterus was suspected. On 22 Jan 2021 (Day 149), the serum beta-human chorionic gonadotropin was 131,546 IU/L (normal range not reported). The subject was feeling well and asymptomatic. On 11 Feb 2021 (Day 169), a chorionic biopsy showed a normal male karyotype 46 XY. The next obstetrician/gynecologist appointment was scheduled in 3 weeks.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1991	28	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
181 cm	70.8 kg	21.6 kg/m2	27AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27AUG2020 (1)	10:13
2	BNT162b2	15SEP2020 (20)	17:10

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy (female partner)	12NOV2020 (78)	08:00	ONGOING		
2	REPRO	Haematospermia	Hemospermia	26SEP2020 (31)	10:00	26SEP2020 (31)	10:05	1

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		N	N	Yes	NOT RELATED/OTHER: unknown	2	59	Y
2	1	N	N	Resolved (26SEP2020)	NOT RELATED/OTHER: unknown	2	12	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12314395, a 28-year-old white male with no reported medical history, received Dose 1 on 27 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 20). The subject's partner had an exposure during pregnancy on 12 Nov 2020, 58 days after the subject received Dose 2. On 03 Jan 2021 (Day 130), the subject's partner's urine pregnancy test was positive. She was taking oral contraceptives. The first day of her last menstrual period was 20 Oct 2020 (Day 55) and the estimated date of conception was 12 Nov 2020 (Day 78). On 25 Jan 2021 (Day 152), a transvaginal ultrasound examination showed a uterus with a single embryo inside. The gestational age was 10 weeks 4 days; heart rate was positive; and movements were positive. The subject's partner had no medical history, exposure to products, previous pregnancy, or obstetrical history. He and his partner did not smoke, drink alcohol, or use illicit drugs during this pregnancy. On 12 Feb 2021 (Day 170), the subject's partner's bloodwork was unremarkable; urine culture was negative; and immunoserology results including Venereal Disease Research Laboratory (VDRL), human immunodeficiency virus, toxoplasmosis immunoglobulin G, hepatitis B virus surface antigen, hepatitis B core antibody, and hepatitis C virus tests were negative. On 19 Feb 2021 (Day 177), a transvaginal ultrasound examination showed a single embryo with a gestational age of 14 weeks 3 days; normal amniotic fluid; positive cardiac activity with 158 beats/min, movements was positive; nuchal translucency of 1.8 mm, nasal bone of 3 mm; and normoinserted placenta. Doppler ultrasound of the uterine arteries was unremarkable. The subject's partner was feeling well and asymptomatic. The next obstetrician/gynecologist appointment was scheduled in 2 weeks.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1998	21	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
168 cm	89 kg	31.5 kg/m2	27AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	27AUG2020 (1)	15:20
2	Placebo	28SEP2020 (33)	12:30

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Exposure during pregnancy	exposure during pregnancy	30SEP2020 (35)	09:00	ONGOING			
2	INFEC	Urinary tract infection	Complicated urinary infection	08JAN2021 (135)	08:00	23FEB2021 (181)	19:00	47	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: unplanned pregnancy	2	3	Y
2	TC	Y	Resolved (23FEB2021)	NOT RELATED/OTHER: it is unknown	2	103	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	29OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1231 12314531, a 21-year-old white female with an obstetrical history of 2 pregnancies that resulted in 2 miscarriages, received Dose 1 on 27 Aug 2020 and Dose 2 on 28 Sep 2020 (Day 33). The subject had an exposure during pregnancy on 30 Sep 2020, 2 days after receiving Dose 2. She was diagnosed with a urinary tract infection on 08 Jan 2021, 102 days after receiving Dose 2.

On an unspecified date, the subject informed the site that she had a positive urine pregnancy test on 01 Nov 2020 (Day 67). The first day of her last menstrual period was estimated as an unspecified date in Sep 2020 and the estimated date of conception was 30 Sep 2020 (Day 35), which was calculated based on echography. The gestational age at the time of initial exposure was first trimester. The subject was feeling well. She had a blood test to measure human chorionic gonadotropin, and the results showed high levels (unknown date and values). Her 37-year-old partner had no relevant medical history and he was taking bisoprolol once a day during her pregnancy. She and her partner did not smoke, drink alcohol, or use illicit drugs during the pregnancy. She remained asymptomatic and a transvaginal ultrasound examination was performed on 01 Dec 2020 (Day 97), which showed an anteverted and anteflexed uterus, increased in size at the expense of a normoinserted gestational sac measuring 22 mm that contained an embryo with movements and positive cardiac activity; and the gestational age was estimated at 8 weeks 6 days ± 5 days, with a yolk sac of 4.6 mm. The subject said that she was feeling well and asymptomatic. A transvaginal ultrasound (US) examination performed on 04 Jan 2021 (Day 131) showed an increase in size of the uterus at the expense of a normoinserted gestational sac that contained an embryo with movements and positive cardiac activity, with a gestational age of 14 weeks 1 day. Nuchal translucency was 2 mm (normal for gestational age), and periovular liquid collections were not observed. On 08 Jan 2021 (Day 135), the subject experienced a complicated urinary tract infection, which required a visit to the emergency room and was considered a medically significant event. She was 16 weeks 5 days pregnant. She was seen by her obstetrician, who ordered tests that were performed on 08 Jan 2021 (Day 135): hematocrit of 32% (normal range [NR]: 37%-47%), hemoglobin of 11.3 g% (NR: 11.5-16 g%), red blood cell (RBC) count of 3,700,000/mm^3 (NR: 4,500,000-5,200,000/mm^3), white blood cell (WBC) count of 8090/mm^3 (NR: 4000-10,000/mm^3), and neutrophils of 69% (NR: 50%-60%); along with immunoserology tests including Venereal Disease Research Laboratory (VDRL), human immunodeficiency virus, hepatitis B virus surface antigen, and Chagas disease (American trypanosomiasis), which were all negative. The transvaginal ultrasound examination performed on 14 Jan 2021 (Day 141) showed a single fetus with a longitudinal lie and cephalic presentation; the gestational age was 15.4 ± 2 weeks, and the fetal biometry showed a fetus with a biparietal

Narrative Comment
diameter of 29 mm, head circumference of 114 mm, abdominal circumference of 106 mm, femoral diaphysis length of 15 mm, weight of 128 g ± 10%, and normal amniotic fluid with normal cardiac activity, fetal movements, and anterior placenta. On 08 Jan 2021 (Day 135), a urine culture was positive for *Staphylococcus saprophyticus* sensitive to nitrofurantoin and ampicillin/sulbactam (by antibiogram). The subject was treated with nitrofurantoin and ampicillin sodium/sulbactam sodium. On 21 Jan 2021 (Day 148), the subject reported mild polyuria; she denied fever or any other symptoms. On 22 Jan 2021 (Day 149), she visited the emergency room (ER), where a complicated urinary tract infection was diagnosed, and oral antibiotics were started (nitrofurantoin at 100 mg 4 times a day [QID] for 7 days). That same day, the subject was contacted by the investigator and the subject reported that she was feeling well with mild improvement of symptoms. On 29 Jan 2021 (Day 156), the subject reported during a telephone consultation that on 23 Jan 2021 (Day 150), she experienced an isolated episode of fever (38°C) in the context of a diagnosis of complicated urinary tract infection. She did not consult the ER because her physician said that fever was expected, nor did she call the emergency study number. On 30 Jan 2021 (Day 157), she completed the antibiotic treatment (nitrofurantoin 100 mg QID). A urine culture was performed on 04 Feb 2021 (Day 162), with results that showed mixed organisms. On 11 Feb 2021 (Day 169), it was reported that the subject was feeling well and asymptomatic. As of 15 Feb 2021 (Day 173), she was 19 weeks and 5 days pregnant. On 23 Feb 2021 (Day 181), her urine culture showed a contaminated sample and the urinary tract infection was considered resolved. A transvaginal ultrasound examination showed a single fetus, in a longitudinal lie, podalic presentation, anterior placenta with a gestational age of 19 weeks 6 days, and normal amniotic fluid, with cardiac activity and fetal movements present. The fetal biometry showed a fetus biparietal diameter of 46 mm, a head circumference of 171 mm, abdominal circumference of 142 mm, femoral diaphysis length of 31 mm, and weight of 306 g (±15%). A fetal scan showed a brain unaltered and a normal-looking face, with upper lip not visualized. On 05 Mar 2021 (Day 191), a urine culture was negative. The subject was feeling well and asymptomatic as of 12 Mar 2021 (Day 198). In the opinion of the investigator, there was no reasonable possibility that the urinary tract infection was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1982	38	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
170 cm	80 kg	27.7 kg/m2	31AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	31AUG2020 (1)	18:50
2	BNT162b2	19SEP2020 (20)	10:13

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy	12DEC2020 (104)	08:00	11FEB2021 (165)	23:00	62

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		N	N	Resolved (11FEB2021)	NOT RELATED/OTHER: it is unknown	2	85	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	22OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12315677, a 38-year-old white female with a pertinent obstetrical history of 3 previous pregnancies with 2 live births and 1 spontaneous abortion, received Dose 1 on 31 Aug 2020 and Dose 2 on 19 Sep 2020 (Day 20). The subject had an exposure during pregnancy on 12 Dec 2020, 84 days after receiving Dose 2. On 13 Jan 2021 (Day 136), the subject's urine pregnancy test was positive. The first day of her last menstrual period was 12 Dec 2020 (Day 104) and the estimated date of conception was unknown. The contraceptive method used was a barrier method (condom). She smoked 4 cigarettes per day and her 45-year-old partner smoked 2 cigarettes per day, but neither of them drank alcohol or used any drugs/illicit drugs during this pregnancy. On 21 Jan 2021 (Day 144), the subject was feeling well and asymptomatic. On 22 Jan 2021 (Day 145), a scheduled vaginal ultrasound examination was not done. On 02 Feb 2021 (Day 156), the subject continued to feel well and asymptomatic, but she decided to terminate the pregnancy. On 05 Feb 2021 (Day 159), a termination of the pregnancy was performed. The subject's obstetrician/gynecologist prescribed intravaginal misoprostol 400 µg. During a telephone consultation, the subject noted that she had mild vaginal bleeding without other symptoms. On 11 Feb 2021 (Day 165), a transvaginal ultrasound examination showed anteversion and anteflexion of the uterus (96 × 53 × 59 mm) with nonhomogeneous echostructure; slightly nonhomogeneous endometrium of 15.3 mm; and no evidence of an embryo. On the same day (Day 165), the ultrasound report was seen by her obstetrician/gynecologist, who then prescribed intravaginal misoprostol 200 µg. At the time of contact with the subject (date unspecified), the subject noted that she had scanty vaginal bleeding without other symptoms.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	22	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	77.27 kg	28.3 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ADHD	Attention deficit hyperactivity disorder	2011	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02SEP2020 (1)	09:20
2	BNT162b2	23SEP2020 (22)	16:19

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	exposure during pregnancy	28DEC2020 (118)	00:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	N	N	Yes	NOT RELATED/OTHER: pregnancy	2	97	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1232 12321159, a 22-year-old white female with no pertinent medical or obstetrical history, received Dose 1 on 02 Sep 2020 and Dose 2 on 23 Sep 2020 (Day 22). The subject had an exposure during pregnancy on 28 Dec 2020, 96 days after receiving Dose 2. It was reported that the subject was not pregnant when she received Dose 2 on 23 Sep 2020 (Day 22). On 04 Feb 2021 (Day 156), the subject contacted the site to inform them that she was around 5 weeks pregnant and intended to continue the pregnancy. The first date of her last menstrual period was on 28 Dec 2020 (Day 118). She and her partner did not smoke, drink alcohol, or use illicit drugs during the pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	82.3 kg	28.8 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
abdominal pain	Abdominal pain	30JUL2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	12:20
2	BNT162b2	11SEP2020 (23)	11:09

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	MUSC	Back pain	Backache	12SEP2020 (24)		14SEP2020 (26)		3
2	GENRL	Injection site pain	Injection site pain	12SEP2020 (24)		14SEP2020 (26)		3
3	INJ&P	Maternal exposure during pregnancy	Maternal exposure during pregnancy	30OCT2020 (72)		ONGOING		
4	MUSC	Pain in extremity	Legs pain	12SEP2020 (24)		14SEP2020 (26)		3

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC	N	Resolved (14SEP2020)	Study Treatment	2	2	N
2	1	N	N	Resolved (14SEP2020)	Study Treatment	2	2	N
3		N	N	Yes	NOT RELATED/OTHER: Pregnancy	2	50	Y
4	2	TC	N	Resolved (14SEP2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1241 12411343, a 34-year-old black or African American female with a pertinent family history of hypertension and diabetes mellitus, received Dose 1 on 20 Aug 2020 and Dose 2 on 11 Sep 2020 (Day 23). The subject had a maternal exposure during pregnancy on 30 Oct 2020, 49 days after receiving Dose 2. On 05 Mar 2021 (Day 198), the subject came to the site for Visit 4 and reported that she had a positive pregnancy test (beta-human chorionic gonadotropin) on 22 Jan 2021 (Day 156) and an obstetric ultrasonography was compatible with a pregnancy with gestational age of 12 weeks 5 days on 25 Jan 2021 (Day 159). The first day of her last menstrual period was 18 Oct 2020 (Day 60) and an estimated date of conception was 30 Oct 2020 (Day 72). She did not smoke, drink alcohol, or use illicit drugs during the pregnancy; her partner did not smoke or use illicit drugs, but he drank alcohol 3 times per month during the pregnancy. Her partner had a family history of Down syndrome.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	31	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171 cm	56 kg	19.2 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic rhinitis	Rhinitis allergic	2008	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14SEP2020 (1)	14:14
2	Placebo	05OCT2020 (22)	16:59

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	MUSC	Back pain	Backache	15NOV2020 (63)		16NOV2020 (64)		2	2
2	INJ&P	Maternal exposure during pregnancy	Maternal exposure during pregnancy	01NOV2020 (49)		ONGOING			
3	REPRO	Uterine inflammation	Uterine inflammation	01OCT2020 (18)		05OCT2020 (22)		5	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (16NOV2020)	NOT RELATED/OTHER: Occupational activity	2	42	N
2	N	N	Yes	NOT RELATED/OTHER: Pregnancy	2	28	Y
3	TCN	N	Resolved (05OCT2020)	NOT RELATED/OTHER: Withdrawal of intrauterine device	1	18	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	03NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1241 12411679, a 31-year-old multiracial female with a pertinent medical history of rhinitis allergic (since 2008) and familial history of gestational diabetes and hypertension, received Dose 1 on 14 Sep 2020 and Dose 2 on 05 Oct 2020 (Day 22). The subject had a maternal exposure during pregnancy on 01 Nov 2020, 27 days after receiving Dose 2. On an unspecified date, the site contacted the subject, during which she informed them about her pregnancy. On 11 Dec 2020 (Day 89), the subject had a positive pregnancy test with a human chorionic gonadotropin level of 16,443 mIU/mL (normal range: 1.0-5.3 mIU/mL). The obstetric ultrasonographies on 14 Dec 2020 (Day 92) and on 22 Jan 2021 (Day 131) showed a pregnancy of 6 weeks and 12 weeks of gestation, respectively. The first day of her last menstrual period was 19 Oct 2020 (Day 36) and an estimated date of conception was 01 Nov 2020 (Day 49). The subject and her partner did not smoke or use illicit drugs, but she drank alcohol 2 to 3 times per week and her partner drank alcohol once per week during this pregnancy. It was reported that the subject's 31-year-old male partner was also part of the study. The subject did not meet the eligibility criteria for receiving a first dose of unblinded BNT162b2. However, she was oriented to continue study visits according to protocol.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	37	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	94.2 kg	37.7 kg/m2	18SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18SEP2020 (1)	15:27
2	BNT162b2	09OCT2020 (22)	15:53

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Maternal exposure during pregnancy	Maternal exposure during pregnancy	15DEC2020 (89)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N	Yes	NOT RELATED/OTHER: Pregnancy	2	68	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18SEP2020	
Completed	VACCINATION	06NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1241 12411915, a 37-year-old black or African American female with a pertinent obstetrical history of 1 previous pregnancy that resulted in a miscarriage (in 2013), received Dose 1 on 18 Sep 2020 and Dose 2 on 09 Oct 2020 (Day 22). The subject had a maternal exposure during pregnancy on 15 Dec 2020, 67 days after receiving Dose 2. On an unspecified date, the subject reported to the site that she was pregnant. The first day of her last menstrual period was 07 Dec 2020 (Day 81) and the estimated date of conception was 15 Dec 2020 (Day 89). She and her partner did not smoke, drink alcohol, or use illicit drugs during this pregnancy. She underwent laboratory tests and procedures (no details reported), and an obstetric ultrasonography on 14 Jan 2021 (Day 119) showed the pregnancy at approximately 5 weeks of gestation.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2000	20	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	72 kg	27.1 kg/m2	23OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23OCT2020 (1)	18:31
2	Placebo	12NOV2020 (21)	15:52

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	INJ&P	Maternal exposure during pregnancy	Maternal exposure during pregnancy	26DEC2020 (65)		ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1			N	N	Yes	NOT RELATED/OTHER: Pregnancy	2	45	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23OCT2020	
Completed	VACCINATION	10DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1241 12412546, a 20-year-old multiracial female with a family history of hypertension in her mother, received Dose 1 on 23 Oct 2020 and Dose 2 on 12 Nov 2020 (Day 21). The subject had a maternal exposure during pregnancy on 26 Dec 2020, 44 days after receiving Dose 2. On 01 Feb 2021 (Day 102), the subject's pregnancy (β-human chorionic gonadotropin) test was positive. On 06 Feb 2021 (Day 107), an obstetric ultrasonography confirmed the pregnancy with a gestational age of approximately 6 weeks 4 days. On 09 Feb 2021 (Day 110), during a convalescent visit, the subject reported to the site that she was pregnant. The first day of her last menstrual period was in Dec 2020 and the estimated date of conception was 26 Dec 2020 (Day 65). She did not smoke, drink alcohol, or use illicit drugs during this pregnancy. Her 21-year-old partner smoked (3 cigarettes per day) and drank alcohol (4 cans per week) with no usage of illicit drugs during this pregnancy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1987	33	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	157.73 kg	51.2 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
sinus headaches	Sinus headache	2000	Present
obesity	Obesity	2011	Present
Acid Reflux	Gastrooesophageal reflux disease	2016	Present
Hemorrhoids	Haemorrhoids	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	15:30
2	BNT162b2	16SEP2020 (22)	08:34

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	Exposure during pregnancy	exposure during pregnancy subjects wife is pregnant	JAN2021 ()		ONGOING			1	N	N
2	RESP	Nasal congestion	Nasal Congestion	02SEP2020 (8)		04SEP2020 (10)		3	1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: exposure during pregnancy subject became pregnant January 2021	2		Y
2	Resolved (04SEP2020)	Study Treatment	1	8	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1251 12511060, a 33-year-old black or African American male with no pertinent medical history, received Dose 1 on 26 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 22). The subject's partner had an exposure during pregnancy in Jan 2021. Concomitant medications during the subject's partner's pregnancy included calcium, a multivitamin, and ergocalciferol (all since Jan 2020) as supplements; zinc (since 2020) as a supplement; and liraglutide (since 29 Jan 2021) for obesity. On 11 Mar 2021 (Day 198) during the Visit 4 follow-up, the subject notified the site that his wife was pregnant. The first day of his partner's last menstrual period was unknown and the estimated date of conception was in Jan 2021. The pregnancy was reported to be normal with an estimated date of delivery of 05 Sep 2021. The subject did not smoke, drink alcohol, or use illicit drugs and it was unknown if the subject's partner smoked, drank alcohol, or used illicit drugs during this pregnancy.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1987	32	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	86.8 kg	30 kg/m2	12SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
left knee injury	Joint injury	1989	Past
left knee surgery	Knee operation	1989	Past
cholelithiasis	Cholelithiasis	2010	Past
cholecystectomy	Cholecystectomy	DEC2012	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12SEP2020 (1)	16:25
2	Placebo	02OCT2020 (21)	10:49

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy	22SEP2020 (11)		ONGOING			
2	GENRL	Injection site pain	Injection site pain	12SEP2020 (1)	20:00	13SEP2020 (2)	12:00	2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: HAVING INTERCOURSE	1	11	Y
2	N	N	Resolved (13SEP2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12SEP2020	
Completed	VACCINATION	30OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1254 12541145, a 32-year-old black or African American female with a pertinent obstetrical history of 5 previous pregnancies resulting in 2 live births and 3 therapeutic abortions, received Dose 1 on 12 Sep 2020 and Dose 2 on 02 Oct 2020 (Day 21). The subject had an exposure during pregnancy on 22 Sep 2020, 10 days after receiving Dose 1. On 30 Oct 2020 (Day 49), at Visit 3, the subject's urine pregnancy test was positive, and she confirmed contraception use (condom). She also confirmed that her urine pregnancy test showed negative results prior to dosing during Visit 1 and Visit 2. The first day of her last menstrual period was 10 Sep 2020 (Day -2) and the estimated date of conception was 26 Sep 2020 (Day 15). The gestational age at the time of initial exposure was first trimester. The subject did not smoke, drink alcohol, or use illicit drugs during this pregnancy. She agreed to continue in the study and would follow up with an obstetrician/gynecologist on 31 Oct 2020 (Day 50). On 16 Nov 2020 (Day 66), she underwent an elective termination/induced abortion and after the procedure, she was doing well.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	56.5 kg	19.8 kg/m2	05AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	05AUG2020 (1)	16:00
2	Placebo	24AUG2020 (20)	15:47
3	BNT162b2	14JAN2021 (163)	12:58
4	BNT162b2	19FEB2021 (199)	11:38

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Injection site pain	Left arm pain at injection site	15JAN2021 (164)		16FEB2021 (196)	
2	BLOOD	Lymphadenopathy	Left axilla lymphadenopathy	15JAN2021 (164)		26JAN2021 (175)	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	33	2	TC	N	Resolved (16FEB2021)	Study Treatment	3	2	N
2	12	2	N	N	Resolved (26JAN2021)	Study Treatment	3	2	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	23SEP2020	
Completed	REPEAT SCREENING 1	14JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	71.27 kg	27.8 kg/m2	22OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ENVIRONMENTAL ALLERGIES	Hypersensitivity	1970	Present
BREAST LUMPECTOMY	Breast conserving surgery	1993	Past
BENIGN BREAST FIBROIDS	Breast fibroma	1993	Past
HIGH BLOOD PRESSURE	Hypertension	1993	Present
DYSMENORRHEA	Dysmenorrhoea	2008	Past
UTERINE ABLATION	Endometrial ablation	2008	Past
MENOPAUSE	Menopause	2009	Present
CHOLECYSTECTOMY	Cholecystectomy	2018	Past
GALLSTONES	Cholelithiasis	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22OCT2020 (1)	08:59
2	Placebo	12NOV2020 (22)	16:09
3	BNT162b2	18DEC2020 (58)	08:35
4	BNT162b2	11JAN2021 (82)	15:58

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	CHILLS	12JAN2021 (83)	02:00	12JAN2021 (83)	04:00
2	GENRL	Injection site pain	INJECTION SITE PAIN	12JAN2021 (83)		13JAN2021 (84)	
3	BLOOD	Lymphadenopathy	ENLARGED LYMPH NODE LEFT AXILLA	12JAN2021 (83)		26JAN2021 (97)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	N	N	Resolved (12JAN2021)	Study Treatment	4	2	N
2	2	1	N	N	Resolved (13JAN2021)	Study Treatment	4	2	N
3	15	1	N	N	Resolved (26JAN2021)	Study Treatment	4	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	22OCT2020	
Completed	VACCINATION	10DEC2020	
Completed	REPEAT SCREENING 1	18DEC2020	
Completed	OPEN LABEL TREATMENT	08FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	102.27 kg	32.7 kg/m2	29OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ASTHMA	Asthma	1994	Present
ENVIRONMENTAL ALLERGIES	Hypersensitivity	1994	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	1997	Present
NISSAN FUNDOPLICATION	Oesophagogastric fundoplasty	1999	Past
RIGHT OOPHORECTOMY	Oophorectomy	2006	Past
HYPOTHYROID	Hypothyroidism	2010	Present
OVERWEIGHT	Overweight	2010	Present
HIGH BLOOD PRESSURE	Hypertension	2012	Present
MENOPAUSE	Menopause	2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
RIGHT FOREARM MELANOMA	Malignant melanoma	2018	Past
MELANOMA REMOVAL FROM RIGHT FOREARM	Skin neoplasm excision	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29OCT2020 (1)	09:12
2	BNT162b2	17NOV2020 (20)	08:36

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site pain	INJECTION SITE PAIN	30OCT2020 (2)		31OCT2020 (3)	
2	BLOOD	Lymphadenopathy	SWOLLEN LYMPH NODE UNDER LEFT ARM	18NOV2020 (21)	21:00	19DEC2020 (52)	
3	MUSC	Myalgia	MYALGIA	17NOV2020 (20)	20:30	18NOV2020 (21)	08:30

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (31OCT2020)	Study Treatment	1	2	N

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	32	1	N	N	Resolved (19DEC2020)	Study Treatment	2	2	Y
3	2	2	N	N	Resolved (18NOV2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	29OCT2020	
Completed	VACCINATION	15DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	Asian	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	64.6 kg	22.6 kg/m2	11JUN2020 (-11)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergy	Seasonal allergy	2016	Present
Anemia	Anaemia	SEP2019	Present
Uterine leiomyoma	Uterine leiomyoma	SEP2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	22JUN2020 (1)	11:17
2	BNT162b2	13JUL2020 (22)	15:08

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	Right axillary lymph node enlargement	15JUL2020 (24)		27JUL2020 (36)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	13	1	N	N	Resolved (27JUL2020)	Study Treatment	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22JUN2020	
Completed	VACCINATION	10AUG2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	100.5 kg	34 kg/m2	30JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergy	Seasonal allergy	1985	Present
Depression	Depression	1999	Present
Allergy to antibiotic erythromycin	Drug hypersensitivity	2001	Present
Migraine	Migraine	2002	Present
LASIK eye surgery	Keratomileusis	2006	Past
Insomnia	Insomnia	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30JUL2020 (1)	11:42
2	BNT162b2	20AUG2020 (22)	09:54

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	BLOOD	Lymphadenopathy	Bilateral Swollen Cervical Lymph Nodes	23AUG2020 (25)		03SEP2020 (36)		12	1	TC	N
2	MUSC	Myalgia	Right Scapular Muscle Pain	21AUG2020 (23)	12:00	01SEP2020 (34)		12	3	TC/TCN	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (03SEP2020)	NOT RELATED/OTHER: Possible viral syndrome	2	4	Y
2	Resolved (01SEP2020)	NOT RELATED/OTHER: possible muscle spasm. Unclear exact etiology	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30JUL2020	
Completed	VACCINATION	17SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	90.4 kg	30.2 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Drug allergy ferrous sulfate	Drug hypersensitivity	1974	Present
Latex allergy	Rubber sensitivity	1974	Present
Migraine	Migraine	1982	Present
Seasonal asthma	Asthma	1991	Present
Drug allergy demerol	Drug hypersensitivity	2001	Present
Dilation and curettage	Uterine dilation and curettage	MAY2019	Past
Hysterectomy	Hysterectomy	DEC2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03AUG2020 (1)	15:19
2	Placebo	24AUG2020 (22)	14:27
3	BNT162b2	15FEB2021 (197)	11:27
4	BNT162b2	08MAR2021 (218)	13:49

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	chills	09MAR2021 (219)	07:00	09MAR2021 (219)	12:00
2	BLOOD	Lymphadenopathy	right supraclavicular swollen lymph node	09MAR2021 (219)		ONGOING	
3	MUSC	Myalgia	myalgias	09MAR2021 (219)	07:00	09MAR2021 (219)	12:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	N	N	Resolved (09MAR2021)	Study Treatment	4	2	N
2		1	N	N	Yes	Study Treatment	4	2	Y
3	1	1	N	N	Resolved (09MAR2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	21SEP2020	
Completed	REPEAT SCREENING 1	15FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	68	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.2 cm	67 kg	25.2 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Drug allergy pencillin	Drug hypersensitivity	1963	Present
Breast cancer stage I	Breast cancer stage I	1993	Past
Lumpectomy (breast cancer)	Breast conserving surgery	1993	Past
Seasonal allergy	Seasonal allergy	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	05AUG2020 (1)	11:14
2	Placebo	26AUG2020 (22)	12:16
3	BNT162b2	19JAN2021 (168)	10:46
4	BNT162b2	09FEB2021 (189)	13:37

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	chills	09FEB2021 (189)	18:00	10FEB2021 (190)	18:00
2	NERV	Headache	headache	09FEB2021 (189)	18:00	10FEB2021 (190)	18:00
3	GENRL	Injection site pain	injection site pain	10FEB2021 (190)		11FEB2021 (191)	
4	BLOOD	Lymphadenopathy	axillary lymphadenopathy	10FEB2021 (190)		12FEB2021 (192)	
5	MUSC	Myalgia	generalized myalgia	09FEB2021 (189)	18:00	10FEB2021 (190)	18:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (10FEB2021)	Study Treatment	4	1	N
2	2	2	N	N	Resolved (10FEB2021)	Study Treatment	4	1	N
3	2	1	N	N	Resolved (11FEB2021)	Study Treatment	4	2	N
4	3	1	N	N	Resolved (12FEB2021)	Study Treatment	4	2	Y
5	2	1	N	N	Resolved (10FEB2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	23SEP2020	
Completed	REPEAT SCREENING 1	19JAN2021	
Completed	OPEN LABEL TREATMENT	09MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	48	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	125.3 kg	46 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Headache	Headache	1985	Present
Allergy codeine	Drug hypersensitivity	1995	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10AUG2020 (1)	14:50
2	BNT162b2	31AUG2020 (22)	11:23

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	Left axilla enlarged lymph node	11AUG2020 (2)		12AUG2020 (3)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	TC	N	Resolved (12AUG2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10AUG2020	
Completed	VACCINATION	28SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	75.4 kg	24.9 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic to cats	Allergy to animal	1990	Present
Dust allergy	Dust allergy	1990	Present
Seasonal allergy	Seasonal allergy	1990	Present
Overweight	Overweight	1996	Past
Asthma	Asthma	1997	Present
Sleeve gastrectomy	Gastrectomy	MAY2019	Past
Lithotripsy	Lithotripsy	NOV2019	Past
Kidney stones	Nephrolithiasis	NOV2019	Past
Pyeloplasty	Pyeloplasty	04AUG2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	10:14
2	Placebo	23SEP2020 (28)	09:15
3	BNT162b2	28JAN2021 (155)	13:14
4	BNT162b2	17FEB2021 (175)	13:35

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site pain	Muscle Soreness in arm of injection	28JAN2021 (155)	20:00	30JAN2021 (157)	08:00
2	BLOOD	Lymphadenopathy	bilateral deep cervical swollen lymph nodes	18FEB2021 (176)	08:00	25FEB2021 (183)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	1	TC	N	Resolved (30JAN2021)	Study Treatment	3	1	N
2	8	1	N	N	Resolved (25FEB2021)	Study Treatment	4	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	21OCT2020	
Completed	REPEAT SCREENING 1	28JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	57.45 kg	22.4 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	2010	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	OCT2019	Present
Migraines	Migraine	OCT2019	Present
Acne	Acne	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	14:41
2	Placebo	06NOV2020 (22)	15:00
3	BNT162b2	22JAN2021 (99)	14:46
4	BNT162b2	12FEB2021 (120)	14:32

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Fatigue	fatigue	13FEB2021 (121)		14FEB2021 (122)	
2	NERV	Headache	headache	13FEB2021 (121)		14FEB2021 (122)	
3	GENRL	Injection site erythema	injection site redness	13FEB2021 (121)		18FEB2021 (126)	
4	GENRL	Injection site pain	injection site pain	13FEB2021 (121)		16FEB2021 (124)	
5	BLOOD	Lymphadenopathy	swollen lymph nodes left armpit	13FEB2021 (121)		14FEB2021 (122)	
6	GENRL	Pain	body aches	13FEB2021 (121)		14FEB2021 (122)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	2	TC	N	Resolved (14FEB2021)	Study Treatment	4	2	N
2	2	2	TC	N	Resolved (14FEB2021)	Study Treatment	4	2	N
3	6	1	N	N	Resolved (18FEB2021)	Study Treatment	4	2	N
4	4	2	TC	N	Resolved (16FEB2021)	Study Treatment	4	2	N

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	2	1	N	N	Resolved (14FEB2021)	Study Treatment	4	2	Y
6	2	2	N	N	Resolved (14FEB2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	16OCT2020	
Completed	VACCINATION	07DEC2020	
Completed	REPEAT SCREENING 1	22JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1978	42	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
177.5 cm	76 kg	24.1 kg/m2	07OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	07OCT2020 (1)	11:30
2	BNT162b2	27OCT2020 (21)	13:52

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	LYMPH NODE SWELLING LEFT AUXILLARY	28OCT2020 (22)	18:00	30OCT2020 (24)	08:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	1	N	N	Resolved (30OCT2020)	Study Treatment	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07OCT2020	
Completed	VACCINATION	24NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	24	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	62.73 kg	23 kg/m2	16AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16AUG2020 (1)	12:50
2	BNT162b2	04SEP2020 (20)	15:54

Adverse Events						
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	BLOOD	Lymphadenopathy	Swollen lymph node - left armpit axillary	04SEP2020 (20)	17:00	08SEP2020 (24)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	5	1	N	N	Resolved (08SEP2020)	Study Treatment	2	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	84.09 kg	30.8 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Migraines	Migraine	1991	Present
Allergies	Multiple allergies	1995	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	15:05
2	BNT162b2	11SEP2020 (22)	11:18

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	Swollen left axillary lymph node	11SEP2020 (22)	22:00	18SEP2020 (29)	
2	INJ&P	Procedural pain	Whole arm pain - received injection	11SEP2020 (22)	22:00	13SEP2020 (24)	
3	GENRL	Pyrexia	Fever	11SEP2020 (22)	22:00	13SEP2020 (24)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	8	1	N	N	Resolved (18SEP2020)	Study Treatment	2	1	Y
2	3	1	TC	N	Resolved (13SEP2020)	Study Treatment	2	1	N
3	3	1	TC	N	Resolved (13SEP2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu vaccine	INFLUENZA VACCINE	08OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	25	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
147.32 cm	43.18 kg	19.9 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	2013	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15SEP2020 (1)	09:47
2	Placebo	08OCT2020 (24)	09:12

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	22DEC2020 (99)	11:05
4	BNT162b2	14JAN2021 (122)	09:40

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Chills	14JAN2021 (122)	13:00	16JAN2021 (124)	
2	NERV	Dizziness	Dizziness	08OCT2020 (24)	20:00	12OCT2020 (28)	
3	GENRL	Fatigue	Fatigue	14JAN2021 (122)	13:00	16JAN2021 (124)	
4	NERV	Headache	Headache	14JAN2021 (122)	13:00	16JAN2021 (124)	
5	GENRL	Injection site pain	Injection site pain	23DEC2020 (100)		24DEC2020 (101)	
6	BLOOD	Lymphadenopathy	Swollen neck lymph nodes - both sides	23DEC2020 (100)		24DEC2020 (101)	
7	MUSC	Myalgia	General muscle aches	23DEC2020 (100)		24DEC2020 (101)	
8	MUSC	Myalgia	Myalgia	14JAN2021 (122)	13:00	16JAN2021 (124)	
9	GENRL	Pyrexia	Fever 100.7	23DEC2020 (100)		24DEC2020 (101)	
10	GENRL	Pyrexia	Fever 101.0	14JAN2021 (122)	13:00	16JAN2021 (124)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	2	N	N	Resolved (16JAN2021)	Study Treatment	4	1	N
2	5	1	N	N	Resolved (12OCT2020)	Study Treatment	2	1	N

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	3	2	N	N	Resolved (16JAN2021)	Study Treatment	4	1	N
4	3	2	TC	N	Resolved (16JAN2021)	Study Treatment	4	1	N
5	2	1	N	N	Resolved (24DEC2020)	Study Treatment	3	2	N
6	2	1	TC	N	Resolved (24DEC2020)	Study Treatment	3	2	Y
7	2	1	TC	N	Resolved (24DEC2020)	Study Treatment	3	2	N
8	3	2	TC	N	Resolved (16JAN2021)	Study Treatment	4	1	N
9	2	1	TC	N	Resolved (24DEC2020)	Study Treatment	3	2	N
10	3	2	TC	N	Resolved (16JAN2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Flucelvax	INFLUENZA VACCINE INACT SAG 3V	23OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15SEP2020	
Completed	VACCINATION	05NOV2020	
Completed	REPEAT SCREENING 1	22DEC2020	
Completed	OPEN LABEL TREATMENT	17FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	Asian	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	95.86 kg	35.1 kg/m2	02OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Penicillin Allergy	Drug hypersensitivity	1998	Present
Eczema Bilateral Hands	Hand dermatitis	2003	Present
Anxiety	Anxiety	2012	Present
Recurrent Knee Pain	Arthralgia	2014	Present
Recurrent Back Pain	Back pain	2014	Present
Irritable Bowel Syndrome	Irritable bowel syndrome	2014	Present
Heartburn	Dyspepsia	2019	Present
Sleep Apnea	Sleep apnoea syndrome	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	02OCT2020 (1)	15:48
2	BNT162b2	22OCT2020 (21)	08:27

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Chills	chills	22OCT2020 (21)	20:00	24OCT2020 (23)		3
2	GENRL	Fatigue	Fatigue	22OCT2020 (21)	20:00	24OCT2020 (23)		3
3	GENRL	Injection site pain	L Arm Pain Injection Site	22OCT2020 (21)	20:00	24OCT2020 (23)		3
4	GENRL	Injection site pain	Left arm site injection pain	03OCT2020 (2)		05OCT2020 (4)		3
5	INJ&P	Ligament sprain	Left Ankle Sprain	10NOV2020 (40)		03FEB2021 (125)		86
6	BLOOD	Lymphadenopathy	Axial Lymph Node Swelling Left	03OCT2020 (2)		05OCT2020 (4)		3

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (24OCT2020)	Study Treatment	2	1	N
2	1	N	N	Resolved (24OCT2020)	Study Treatment	2	1	N
3	1	N	N	Resolved (24OCT2020)	Study Treatment	2	1	N
4	1	N	N	Resolved (05OCT2020)	Study Treatment	1	2	N

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
5	1	N	N	Resolved (03FEB2021)	NOT RELATED/OTHER: injury	2	20	N
6	1	N	N	Resolved (05OCT2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccine	INFLUENZA VACCINE	11SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16SEP2020	
Completed	VACCINATION	24NOV2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1993	26	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	103.64 kg	34.7 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	01DEC2016	Present
Headaches	Headache	23JAN2017	Present
Obesity	Obesity	23JAN2017	Present
Migraines	Migraine	21MAY2018	Present
Depression	Depression	06JUL2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	11:30
2	Placebo	08SEP2020 (22)	15:55
3	BNT162b2	16DEC2020 (121)	12:40
4	BNT162b2	05JAN2021 (141)	08:47

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Axillary pain	Axillary Pain	18AUG2020 (1)	20:00	21AUG2020 (4)	14:10
2	GENRL	Chills	Mild Chills	05JAN2021 (141)	20:00	06JAN2021 (142)	20:00
3	GASTR	Diarrhoea	Loose Stools	09SEP2020 (23)	18:00	10SEP2020 (24)	14:00
4	GENRL	Fatigue	Fatigue	16DEC2020 (121)	14:00	17DEC2020 (122)	16:00
5	MUSC	Groin pain	Groin Pain	18AUG2020 (1)	20:00	21AUG2020 (4)	14:10
6	NERV	Headache	Exacerbation of Headache	05JAN2021 (141)	20:00	06JAN2021 (142)	20:00
7	GENRL	Injection site pain	Mild Injection Site Pain	16DEC2020 (121)	14:00	17DEC2020 (122)	14:00
8	BLOOD	Lymphadenopathy	Lymphadenopathy of Head (left side)	22SEP2020 (36)	08:00	03NOV2020 (78)	
9	MUSC	Myalgia	Generalized Myalgias	05JAN2021 (141)	20:00	06JAN2021 (142)	20:00
10	GENRL	Pyrexia	Low Grade Fever	05JAN2021 (141)	20:00	06JAN2021 (142)	20:00

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	1	N	N	Resolved (21AUG2020)	Study Treatment	1	1	N
2	2	1	N	N	Resolved (06JAN2021)	Study Treatment	4	1	N
3	2	1	N	N	Resolved (10SEP2020)	Study Treatment	2	2	N
4	2	1	N	N	Resolved (17DEC2020)	Study Treatment	3	1	N
5	4	1	N	N	Resolved (21AUG2020)	Study Treatment	1	1	N
6	2	1	N	N	Resolved (06JAN2021)	Study Treatment	4	1	N
7	2	1	N	N	Resolved (17DEC2020)	Study Treatment	3	1	N
8	43	1	N	N	Resolved (03NOV2020)	Study Treatment	2	15	Y
9	2	1	N	N	Resolved (06JAN2021)	Study Treatment	4	1	N
10	2	1	N	N	Resolved (06JAN2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	06OCT2020	
Completed	REPEAT SCREENING 1	16DEC2020	
Completed	OPEN LABEL TREATMENT	02FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	51	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	98.73 kg	29.5 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Gallstones	Cholelithiasis	2018	Past
Cholecystectomy	Cholecystectomy	01JUN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02SEP2020 (1)	09:46
2	BNT162b2	22SEP2020 (21)	10:08

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Moderate Chills	23SEP2020 (22)	07:00	24SEP2020 (23)	07:00
2	NERV	Headache	Moderate Headache	22SEP2020 (21)	16:00	24SEP2020 (23)	07:00
3	BLOOD	Lymphadenopathy	Left Axillary Adenopathy	24SEP2020 (23)	07:00	28SEP2020 (27)	
4	MUSC	Myalgia	Moderate Myalgias	22SEP2020 (21)	16:00	24SEP2020 (23)	07:00
5	GENRL	Injection site pain	Mild Injection site pain	02SEP2020 (1)	10:00	03SEP2020 (2)	16:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	2	N	N	Resolved (24SEP2020)	Study Treatment	2	2	N
2	3	2	N	N	Resolved (24SEP2020)	Study Treatment	2	1	N
3	5	1	N	N	Resolved (28SEP2020)	Study Treatment	2	3	Y
4	3	2	N	N	Resolved (24SEP2020)	Study Treatment	2	1	N
5	2	1	N	N	Resolved (03SEP2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu Shot	INFLUENZA VACCINE	15OCT2020
Shingrix	VARICELLA ZOSTER VACCINE RGE (CHO)	15OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	68.27 kg	26.6 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Migraine	Migraine	08DEC2015	Present
Overweight	Overweight	08DEC2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	15:18

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	28SEP2020 (21)	12:12
3	BNT162b2	19JAN2021 (134)	13:25
4	BNT162b2	09FEB2021 (155)	13:15

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Arthropod bite	Mosquito Bite inner thigh	10OCT2020 (33)	16:00	16OCT2020 (39)	08:00	7
2	GENRL	Fatigue	Mild Fatigue	20JAN2021 (135)	07:00	20JAN2021 (135)	22:00	1
3	GENRL	Fatigue	Mild Fatigue	10FEB2021 (156)	02:00	11FEB2021 (157)	12:00	2
4	GENRL	Injection site pain	Mild Injection Site Pain	19JAN2021 (134)	16:00	22JAN2021 (137)	07:00	4
5	GENRL	Injection site pain	Mild Injection Site Pain	09FEB2021 (155)	14:00	10FEB2021 (156)	07:00	2
6	BLOOD	Lymphadenopathy	Swollen Gland in left arm	10FEB2021 (156)	02:00	14FEB2021 (160)	08:00	5
7	MUSC	Myalgia	Generalized Myalgias	20JAN2021 (135)	07:00	20JAN2021 (135)	22:00	1
8	MUSC	Myalgia	Generalized Myalgias	10FEB2021 (156)	02:00	11FEB2021 (157)	12:00	2
9	MUSC	Pain in extremity	Pain in whole left arm	10FEB2021 (156)	02:00	11FEB2021 (157)	12:00	2
10	GENRL	Pyrexia	Fever	10FEB2021 (156)	02:00	11FEB2021 (157)	12:00	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (16OCT2020)	NOT RELATED/OTHER: arthropod bite	2	13	N
2	1	N	N	Resolved (20JAN2021)	Study Treatment	3	2	N

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	1	N	N	Resolved (11FEB2021)	Study Treatment	4	2	N
4	1	N	N	Resolved (22JAN2021)	Study Treatment	3	1	N
5	1	N	N	Resolved (10FEB2021)	Study Treatment	4	1	N
6	1	N	N	Resolved (14FEB2021)	Study Treatment	4	2	Y
7	1	N	N	Resolved (20JAN2021)	Study Treatment	3	2	N
8	1	N	N	Resolved (11FEB2021)	Study Treatment	4	2	N
9	1	N	N	Resolved (11FEB2021)	Study Treatment	4	2	N
10	1	N	N	Resolved (11FEB2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	28OCT2020	
Completed	REPEAT SCREENING 1	19JAN2021	
Completed	OPEN LABEL TREATMENT	09MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1987	33	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	78.27 kg	25.1 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
BICYCLE ACCIDENT	Road traffic accident	2003	Past
Removed scar tissue REMOVAL, URETHRA	Urethral operation	2008	Past
OTITIS MEDIA LEFT	Otitis media	31DEC2019	Past
Acute non-recurrent pansinusitis	Sinusitis	14JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	09:45
2	Placebo	10SEP2020 (22)	16:32
3	BNT162b2	18FEB2021 (183)	14:00
4	BNT162b2	11MAR2021 (204)	15:50

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Fatigue	fatigue	19FEB2021 (184)		20FEB2021 (185)	
2	NERV	Headache	headache	19FEB2021 (184)		20FEB2021 (185)	
3	BLOOD	Lymphadenopathy	enlarged lymph glands left armpit	19FEB2021 (184)		20FEB2021 (185)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	2	N	N	Resolved (20FEB2021)	Study Treatment	3	2	N
2	2	2	N	N	Resolved (20FEB2021)	Study Treatment	3	2	N
3	2	2	N	N	Resolved (20FEB2021)	Study Treatment	3	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	08OCT2020	
Completed	REPEAT SCREENING 1	18FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1991	28	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168.58 cm	110.09 kg	38.7 kg/m2	18SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cat Allergy	Allergy to animal	1996	Present
Seasonal Allergies	Seasonal allergy	1996	Present
Asthma	Asthma	1999	Present
Headache	Headache	2001	Present
Migraine	Migraine	2001	Present
Codeine Allergy	Drug hypersensitivity	2006	Present
IBS-c	Irritable bowel syndrome	2006	Present
Latex Allergy	Rubber sensitivity	2006	Present
Chronic Interstitial Cystitis	Cystitis interstitial	2011	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertonicity of Bladder	Hypertonic bladder	2011	Present
Polycystic Ovarian Syndrome	Polycystic ovaries	2011	Present
Chronic Idiopathic Urticaria	Chronic spontaneous urticaria	JAN2017	Present
Anxiety	Anxiety	JUN2017	Present
Hypertension	Hypertension	JUN2017	Present
Cesarean Section	Caesarean section	04JUN2017	Past
Obesity	Obesity	DEC2017	Present
GERD	Gastrooesophageal reflux disease	OCT2018	Present
Cesarean Section	Caesarean section	23MAR2019	Past
Acne	Acne	JAN2020	Present
Rectal Bleeding	Rectal haemorrhage	MAR2020	Past
Tubular Adenoma, Benign	Adenoma benign	22APR2020	Past
Benign Tubular Adenoma Removal	Benign tumour excision	22APR2020	Past
Colonoscopy	Colonoscopy	22APR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18SEP2020 (1)	12:07
2	Placebo	08OCT2020 (21)	11:15
3	BNT162b2	26JAN2021 (131)	09:46
4	BNT162b2	16FEB2021 (152)	09:41

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Injection site pain	right arm soreness at injection site	26JAN2021 (131)	12:00	29JAN2021 (134)	12:00
2	BLOOD	Lymphadenopathy	enlarged lymph glands left armpit	16FEB2021 (152)	17:00	21FEB2021 (157)	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	2	N	N	Resolved (29JAN2021)	Study Treatment	3	1	N
2	6	1	N	N	Resolved (21FEB2021)	Study Treatment	4	1	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18SEP2020	
Completed	VACCINATION	05NOV2020	
Completed	REPEAT SCREENING 1	26JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.4 cm	83 kg	28.6 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tonsillectomy	Tonsillectomy	1956	Past
Lumbar pain	Back pain	1970	Present
breast biopsy	Biopsy breast	2000	Past
cholecystectomy	Cholecystectomy	2000	Past
Total knee replacement (Left)	Knee arthroplasty	2000	Past
postmenopausal	Postmenopause	2000	Present
cataracts	Cataract	2013	Present
depression	Depression	2013	Present
allergic Rhinitis	Rhinitis allergic	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	14:41
2	Placebo	16SEP2020 (22)	13:13
3	BNT162b2	04JAN2021 (132)	13:23
4	BNT162b2	25JAN2021 (153)	11:51

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	left axillary lymphadenopathy	25JAN2021 (153)	18:00	26JAN2021 (154)	12:00
2	MUSC	Myalgia	left pectoral muscle pain	25JAN2021 (153)	18:00	26JAN2021 (154)	12:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (26JAN2021)	Study Treatment	4	1	Y
2	2	1	N	N	Resolved (26JAN2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	04JAN2021	
Completed	OPEN LABEL TREATMENT	22FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	37	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.6 cm	69.8 kg	26.1 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
asthma	Asthma	1986	Present
appendectomy	Appendicectomy	2002	Past
polycystic ovary syndrome	Polycystic ovaries	2012	Present
allergic rhinitis - seasonal	Seasonal allergy	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15SEP2020 (1)	08:15
2	Placebo	06OCT2020 (22)	07:35
3	BNT162b2	19JAN2021 (127)	09:55
4	BNT162b2	09FEB2021 (148)	07:41

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Chills	09FEB2021 (148)	21:00	10FEB2021 (149)	10:00
2	GENRL	Fatigue	fatigue	19JAN2021 (127)	21:00	21JAN2021 (129)	
3	NERV	Headache	Headache	10FEB2021 (149)		11FEB2021 (150)	
4	GENRL	Injection site pain	injection site soreness	19JAN2021 (127)	21:00	21JAN2021 (129)	
5	BLOOD	Lymphadenopathy	Lymphadenopathy Left armpit	12FEB2021 (151)		15FEB2021 (154)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	TC	N	Resolved (10FEB2021)	Study Treatment	4	1	N
2	3	1	N	N	Resolved (21JAN2021)	Study Treatment	3	1	N
3	2	1	TC	N	Resolved (11FEB2021)	Study Treatment	4	2	N
4	3	1	TC	N	Resolved (21JAN2021)	Study Treatment	3	1	N
5	4	1	N	N	Resolved (15FEB2021)	Study Treatment	4	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15SEP2020	
Completed	VACCINATION	04NOV2020	
Completed	REPEAT SCREENING 1	19JAN2021	
Completed	OPEN LABEL TREATMENT	09MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152.4 cm	52.27 kg	22.5 kg/m2	05OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergy to dust	Dust allergy	1988	Present
Allergic Rhinitis	Rhinitis allergic	1988	Present
Allergic Rhinitis (Pollen)	Seasonal allergy	1988	Present
Hernia Procedure	Hernia repair	27APR2002	Past
Breast Implants insertion	Mammoplasty	2004	Past
Caesarean Section	Caesarean section	03APR2007	Past
Heartburn	Dyspepsia	2019	Present
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	2019	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Breast Implant Removal	Breast prosthesis removal	16SEP2019	Past
Irritable Bowel Syndrome	Irritable bowel syndrome	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05OCT2020 (1)	16:55
2	BNT162b2	26OCT2020 (22)	12:38

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site pain	PAIN AT INJECTION SITE	06OCT2020 (2)		07OCT2020 (3)	
2	BLOOD	Lymphadenopathy	ENLARGED LYMPHNODES LEFT AXILLA	06OCT2020 (2)		07OCT2020 (3)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (07OCT2020)	Study Treatment	1	2	N
2	2	1	N	N	Resolved (07OCT2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	05OCT2020	
Completed	VACCINATION	24NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	37	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	75 kg	27.5 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Left Shoulder Pain	Arthralgia	1998	Past
Left Shoulder Repair	Shoulder operation	1998	Past
Migraines	Migraine	2005	Present
Depression	Depression	2011	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	15:25
2	BNT162b2	08SEP2020 (23)	13:50

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	BLOOD	Lymphadenopathy	Swollen Lymph Node on left side of Neck	14SEP2020 (29)	08:30	20SEP2020 (35)	08:00	7

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (20SEP2020)	NOT RELATED/OTHER: unknown	2	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	08OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1991	28	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	95.91 kg	27.8 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
mild depression	Depression	2015	Present
tonsillectomy	Tonsillectomy	09MAY2019	Past
Tonsillitis	Tonsillitis	09MAY2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	12:47
2	Placebo	01OCT2020 (21)	15:50
3	BNT162b2	18DEC2020 (99)	08:50
4	BNT162b2	08JAN2021 (120)	10:20

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PSYCH	Cyclothymic disorder	cyclothyma	01NOV2020 (52)		ONGOING		
2	GENRL	Fatigue	fatigue	08JAN2021 (120)	17:00	11JAN2021 (123)	07:00	4
3	NERV	Headache	headache	08JAN2021 (120)	17:00	11JAN2021 (123)	07:00	4
4	BLOOD	Lymphadenopathy	swollen lymph node (left shoulder)	21JAN2021 (133)		28JAN2021 (140)		8
5	GENRL	Pain	body ache	08JAN2021 (120)	17:00	11JAN2021 (123)	07:00	4
6	INJ&P	Procedural pain	post injection pain	08JAN2021 (120)	17:00	11JAN2021 (123)	07:00	4

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Yes	NOT RELATED/OTHER: unknown	2	32	N
2	1	N	N	Resolved (11JAN2021)	Study Treatment	4	1	N
3	1	N	N	Resolved (11JAN2021)	Study Treatment	4	1	N
4	1	N	N	Resolved (28JAN2021)	Study Treatment	4	14	Y

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	1	N	N	Resolved (11JAN2021)	Study Treatment	4	1	N
6	1	N	N	Resolved (11JAN2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	29OCT2020	
Completed	REPEAT SCREENING 1	18DEC2020	
Completed	OPEN LABEL TREATMENT	04FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1980	40	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	62.73 kg	25.2 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Aleve Allergy	Drug hypersensitivity	2008	Present
enlarged Thyroid	Goitre	2009	Past
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	2010	Present
seasonal allergies	Seasonal allergy	2013	Present
anxiety	Anxiety	2019	Present
Perimenopausal	Menopause	2019	Present
Allergy to Sulfa	Drug hypersensitivity	JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21SEP2020 (1)	13:50
2	Placebo	12OCT2020 (22)	15:50
3	BNT162b2	18DEC2020 (89)	09:59
4	BNT162b2	08JAN2021 (110)	11:41

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Fatigue	Fatigue	13OCT2020 (23)	05:30	13OCT2020 (23)	12:00
2	NERV	Headache	headache	08JAN2021 (110)	15:00	09JAN2021 (111)	16:00
3	BLOOD	Lymphadenopathy	swollen lymph node (left armpit)	09JAN2021 (111)	13:00	05FEB2021 (138)	
4	GASTR	Nausea	Nausea	13OCT2020 (23)	05:30	13OCT2020 (23)	12:00
5	GENRL	Pain	body aches	09JAN2021 (111)	11:00	09JAN2021 (111)	16:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	N	N	Resolved (13OCT2020)	Study Treatment	2	2	N
2	2	1	N	N	Resolved (09JAN2021)	Study Treatment	4	1	N
3	28	1	N	N	Resolved (05FEB2021)	Study Treatment	4	2	Y

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	1	1	N	N	Resolved (13OCT2020)	Study Treatment	2	2	N
5	1	1	N	N	Resolved (09JAN2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21SEP2020	
Completed	VACCINATION	11NOV2020	
Completed	REPEAT SCREENING 1	18DEC2020	
Completed	OPEN LABEL TREATMENT	08FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	64	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	61 kg	24.4 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergies	Seasonal allergy	1958	Present
Keratoconus, bilateral eyes	Keratoconus	1969	Present
Hypothyroid	Hypothyroidism	SEP1988	Present
Lactose intolerance	Lactose intolerance	1993	Present
GERD	Gastrooesophageal reflux disease	SEP1993	Present
Sulfite allergy	Reaction to preservatives	1999	Present
Osteoarthritis, bilateral thumbs	Osteoarthritis	2002	Present
Benign Pulmonary Granulomas	Pulmonary granuloma	2009	Present
Rosacea	Rosacea	2010	Present

Medical History

Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Post-menopausal	Postmenopause	DEC2010	Present
Hyperlipidemia	Hyperlipidaemia	SEP2018	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	07AUG2020 (1)	10:31
2	Placebo	26AUG2020 (20)	10:08
3	BNT162b2	22DEC2020 (138)	09:02
4	BNT162b2	11JAN2021 (158)	09:00

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GENRL	Chills	chills	11JAN2021 (158)	19:00	11JAN2021 (158)	20:00	1	1
2	GENRL	Fatigue	fatigue	12JAN2021 (159)	12:00	12JAN2021 (159)	15:00	1	1
3	GENRL	Injection site pain	Injection site pain	22DEC2020 (138)	09:02	24DEC2020 (140)	08:00	3	2
4	GENRL	Injection site pain	injection site pain	11JAN2021 (158)	14:00	12JAN2021 (159)	18:00	2	1
5	BLOOD	Lymphadenopathy	lymph node swelling	12JAN2021 (159)	12:00	12JAN2021 (159)	15:00	1	1
6	INFEC	Urinary tract infection	Urinary Tract Infection	01SEP2020 (26)	22:01	06SEP2020 (31)	08:00	6	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (11JAN2021)	Study Treatment	4	1	N
2	N	N	Resolved (12JAN2021)	Study Treatment	4	2	N
3	TC	N	Resolved (24DEC2020)	Study Treatment	3	1	N
4	TC	N	Resolved (12JAN2021)	Study Treatment	4	1	N
5	N	N	Resolved (12JAN2021)	Study Treatment	4	2	Y
6	TC	N	Resolved (06SEP2020)	NOT RELATED/OTHER: Bacterial Infection	2	7	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Influenza Vaccine	INFLUENZA VACCINE	20SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	24SEP2020	
Completed	REPEAT SCREENING 1	22DEC2020	
Completed	OPEN LABEL TREATMENT	12FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	32	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156 cm	59.6 kg	24.5 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergies	Seasonal allergy	01JAN1993	Present
Asthma	Asthma	01JAN1996	Present
Zithromax allergy	Drug hypersensitivity	DEC1998	Present
Hypothyroid	Hypothyroidism	06MAR2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10AUG2020 (1)	12:10
2	BNT162b2	01SEP2020 (23)	14:31

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Herpes zoster	Shingles	08FEB2021 (183)	19:00	09MAR2021 (212)	22:00	30
2	BLOOD	Lymphadenopathy	Left supraclavicular adenopathy	02SEP2020 (24)	07:00	03SEP2020 (25)	07:00	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Resolved (09MAR2021)	NOT RELATED/OTHER: viral infection	2	161	N
2	1	N	N	Resolved (03SEP2020)	Study Treatment	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	30SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10AUG2020	
Completed	VACCINATION	29SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	75.4 kg	27 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Dermatomyositis	Dermatomyositis	1995	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	12:32
2	Placebo	14SEP2020 (22)	10:53

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	21JAN2021 (151)	14:54
4	BNT162b2	11FEB2021 (172)	12:04

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Headache	Headache	15SEP2020 (23)		16SEP2020 (24)	
2	NERV	Headache	Headache	12FEB2021 (173)	06:00	13FEB2021 (174)	06:00
3	GENRL	Injection site pain	Injection Site Pain	15SEP2020 (23)		16SEP2020 (24)	
4	GENRL	Injection site pain	Injection Site Pain	11FEB2021 (172)	16:00	13FEB2021 (174)	07:00
5	GENRL	Injection site pain	injection site soreness	22JAN2021 (152)	04:00	23JAN2021 (153)	06:00
6	BLOOD	Lymphadenopathy	Left Axillary Adenopathy	12FEB2021 (173)	06:00	15FEB2021 (176)	06:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (16SEP2020)	Study Treatment	2	2	N
2	2	1	TC	N	Resolved (13FEB2021)	Study Treatment	4	2	N
3	2	1	N	N	Resolved (16SEP2020)	Study Treatment	2	2	N
4	3	1	TC	N	Resolved (13FEB2021)	Study Treatment	4	1	N
5	2	1	TC	N	Resolved (23JAN2021)	Study Treatment	3	2	N
6	4	1	N	N	Resolved (15FEB2021)	Study Treatment	4	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	12OCT2020	
Completed	REPEAT SCREENING 1	21JAN2021	
Completed	OPEN LABEL TREATMENT	11MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	26	Multiple	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174.5 cm	120.2 kg	39.5 kg/m2	27AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	13:05
2	Placebo	17SEP2020 (22)	10:59

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	18JAN2021 (145)	09:46
4	BNT162b2	08FEB2021 (166)	09:31

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Headache	Headache	09FEB2021 (167)	02:00	09FEB2021 (167)	20:00
2	BLOOD	Lymphadenopathy	Left Axillary Lymphadenopathy	09FEB2021 (167)	08:00	10FEB2021 (168)	20:00
3	MUSC	Myalgia	Myalgias	09FEB2021 (167)	02:00	09FEB2021 (167)	18:00
4	GENRL	Pyrexia	Fever	09FEB2021 (167)	02:00	09FEB2021 (167)	20:00
5	GENRL	Injection site pain	injection site pain	18JAN2021 (145)	09:47	21JAN2021 (148)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	2	N	N	Resolved (09FEB2021)	Study Treatment	4	2	N
2	2	1	N	N	Resolved (10FEB2021)	Study Treatment	4	2	Y
3	1	2	N	N	Resolved (09FEB2021)	Study Treatment	4	2	N
4	1	3	TC	N	Resolved (09FEB2021)	Study Treatment	4	2	N
5	4	1	N	N	Resolved (21JAN2021)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu Vaccination	INFLUENZA VACCINE	21SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	15OCT2020	
Completed	REPEAT SCREENING 1	18JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	Asian	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.5 cm	65.3 kg	25 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	DEC2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	12:14
2	Placebo	17SEP2020 (21)	14:21

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	20JAN2021 (146)	09:05
4	BNT162b2	10FEB2021 (167)	09:16

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Chills	10FEB2021 (167)	15:00	11FEB2021 (168)	08:00
2	GENRL	Chills	chills	21JAN2021 (147)	14:00	22JAN2021 (148)	08:00
3	GENRL	Injection site pain	Injection Site Pain	11FEB2021 (168)	08:00	13FEB2021 (170)	10:00
4	GENRL	Injection site pain	injection site soreness	20JAN2021 (146)	18:00	22JAN2021 (148)	08:00
5	BLOOD	Lymphadenopathy	Right Axillary Adenopathy	11FEB2021 (168)	08:00	12FEB2021 (169)	08:00
6	GASTR	Nausea	Nausea	10FEB2021 (167)	15:00	11FEB2021 (168)	20:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	TC	N	Resolved (11FEB2021)	Study Treatment	4	1	N
2	2	1	TC	N	Resolved (22JAN2021)	Study Treatment	3	2	N
3	3	1	N	N	Resolved (13FEB2021)	Study Treatment	4	2	N
4	3	1	N	N	Resolved (22JAN2021)	Study Treatment	3	1	N
5	2	1	N	N	Resolved (12FEB2021)	Study Treatment	4	2	Y
6	2	1	N	N	Resolved (11FEB2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine	INFLUENZA VACCINE	14OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	16OCT2020	
Completed	REPEAT SCREENING 1	20JAN2021	
Completed	OPEN LABEL TREATMENT	12MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	51	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	86.3 kg	29.9 kg/m2	22AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
TONSILLECTOMY	Tonsillectomy	1975	Past
TONSILLITIS	Tonsillitis	1975	Past
HYPERTENSION	Hypertension	2016	Present
DIABETES MELLITUS TYPE II	Type 2 diabetes mellitus	2016	Present
OVERWEIGHT	Overweight	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	22AUG2020 (1)	13:35
2	BNT162b2	11SEP2020 (21)	09:11

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site erythema	INJECTION SITE ERYTHEMA	11SEP2020 (21)		13SEP2020 (23)	
2	GENRL	Injection site pain	PAIN AT INJECTION SITE	11SEP2020 (21)		14SEP2020 (24)	
3	BLOOD	Lymphadenopathy	SWOLLEN LEFT AXILLARY LYMPH NODES	11SEP2020 (21)		13SEP2020 (23)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	1	N	N	Resolved (13SEP2020)	Study Treatment	2	1	N
2	4	1	N	N	Resolved (14SEP2020)	Study Treatment	2	1	N
3	3	1	N	N	Resolved (13SEP2020)	Study Treatment	2	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	42	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	68.23 kg	22.2 kg/m2	07SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
acne	Acne	1996	Present
depression	Depression	2000	Present
endometriosis	Endometriosis	2000	Past
hysterectomy	Hysterectomy	2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07SEP2020 (1)	12:34
2	Placebo	30SEP2020 (24)	16:58
3	BNT162b2	17DEC2020 (102)	07:35
4	BNT162b2	08JAN2021 (124)	07:34

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Fatigue	fatigue	08JAN2021 (124)		10JAN2021 (126)	
2	BLOOD	Lymphadenopathy	L side axillary lymph node swelling	08JAN2021 (124)		10JAN2021 (126)	
3	GENRL	Pyrexia	fever	08JAN2021 (124)		09JAN2021 (125)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	2	N	N	Resolved (10JAN2021)	Study Treatment	4	1	N
2	3	2	N	N	Resolved (10JAN2021)	Study Treatment	4	1	Y
3	2	2	TC	N	Resolved (09JAN2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07SEP2020	
Completed	VACCINATION	30OCT2020	
Completed	REPEAT SCREENING 1	17DEC2020	
Completed	OPEN LABEL TREATMENT	11FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186 cm	78 kg	22.5 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
atrial fibrillation	Atrial fibrillation	17OCT2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	14:18
2	Placebo	17SEP2020 (21)	17:03

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	21DEC2020 (116)	07:44
4	BNT162b2	12JAN2021 (138)	07:50

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	chills	13JAN2021 (139)	07:00	14JAN2021 (140)	19:00
2	GASTR	Gingival swelling	Gum Swelling	28AUG2020 (1)	18:00	30AUG2020 (3)	18:00
3	BLOOD	Lymphadenopathy	Left swollen cervical lymph node	28AUG2020 (1)	18:00	30AUG2020 (3)	18:00
4	GENRL	Pain	body aches	13JAN2021 (139)	07:00	14JAN2021 (140)	19:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (14JAN2021)	Study Treatment	4	2	N
2	3	1	N	N	Resolved (30AUG2020)	Study Treatment	1	1	N
3	3	1	N	N	Resolved (30AUG2020)	Study Treatment	1	1	Y
4	2	1	TC	N	Resolved (14JAN2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	15OCT2020	
Completed	REPEAT SCREENING 1	21DEC2020	
Completed	OPEN LABEL TREATMENT	09FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	62	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
149.9 cm	70.9 kg	31.6 kg/m2	04SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	16:34
2	BNT162b2	25SEP2020 (22)	16:56

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site pain	Injection Site Pain	05SEP2020 (2)		07SEP2020 (4)	
2	BLOOD	Lymphadenopathy	Swollen Cervical Lymph Nodes bilateral	05SEP2020 (2)		07SEP2020 (4)	
3	RESP	Rhinorrhoea	Rhinorrhea	05SEP2020 (2)		07SEP2020 (4)	
4	RESP	Sneezing	Sneezing	05SEP2020 (2)		07SEP2020 (4)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	1	N	N	Resolved (07SEP2020)	Study Treatment	1	2	N
2	3	1	N	N	Resolved (07SEP2020)	Study Treatment	1	2	Y
3	3	1	N	N	Resolved (07SEP2020)	Study Treatment	1	2	N
4	3	1	N	N	Resolved (07SEP2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	27OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	40	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.8 cm	84.8 kg	33.6 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ALLERGY TO CYCLOBENZAPRINE	Drug hypersensitivity	2017	Present
OBESITY	Obesity	2019	Present
TYPE II DIABETES	Type 2 diabetes mellitus	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15SEP2020 (1)	16:15
2	BNT162b2	05OCT2020 (21)	17:20

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	SWOLLEN LYMPH NODE UNDER LEFT ARMPIT	07OCT2020 (23)		12OCT2020 (28)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	6	2	N	N	Resolved (12OCT2020)	Study Treatment	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15SEP2020	
Completed	VACCINATION	03NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.75 cm	80.55 kg	31.9 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
right ankle fracture	Ankle fracture	1979	Past
c-section	Caesarean section	MAY1983	Past
torn tendon left foot	Tendon rupture	1988	Past
total abdominal hysterectomy with bilateral oophorectomy	Hysterosalpingo-oophorectomy	JUL1993	Past
deviated septum	Nasal septum deviation	1996	Past
right foot bunion	Foot deformity	1998	Past
left foot bunion	Foot deformity	2000	Past
pelvic mass	Pelvic mass	JUN2007	Past
EPITHELIAL INCLUSION CYST OF VAGINA	Vaginal cyst	JUN2007	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
intermittent constipation	Constipation	2011	Present
redundant colon	Dolichocolon	JAN2011	Past
small bowel obstruction	Small intestinal obstruction	JUL2011	Past
dyslipidemia	Dyslipidaemia	2015	Present
GERD	Gastrooesophageal reflux disease	2015	Present
bilateral cataract extraction	Cataract operation	JUL2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18AUG2020 (1)	16:08
2	BNT162b2	03SEP2020 (17)	16:09

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	SKIN	Dermatitis contact	Contact Dermatitis on lower extremities	11SEP2020 (25)		22SEP2020 (36)		12	2
2	BLOOD	Lymphadenopathy	Lymphadenopathy Under left ear	10SEP2020 (24)	08:01	23SEP2020 (37)	08:00	14	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (22SEP2020)	NOT RELATED/OTHER: contact with allergen or irritant	2	9	N
2	TC	N	Resolved (23SEP2020)	NOT RELATED/OTHER: Bacterial Infection	2	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine	INFLUENZA VACCINE	16SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	01OCT2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2000	20	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	75.09 kg	24.4 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic Rhinitis-Seasonal	Seasonal allergy	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	16:37

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	09SEP2020 (22)	17:27
3	BNT162b2	06MAR2021 (200)	12:14

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Fatigue	Fatigue	07MAR2021 (201)	00:00	08MAR2021 (202)	00:00	2	1
2	NERV	Headache	Headache	06MAR2021 (200)	00:00	08MAR2021 (202)	00:00	3	1
3	GENRL	Injection site erythema	Injection Site Redness-5.5 centimeters	07MAR2021 (201)	00:00	ONGOING			2
4	GENRL	Injection site pain	Injection Site Pain-Left	07MAR2021 (201)	00:00	08MAR2021 (202)	00:00	2	1
5	BLOOD	Lymphadenopathy	Enlarged Lymph Node-Left Side	07MAR2021 (201)	00:00	ONGOING			1
6	MUSC	Myalgia	Muscle Aches	07MAR2021 (201)	00:00	08MAR2021 (202)	00:00	2	1
7	INJ&P	Stress fracture	StressFracture-Right Foot	14JAN2021 (149)	00:00	ONGOING			1
8	VASC	Varicose vein	pain secondary to varicose vein in left thigh	06OCT2020 (49)	11:00	20OCT2020 (63)	00:00	15	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (08MAR2021)	Study Treatment	3	2	N
2	TC	N	Resolved (08MAR2021)	Study Treatment	3	1	N
3	N	N	Yes	Study Treatment	3	2	N
4	N	N	Resolved (08MAR2021)	Study Treatment	3	2	N

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	TC	N	Yes	Study Treatment	3	2	Y
6	TC	N	Resolved (08MAR2021)	Study Treatment	3	2	N
7	N	N	Yes	NOT RELATED/OTHER: Injury	2	128	N
8	TC	N	Resolved (20OCT2020)	NOT RELATED/OTHER: Vascular insufficiency	2	28	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	08OCT2020	
Completed	REPEAT SCREENING 1	06MAR2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.9 cm	127.7 kg	38.2 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DEEP VEIN THROMBOSIS	Deep vein thrombosis	1994	Present
ALLERGY TO CORTISONE	Drug hypersensitivity	2010	Present
ALLERGY TO CODEINE	Drug hypersensitivity	2010	Present
Chronic Atrial Fibrillation	Atrial fibrillation	06JUN2017	Present
Coronary Artery Disease	Coronary artery disease	06JUN2017	Present
CHRONIC BACK PAIN	Back pain	2018	Present
HYPERTENSION	Hypertension	2018	Present
NEUROPATHY (BILATERAL LEGS)	Neuropathy peripheral	2018	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	11:14
2	BNT162b2	09SEP2020 (20)	16:59

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GASTR	Abdominal pain	Abdominal Pain	01SEP2020 (12)		05SEP2020 (16)		5	2
2	GASTR	Femoral hernia	Femoral Hernia - Right	01SEP2020 (12)		ONGOING			2
3	VASC	Hypertension	Worsening of Hypertension	01SEP2020 (12)		03SEP2020 (14)		3	2
4	METAB	Hypokalaemia	Hypokalemia	01SEP2020 (12)		05SEP2020 (16)		5	2
5	BLOOD	Lymphadenopathy	Prominent Reactive Lymph nodes in Cervical Area	01SEP2020 (12)		05SEP2020 (16)		5	2
6	MUSC	Neck pain	Right Anterior Cervical Tenderness	01SEP2020 (12)		05SEP2020 (16)		5	2
7	GASTR	Odynophagia	Odynophagia	01SEP2020 (12)		05SEP2020 (16)		5	2
8	INFEC	Peritonsillar abscess	Tonsillar Abscess - Right	01SEP2020 (12)		05SEP2020 (16)		5	3
9	INFEC	Pharyngitis streptococcal	STREP THROAT	25AUG2020 (5)		05SEP2020 (16)		12	3
10	RENAL	Pollakiuria	Urinary Frequency	01SEP2020 (12)		05SEP2020 (16)		5	2
11	GENRL	Swelling	Right Anterior Cervical Swelling	01SEP2020 (12)		05SEP2020 (16)		5	2
12	INFEC	Urinary tract infection	Urinary Tract Infection	01SEP2020 (12)		05SEP2020 (16)		5	2

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (05SEP2020)	NOT RELATED/OTHER: Urinary Tract Infection	1	12	N
2	N	N	Yes	NOT RELATED/OTHER: Idiopathic	1	12	N
3	N	N	Resolved (03SEP2020)	NOT RELATED/OTHER: Tonsillar Abscess	1	12	N
4	N	N	Resolved (05SEP2020)	NOT RELATED/OTHER: Urinary Frequency	1	12	N
5	N	N	Resolved (05SEP2020)	NOT RELATED/OTHER: Tonsillar Abscess	1	12	Y
6	N	N	Resolved (05SEP2020)	NOT RELATED/OTHER: Tonsillar Abscess	1	12	N
7	N	N	Resolved (05SEP2020)	NOT RELATED/OTHER: Tonsillar Abscess	1	12	N
8	TC	Y	Resolved (05SEP2020)	NOT RELATED/OTHER: Strep Throat	1	12	Y
9	TC	N	Resolved (05SEP2020)	NOT RELATED/OTHER: BACTERIAL INFECTION	1	5	N
10	TC	N	Resolved (05SEP2020)	NOT RELATED/OTHER: Urinary Tract Infection	1	12	N
11	N	N	Resolved (05SEP2020)	NOT RELATED/OTHER: Tonsillar Abscess	1	12	N
12	TC	N	Resolved (05SEP2020)	NOT RELATED/OTHER: Idiopathic	1	12	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1987	33	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	120.6 kg	40.4 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
TONSILLITIS	Tonsillitis	1993	Past
CHOLECYSTITIS	Cholecystitis	1995	Past
SEASONAL ALLERGIES	Seasonal allergy	JAN2020	Present
HYPERTENSION	Hypertension	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	10:13
2	BNT162b2	11SEP2020 (22)	11:33

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	SKIN	Acne cystic	Cystic Acne	14OCT2020 (55)		ONGOING		
2	BLOOD	Lymphadenopathy	SWOLLEN LYMPH NODES IN LEFT AXILLA	12SEP2020 (23)		04OCT2020 (45)		23

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	N	Yes	NOT RELATED/OTHER: Idiopathic	2	34	N
2	2	N	N	Resolved (04OCT2020)	Study Treatment	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
FLU VACCINE	INFLUENZA VACCINE	01OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.2 cm	73 kg	25.2 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Alopecia	Alopecia	1998	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	10:19
2	Placebo	15SEP2020 (22)	09:50
3	BNT162b2	08FEB2021 (168)	09:56
4	BNT162b2	01MAR2021 (189)	10:08

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	BLOOD	Lymphadenopathy	Swollen Lymph Nodes - Left Axillary Region	02MAR2021 (190)	07:00	ONGOING	
2	GENRL	Pyrexia	Fever	01MAR2021 (189)	19:00	01MAR2021 (189)	23:00

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		2	N	N	Yes	Study Treatment	4	2	Y
2	1	2	N	N	Resolved (01MAR2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	13OCT2020	
Completed	REPEAT SCREENING 1	08FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.7 cm	128.36 kg	43 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to Sulfa	Drug hypersensitivity	1955	Present
Osteoarthritis - ankle	Osteoarthritis	1986	Present
Osteoarthritis - Shoulder	Osteoarthritis	1986	Present
Osteoarthritis - Knee	Osteoarthritis	1986	Present
Inguinal Hernia - Right	Inguinal hernia	1989	Past
Inguinal Hernia - Left	Inguinal hernia	1989	Past
Hernia repair - bilateral	Hernia repair	1990	Past
Hypercholesterolemia	Hypercholesterolaemia	1993	Present
Insomnia	Insomnia	2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
GERD	Gastrooesophageal reflux disease	2005	Present
Tremors	Tremor	2005	Present
Hospitalization due to bleeding ulcer	Ulcer haemorrhage	2005	Past
Bleeding Ulcer	Ulcer haemorrhage	2005	Past
Bipolar Disorder	Bipolar disorder	2009	Present
Left leg compound fracture	Lower limb fracture	2009	Past
Hospitalization for left leg compound fracture due to trauma	Lower limb fracture	2009	Past
Benign Prostate Hyperplasia	Benign prostatic hyperplasia	2013	Past
transurethral resection	Exeresis	2013	Past
Ankle Fusion - Left	Arthrodesis	2014	Past
Knee arthroplasty - right	Knee arthroplasty	2016	Past
Allergy to Adhesive Tape	Dermatitis contact	2018	Present
Hyponatremia	Hyponatraemia	2018	Present
Muscle pain	Myalgia	2018	Present
Cyst - right testicle	Testicular cyst	2018	Past
Orchiectomy - right testicle	Orchidectomy	MAR2018	Past
Chronic Recurrent Infection of Right Total Knee Replacement	Device related infection	JUN2018	Present
Hospitalization due to infection of right knee	Arthritis infective	JUL2018	Past
Hospitalization due to infection of right knee	Arthritis infective	AUG2018	Past
Hospitalization due to infection of right knee	Arthritis infective	NOV2018	Past
Hospitalization due to infection of right knee	Arthritis infective	JAN2019	Past
Knee Arthroplasty - Right	Knee arthroplasty	NOV2019	Past
Allergy to vancomycin	Drug hypersensitivity	JAN2020	Present
Hemarthrosis	Haemarthrosis	JAN2020	Past
Synovectomy - Right Knee	Synovectomy	JUN2020	Past
Total Shoulder Arthroplasty	Shoulder arthroplasty	16JUN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01SEP2020 (1)	15:17
2	BNT162b2	22SEP2020 (22)	13:31

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	MUSC	Arthralgia	Right Knee Pain	16NOV2020 (77)		24NOV2020 (85)		9	3
2	MUSC	Bone disorder	Cortical Irregularity of medial distal femur	16NOV2020 (77)		24NOV2020 (85)		9	3
3	INFEC	Device related infection	Worsening of Chronic Recurrent Infection of Right Total Knee Replacement	16NOV2020 (77)		24NOV2020 (85)		9	3
4	BLOOD	Lymphadenopathy	Enlarged right inguinal lymph nodes	16NOV2020 (77)		24NOV2020 (85)		9	3
5	INJ&P	Patella fracture	Fragmentation of the Patella	16NOV2020 (77)		24NOV2020 (85)		9	3
6	GENRL	Peripheral swelling	Severe Soft Tissue Swelling of Right Lower Extemity	16NOV2020 (77)		24NOV2020 (85)		9	3

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN	N	Resolved (24NOV2020)	NOT RELATED/OTHER: worsening of osteoarthritis	2	56	N
2	TC/TCN	N	Resolved (24NOV2020)	NOT RELATED/OTHER: due to infection	2	56	N
3	TC/TCN	Y	Resolved (24NOV2020)	NOT RELATED/OTHER: Worsening of Pre-existing condition	2	56	Y
4	TC/TCN	N	Resolved (24NOV2020)	NOT RELATED/OTHER: due to infection	2	56	Y
5	TC/TCN	N	Resolved (24NOV2020)	NOT RELATED/OTHER: due to infection	2	56	N
6	TC/TCN	N	Resolved (24NOV2020)	NOT RELATED/OTHER: due to infection	2	56	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01SEP2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	27	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.9 cm	95.3 kg	30.1 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
acne	Acne	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	08SEP2020 (1)	12:54
2	BNT162b2	05OCT2020 (28)	08:59

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	BLOOD	Lymphadenopathy	Swollen Right Cervical Lymph Node	05OCT2020 (28)	19:00	09OCT2020 (32)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	5	1	TC	N	Resolved (09OCT2020)	Study Treatment	2	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	02NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	79.55 kg	29.1 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
insomnia	Insomnia	2010	Present
endometrial cancer	Endometrial cancer	2011	Past
hysterectomy	Hysterectomy	2011	Past
anxiety	Anxiety	2015	Present
depression	Depression	2015	Present
dry eyes	Dry eye	2015	Present
planter fascitis left heel	Plantar fasciitis	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04AUG2020 (1)	14:20
2	BNT162b2	26AUG2020 (23)	13:30

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INV	Blood cholesterol increased	Elevated Cholesterol	AUG2020 ()		ONGOING		
2	BLOOD	Lymphadenopathy	Left Para clavicular lymph node enlargement	28AUG2020 (25)	10:30	03NOV2020 (92)		68

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Yes	NOT RELATED/OTHER: Genetic Make up			N
2	1	N	N	Resolved (03NOV2020)	Study Treatment	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Completed	VACCINATION	23SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	49.3 kg	17.5 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Overactive Bladder	Hypertonic bladder	2017	Past
Partial Hysterectomy	Hysterectomy	2017	Past
Migraines, recurrent	Migraine	2017	Present
OA knee	Osteoarthritis	2017	Present
OA Neck	Spinal osteoarthritis	2017	Present
Bladder Surgery (Sling)	Urinary bladder suspension	2017	Past
Rectocele	Rectocele	MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07AUG2020 (1)	16:01
2	Placebo	28AUG2020 (22)	15:23
3	BNT162b2	28DEC2020 (144)	15:30
4	BNT162b2	29JAN2021 (176)	12:31

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	MUSC	Arthralgia	Generalized arthralgia	29JAN2021 (176)	22:00	31JAN2021 (178)	
2	GENRL	Injection site pain	Injection site pain-severe	29JAN2021 (176)	22:00	31JAN2021 (178)	
3	BLOOD	Lymphadenopathy	Cervical lymphadenopathy-bilateral	30JAN2021 (177)		03FEB2021 (181)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	3	TC	N	Resolved (31JAN2021)	Study Treatment	4	1	N
2	3	3	TC	N	Resolved (31JAN2021)	Study Treatment	4	1	N
3	5	2	N	N	Resolved (03FEB2021)	Study Treatment	4	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	28SEP2020	
Completed	REPEAT SCREENING 1	28DEC2020	
Completed	OPEN LABEL TREATMENT	05MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
183.4 cm	90.2 kg	26.8 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
asthma	Asthma	20JUN1968	Present
GERD	Gastrooesophageal reflux disease	JAN1995	Present
elevated cholesterol	Blood cholesterol increased	JAN1996	Present
Meniere's disease	Meniere's disease	20JAN1998	Present
Post traumatic stress disorder	Post-traumatic stress disorder	2004	Present
inguinal hernia, right side	Inguinal hernia	JAN2004	Past
hypertension	Hypertension	JUL2014	Present
hernia repair surgery	Hernia repair	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	09SEP2020 (1)	09:59
2	BNT162b2	28SEP2020 (20)	14:33

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Chills	28SEP2020 (20)	19:00	02OCT2020 (24)	
2	GENRL	Fatigue	Fatigue	28SEP2020 (20)	18:00	02OCT2020 (24)	
3	NERV	Headache	Headache	28SEP2020 (20)	18:00	02OCT2020 (24)	
4	GENRL	Injection site pain	Injection site pain-left arm	28SEP2020 (20)	23:00	04OCT2020 (26)	
5	BLOOD	Lymphadenopathy	Swollen left axillary lymph node	29SEP2020 (21)		04OCT2020 (26)	
6	GENRL	Pyrexia	Fever	29SEP2020 (21)		30SEP2020 (22)	
7	SKIN	Night sweats	Night sweats	28SEP2020 (20)	15:00	01OCT2020 (23)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	5	2	N	N	Resolved (02OCT2020)	Study Treatment	2	1	N
2	5	2	N	N	Resolved (02OCT2020)	Study Treatment	2	1	N
3	5	1	TC	N	Resolved (02OCT2020)	Study Treatment	2	1	N

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	7	2	TC	N	Resolved (04OCT2020)	Study Treatment	2	1	N
5	6	2	N	N	Resolved (04OCT2020)	Study Treatment	2	2	Y
6	2	1	TC	N	Resolved (30SEP2020)	Study Treatment	2	2	N
7	4	2	N	N	Resolved (01OCT2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Flu vaccine	INFLUENZA VACCINE	27OCT2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	26OCT2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1980	40	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
190 cm	95.3 kg	26.4 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Dust mite allergy	Mite allergy	1995	Present
Allergic Rhinitis	Rhinitis allergic	1995	Present
Shellfish allergy	Food allergy	2010	Present
GERD	Gastrooesophageal reflux disease	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15SEP2020 (1)	12:25
2	BNT162b2	06OCT2020 (22)	12:32

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Fatigue	fatigue	07OCT2020 (23)		10OCT2020 (26)	
2	BLOOD	Lymphadenopathy	Swollen lymph nodes-left axilla	07OCT2020 (23)		03NOV2020 (50)	
3	MUSC	Myalgia	Muscle aches	07OCT2020 (23)		09OCT2020 (25)	
4	GENRL	Pyrexia	fever	06OCT2020 (22)	22:00	07OCT2020 (23)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	2	N	N	Resolved (10OCT2020)	Study Treatment	2	2	N
2	28	3	N	N	Resolved (03NOV2020)	Study Treatment	2	2	Y
3	3	1	N	N	Resolved (09OCT2020)	Study Treatment	2	2	N
4	2	1	N	N	Resolved (07OCT2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15SEP2020	
Completed	VACCINATION	06NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	87.9 kg	30.8 kg/m2	30JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Right Ovarian Torsion	Adnexal torsion	MAR1996	Past
Right Oophorectomy	Oophorectomy	MAR1996	Past
Generalized Osteoarthritis	Osteoarthritis	2010	Present
Post-menopausal	Postmenopause	2010	Present
Reduction Mammaplasty	Mammoplasty	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30JUL2020 (1)	17:33
2	Placebo	18AUG2020 (20)	10:47
3	BNT162b2	14JAN2021 (169)	11:25
4	BNT162b2	02FEB2021 (188)	11:02

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	BLOOD	Lymphadenopathy	Left subclavicular lymph node enlargement	03FEB2021 (189)		06FEB2021 (192)		4	1	N
2	INFEC	Otitis media	BILATERAL SERIOUS OTITIS MEDIA	16AUG2020 (18)	12:00	09FEB2021 (195)		178	1	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Resolved (06FEB2021)	Study Treatment	4	2	Y
2	N	Resolved (09FEB2021)	NOT RELATED/OTHER: EUSTACHIAN TUBE DYSFUNCTION	1	18	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Adacel TDaP	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 5-COMPONENT;TETANUS VACCINE TOXOID	16SEP2020
influenza vaccine	INFLUENZA VACCINE	16SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30JUL2020	
Completed	VACCINATION	15SEP2020	
Completed	REPEAT SCREENING 1	14JAN2021	
Completed	OPEN LABEL TREATMENT	02MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171 cm	105.9 kg	36.2 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	1973	Present
anxiety	Anxiety	1983	Present
sulfa drugs allergy	Drug hypersensitivity	1990	Present
iodine allergy	Iodine allergy	1990	Present
latex allergy	Rubber sensitivity	1990	Present
torn meniscus (right)	Meniscus injury	2015	Past
meniscus repair (right)	Meniscus operation	2015	Past
bilateral osteoarthritis of knees	Osteoarthritis	2015	Present
postmenopausal	Postmenopause	2015	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
torn meniscus (left)	Meniscus injury	2017	Past
meniscus repair (left)	Meniscus operation	2017	Past
osteoarthritis of bilateral hallux	Osteoarthritis	2018	Present
tibia break (left)	Tibia fracture	28DEC2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	11:24
2	BNT162b2	16SEP2020 (23)	11:58

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	enlarged left axillary lymph node	03SEP2020 (10)		30SEP2020 (37)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	28	1	N	N	Resolved (30SEP2020)	Study Treatment	1	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine	INFLUENZA VACCINE	NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	14OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	95.4 kg	29.3 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypercholesterolemia	Hypercholesterolaemia	2015	Present
hypertension	Hypertension	2015	Present
osteoarthritis	Osteoarthritis	2015	Present
gastric ulcers (healed)	Gastric ulcer	2018	Past
iron deficiency	Iron deficiency	JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14SEP2020 (1)	16:10
2	Placebo	05OCT2020 (22)	15:47
3	BNT162b2	20JAN2021 (129)	12:43
4	BNT162b2	08FEB2021 (148)	12:45

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Headache	headache	09FEB2021 (149)	06:00	09FEB2021 (149)	21:00
2	BLOOD	Lymphadenopathy	Swollen left lymph node on neck	12FEB2021 (152)	08:00	03MAR2021 (171)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	2	N	N	Resolved (09FEB2021)	Study Treatment	4	2	N
2	20	1	N	N	Resolved (03MAR2021)	Study Treatment	4	5	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccine	INFLUENZA VACCINE	27OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	05NOV2020	
Completed	REPEAT SCREENING 1	20JAN2021	
Completed	OPEN LABEL TREATMENT	08MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	76.82 kg	28.1 kg/m2	05SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
APPENDECTOMY	Appendicectomy	1987	Past
APPENDICITIS	Appendicitis	1987	Past
ALLERGY TO IODINE	Iodine allergy	2005	Present
KIDNEY STONES	Nephrolithiasis	2005	Present
LITHOTRIPSY	Lithotripsy	2013	Past
HYPERTENSION	Hypertension	2018	Present
HEART BURN	Dyspepsia	24AUG2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	05SEP2020 (1)	18:18
2	Placebo	25SEP2020 (21)	12:26
3	BNT162b2	18JAN2021 (136)	11:03
4	BNT162b2	09FEB2021 (158)	10:38

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	BLOOD	Lymphadenopathy	Right swollen lymph node under jaw	13SEP2020 (9)	02:00	16SEP2020 (12)	09:00	4
2	MUSC	Myalgia	Generalized muscle aches due to exercise	22SEP2020 (18)	19:00	ONGOING		
3	RESP	Oropharyngeal pain	Sore throat	13SEP2020 (9)	02:00	14SEP2020 (10)	17:00	2
4	INFEC	Sialoadenitis	Sialadenitis	13SEP2020 (9)	02:00	16SEP2020 (12)	09:00	4

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (16SEP2020)	NOT RELATED/OTHER: unknown	1	9	Y
2	1	N	N	Yes	NOT RELATED/OTHER: due to exercise	1	18	N
3	1	TC	N	Resolved (14SEP2020)	NOT RELATED/OTHER: Personal infection	1	9	N
4	1	N	N	Resolved (16SEP2020)	NOT RELATED/OTHER: unknown	1	9	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	13OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05SEP2020	
Completed	VACCINATION	27OCT2020	
Completed	REPEAT SCREENING 1	18JAN2021	
Completed	OPEN LABEL TREATMENT	11MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	59	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	73.82 kg	27.9 kg/m2	30JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bipolar Disorder	Bipolar disorder	01JAN1985	Present
Major Depressive Disorder	Major depression	01JAN1985	Present
Hypothyroidism	Hypothyroidism	01JAN2002	Present
Acid Reflux	Gastrooesophageal reflux disease	01JAN2013	Present
Asthma	Asthma	01JAN2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30JUL2020 (1)	16:15
2	Placebo	18AUG2020 (20)	16:47
3	BNT162b2	27JAN2021 (182)	09:53
4	BNT162b2	17FEB2021 (203)	09:26

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	SWOLLEN LYMPH NODES	18FEB2021 (204)		20FEB2021 (206)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	1	N	N	Resolved (20FEB2021)	Study Treatment	4	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30JUL2020	
Completed	VACCINATION	01OCT2020	
Completed	REPEAT SCREENING 1	27JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	86.18 kg	30.7 kg/m2	04SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	15:59
2	BNT162b2	24SEP2020 (21)	15:17

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	BLOOD	Lymphadenopathy	Bilateral axillary adenopathy	25SEP2020 (22)		27SEP2020 (24)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	1	N	N	Resolved (27SEP2020)	Study Treatment	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	28OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	61.7 kg	22.7 kg/m2	29SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	2008	Past
appendicitis	Appendicitis	2008	Past
cesarean section	Caesarean section	07JUL2010	Past
cesarean section	Caesarean section	09NOV2018	Past
bilateral salpingectomy	Salpingectomy	09NOV2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	29SEP2020 (1)	10:12
2	Placebo	20OCT2020 (22)	09:43
3	BNT162b2	18DEC2020 (81)	09:09
4	BNT162b2	06JAN2021 (100)	09:11

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Chills	06JAN2021 (100)	21:00	07JAN2021 (101)	
2	NERV	Headache	Headache	07JAN2021 (101)		ONGOING	
3	BLOOD	Lymphadenopathy	Adenopathy (left armpit)	08FEB2021 (133)		ONGOING	
4	GENRL	Pyrexia	Fever	06JAN2021 (100)		07JAN2021 (101)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (07JAN2021)	Study Treatment	4	1	N
2		1	N	N	Yes	Study Treatment	4	2	N
3		1	N	N	Yes	Study Treatment	4	34	Y
4	2	1	TC	N	Resolved (07JAN2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Quadrivalent Flu Vaccine	INFLUENZA VACCINE	14SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17SEP2020	
Completed	VACCINATION	19NOV2020	
Completed	REPEAT SCREENING 1	18DEC2020	
Completed	OPEN LABEL TREATMENT	04FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	99.59 kg	29.7 kg/m2	30SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
anxiety	Anxiety	2006	Present
hypertension	Hypertension	2006	Present
hyperlipidemia	Hyperlipidaemia	2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30SEP2020 (1)	12:05
2	BNT162b2	20OCT2020 (21)	11:26

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	BLOOD	Lymphadenopathy	Lymphadenopathy to left neck	21OCT2020 (22)		ONGOING
2	BLOOD	Neutropenia	Neutropenia	26OCT2020 (27)		ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			1	N	N	Yes	Study Treatment	2	2	Y
2			3	N	N	Yes	Study Treatment	2	7	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30SEP2020	
Completed	VACCINATION	18NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	73	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	68.82 kg	28.6 kg/m2	31JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
acne	Acne	1960	Present
Anxiety	Anxiety	1970	Present
Uterine Fibroids	Uterine leiomyoma	1970	Past
Back pain	Back pain	1980	Present
Hypothyroidism	Hypothyroidism	1980	Present
Rosacea	Rosacea	1980	Past
High Cholesterol	Blood cholesterol increased	1985	Present
Gout	Gout	1985	Present
Osteoarthritis	Osteoarthritis	1985	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
osteopenia	Osteopenia	1985	Present
Type II Diabetes	Type 2 diabetes mellitus	1985	Present
Carpal tunnel syndrome	Carpal tunnel syndrome	1988	Present
Diabetic neuropathy-hands	Diabetic neuropathy	2000	Present
Incontinence	Incontinence	2002	Present
Basal Skin cancer (back)	Basal cell carcinoma	2005	Past
Tremors	Tremor	2010	Present
Fatty Liver	Hepatic steatosis	2017	Present
Granuloma annulara	Granuloma annulare	2018	Present
Anemia	Anaemia	2019	Past
Cataracts	Cataract	2019	Present
Constipation	Constipation	2019	Present
Glaucoma	Glaucoma	2019	Present
MacularDegeneration	Macular degeneration	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31JUL2020 (1)	15:36
2	BNT162b2	21AUG2020 (22)	11:31

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INV	Blood glucose increased	Increase glucose level	22AUG2020 (23)		17SEP2020 (49)		27	1
2	BLOOD	Lymphadenopathy	Swollen lymph node (neck)	02DEC2020 (125)		09DEC2020 (132)		8	2
3	BLOOD	Lymphadenopathy	Swollen lymph node (neck)	05FEB2021 (190)		12FEB2021 (197)		8	2
4	CARD	Palpitations	Heart palpitations	26AUG2020 (27)		09SEP2020 (41)		15	1
5	INFEC	Tooth infection	Infected tooth bridge	02DEC2020 (125)		09DEC2020 (132)		8	2
6	INFEC	Tooth infection	Infected tooth bridge	05FEB2021 (190)		12FEB2021 (197)		8	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (17SEP2020)	NOT RELATED/OTHER: Unknown	2	2	N
2	TC	N	Resolved (09DEC2020)	NOT RELATED/OTHER: unknown etiology	2	104	Y
3	TC	N	Resolved (12FEB2021)	NOT RELATED/OTHER: unknown etiology	2	169	Y
4	N	N	Resolved (09SEP2020)	NOT RELATED/OTHER: Unknown	2	6	N
5	TC	N	Resolved (09DEC2020)	NOT RELATED/OTHER: Unknown etiology	2	104	N
6	TC	N	Resolved (12FEB2021)	NOT RELATED/OTHER: unknown etiology	2	169	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
FLUAD Quadrivalent	INFLUENZA VACCINE INACT SAG 4V	22SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31JUL2020	
Completed	VACCINATION	18SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	46	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	131.82 kg	48.3 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
nearsighted	Myopia	1983	Present
acne	Acne	1987	Present
anxiety	Anxiety	2001	Present
overweight	Overweight	2010	Present
asthma	Asthma	2017	Present
benign thyroid nodule	Benign neoplasm of thyroid gland	2017	Present
Heart benign physiologic murmur	Cardiac murmur	05DEC2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	10:43
2	Placebo	08SEP2020 (19)	10:48
3	BNT162b2	21DEC2020 (123)	10:27
4	BNT162b2	11JAN2021 (144)	08:37

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	Left axillary lymph node swelling	13JAN2021 (146)		16JAN2021 (149)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	1	N	N	Resolved (16JAN2021)	Study Treatment	4	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	06OCT2020	
Completed	REPEAT SCREENING 1	21DEC2020	
Completed	OPEN LABEL TREATMENT	08FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1999	21	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	114.55 kg	46.1 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergic rhinitis	Seasonal allergy	2003	Present
Obesity	Obesity	2018	Present
Anxiety	Anxiety	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28AUG2020 (1)	15:52
2	BNT162b2	17SEP2020 (21)	13:02

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Fatigue	Fatigue	18SEP2020 (22)		22SEP2020 (26)	
2	BLOOD	Lymph node pain	Lymph node pain, under left arm	18SEP2020 (22)		22SEP2020 (26)	
3	BLOOD	Lymphadenopathy	Lymph node swelling (under left arm)	18SEP2020 (22)		23SEP2020 (27)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	5	3	N	N	Resolved (22SEP2020)	Study Treatment	2	2	N
2	5	3	TC	N	Resolved (22SEP2020)	Study Treatment	2	2	N
3	6	3	TC	N	Resolved (23SEP2020)	Study Treatment	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	61.41 kg	25.5 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2018	Present
Heart Palpitations	Palpitations	04SEP2018	Present
High Cholesterol	Blood cholesterol increased	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	14:40
2	BNT162b2	23SEP2020 (20)	15:44

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site pain	Muscle Pain @ injection site	10SEP2020 (7)	00:00	14SEP2020 (11)	00:00
2	BLOOD	Lymphadenopathy	Left Axillary swollen lymp node	10SEP2020 (7)	00:00	14SEP2020 (11)	00:00
3	MUSC	Myalgia	Generalized Muscle Pain	10SEP2020 (7)		14SEP2020 (11)	
4	MUSC	Myalgia	Muscle Pain @ Chest Wall to Upper Back	10SEP2020 (7)		14SEP2020 (11)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	5	2	N	N	Resolved (14SEP2020)	Study Treatment	1	7	N
2	5	2	N	N	Resolved (14SEP2020)	Study Treatment	1	7	Y
3	5	2	N	N	Resolved (14SEP2020)	Study Treatment	1	7	N
4	5	2	N	N	Resolved (14SEP2020)	Study Treatment	1	7	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	72.36 kg	24.2 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2005	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	16:21
2	BNT162b2	15SEP2020 (22)	16:49

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	NERV	Headache	Headache	27AUG2020 (3)		29AUG2020 (5)		3
2	BLOOD	Lymphadenopathy	SUPRACLAVICULAR LYMPHADENOPATHY, RIGHT	25AUG2020 (1)	15:42	ONGOING		

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	TC	N	Resolved (29AUG2020)	Study Treatment	1	3	N
2	1	N	N	Yes	NOT RELATED/OTHER: UNKNOWN	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
FLU VACCINE	INFLUENZA VACCINE	08OCT2020
Tdap (Tetanus, Diphtheria, Pertussis) Vaccine	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	27OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	13OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	116.73 kg	44.1 kg/m2	22SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
VISION IMPAIRMENT, BILATERAL	Visual impairment	1966	Present
OSTEOARTHRITIS, KNEE, BILATERAL	Osteoarthritis	1967	Present
HERPES LABIALIS	Oral herpes	1970	Present
ECTOPIC PREGNANCY	Ectopic pregnancy	1972	Past
TONSILLECTOMY	Tonsillectomy	APR1977	Past
TONSILLITIS	Tonsillitis	APR1977	Past
HERNIA, ABDOMINAL	Abdominal hernia	1989	Past
HERNIA REPAIR, ABDOMINAL	Abdominal hernia repair	1989	Past
CANCER, CERVICAL	Cervix carcinoma	15JUL1992	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYSTERECTOMY, TOTAL	Hysterectomy	31JUL1992	Past
HERNIA REPAIR, ABDOMINAL	Abdominal hernia repair	1995	Past
HYPERTENSION	Hypertension	2000	Present
MORBID OBESITY	Obesity	2000	Present
RESTLESS LEG SYNDROME	Restless legs syndrome	2005	Present
CHOLECYCSTECTEMY	Cholecystectomy	2006	Past
CHOLELITHIASIS	Cholelithiasis	2006	Past
BARRETT'S SYNDROME	Barrett's oesophagus	2007	Present
PEPTIC ULCER	Peptic ulcer	2007	Past
ARTHROSCOPIC SURGERY, KNEE, BILATERAL	Knee operation	2012	Past
CARPAL TUNNEL SYNDROME, RIGHT	Carpal tunnel syndrome	2014	Past
CHRONIC LOW BACK PAIN	Back pain	2016	Present
BULGING DISC, LUMBAR	Intervertebral disc protrusion	2016	Present
OSTEOARTHRITIS, HIP, BILATERAL	Osteoarthritis	2016	Present
CATARACTS, BILATERAL	Cataract	2017	Past
BRONCHITIS, CHRONIC	Bronchitis chronic	2018	Present
CATARACT REMOVAL, BILATERAL	Cataract operation	2018	Past
EDEMA, LOW EXTERMITY, LEFT	Oedema peripheral	2018	Present
PNEUMONIA	Pneumonia	FEB2018	Past
CARPAL TUNNEL RELEASE, RIGHT	Carpal tunnel decompression	2019	Past
ANEMIA	Anaemia	MAY2020	Present
IDIOPATHIC NEUROPATHY, LOWER EXTREMITY, LEFT	Neuropathy peripheral	MAY2020	Present
OBSTRUCTIVE SLEEP APNEA	Sleep apnoea syndrome	MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22SEP2020 (1)	10:38
2	Placebo	13OCT2020 (22)	12:01
3	BNT162b2	14JAN2021 (115)	14:55
4	BNT162b2	04FEB2021 (136)	14:46

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GASTR	Abdominal hernia	INFRAUMBILICAL VENTRAL HERNIA	27DEC2020 (97)		ONGOING			1	N	N
2	SKIN	Actinic keratosis	ACTINIC KERATOSIS, SCALP, WORSENING	JAN2021 ()		ONGOING			1	N	N
3	HEPAT	Hepatic cyst	HEPATIC CYST	27NOV2020 (67)		ONGOING			1	N	N
4	HEPAT	Hepatic steatosis	HEPATIC STEATOSIS	27NOV2020 (67)		ONGOING			1	N	N
5	GENRL	Inflammation	TOE INFLAMMATION, GREAT TOE, LEFT	19JAN2021 (120)		26JAN2021 (127)		8	2	TC/TCN	N
6	BLOOD	Lymphadenopathy	SWOLLEN LYMPH NODES, RIGHT CERVICAL	23JAN2021 (124)		27JAN2021 (128)		5	1	TCN	N
7	INJ&P	Muscle strain	THIGH MUSCLE, STRAIN, LEFT	11OCT2020 (20)		17OCT2020 (26)		7	1	TC	N
8	GASTR	Small intestinal obstruction	SMALL BOWEL OBSTRUCTION	27NOV2020 (67)		30NOV2020 (70)		4	4	N	Y

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
9	GASTR	Small intestinal obstruction	SMALL BOWEL OBSTRUCTION	27DEC2020 (97)		30DEC2020 (100)		4	3	TC	Y
10	INV	Thyroid function test abnormal	ABNORMAL THRYOID LABORATORY VALUES	NOV2020 ()		ONGOING			1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: MORBID OBESITY	2	76	N
2	Yes	NOT RELATED/OTHER: PREEXISTING CONDITION			N
3	Yes	NOT RELATED/OTHER: ETIOLOGY UNKNOWN	2	46	N
4	Yes	NOT RELATED/OTHER: MORBID OBESITY	2	46	N
5	Resolved (26JAN2021)	NOT RELATED/OTHER: INGROWN TOE NAIL	3	6	N
6	Resolved (27JAN2021)	NOT RELATED/OTHER: ETILOGY UNKNOWN	3	10	Y
7	Resolved (17OCT2020)	NOT RELATED/OTHER: INCIDENTAL MIS-STEP FROM CURB	1	20	N
8	Resolved (30NOV2020)	NOT RELATED/OTHER: ETIOLOGY UNKNOWN	2	46	Y
9	Resolved (30DEC2020)	NOT RELATED/OTHER: INTRAABDOMINAL SCAR FORMATION FROM PRIOR SURGERIES	2	76	Y
10	Yes	NOT RELATED/OTHER: UNKNOWN ETIOLOGY	2		N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
FLU VACCINATION	INFLUENZA VACCINE	03NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22SEP2020	
Completed	VACCINATION	11NOV2020	
Completed	REPEAT SCREENING 1	14JAN2021	
Completed	OPEN LABEL TREATMENT	09MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
193.04 cm	121.59 kg	32.6 kg/m2	13OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
eczema	Eczema	1974	Present
ingrown hair	Ingrown hair	1981	Present
Reconstruction of left shoulder	Shoulder arthroplasty	1990	Past
cold sores	Oral herpes	2001	Present
reduced ejection fraction	Ejection fraction decreased	2008	Past
Viral infection	Viral infection	2008	Past
atypical cardiomegaly	Cardiomegaly	2010	Present
lack of cartilage, bilateral knees	Chondropathy	2012	Present
Joint Debridement Left Knee	Joint debridement	2014	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Joint resurfacing of left knee	Joint resurfacing surgery	2014	Past
Familial Low White blood cell Count	White blood cell count decreased	2015	Present
ADHD	Attention deficit hyperactivity disorder	2018	Present
Flat Feet	Foot deformity	2018	Present
impingement surgery of right shoulder	Shoulder operation	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	13OCT2020 (1)	14:05
2	BNT162b2	04NOV2020 (23)	16:14

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INFEC	Cellulitis	Cellulitis groin	15DEC2020 (64)		25DEC2020 (74)		11	2	TC/TCN	N
2	SKIN	Eczema	flare up of eczema	20OCT2020 (8)		12NOV2020 (31)		24	1	N	N
3	GENRL	Fatigue	fatigue	07NOV2020 (26)		12NOV2020 (31)		6	1	N	N
4	GENRL	Fatigue	very mild fatigue	08NOV2020 (27)		14NOV2020 (33)		7	1	N	N

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
5	BLOOD	Lymph node pain	Tender lymph node right jaw	31DEC2020 (80)		02JAN2021 (82)		3	1	N	N
6	BLOOD	Lymphadenopathy	Swollen lymph node right jaw	31DEC2020 (80)		02JAN2021 (82)		3	1	N	N
7	SKIN	Pruritus	mild body itching-specific region: lateral aspect of right forearm and left side of neck	08NOV2020 (27)		14NOV2020 (33)		7	1	N	N
8	INFEC	Wound infection	Infected laceration right thumb	02JAN2021 (82)		04JAN2021 (84)		3	1	TC/TCN	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (25DEC2020)	NOT RELATED/OTHER: reports use of public hot tub prior to cellulitis	2	42	N
2	Resolved (12NOV2020)	NOT RELATED/OTHER: exacerbation of prior medical condition	1	8	N
3	Resolved (12NOV2020)	Study Treatment	2	4	N
4	Resolved (14NOV2020)	Study Treatment	2	5	N
5	Resolved (02JAN2021)	NOT RELATED/OTHER: states lymph nodes often tender prior to cold sore eruption	2	58	N
6	Resolved (02JAN2021)	NOT RELATED/OTHER: states lymph nodes often swell prior to cold sore eruption	2	58	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
7	Resolved (14NOV2020)	NOT RELATED/OTHER: hx of eczema	2	5	N
8	Resolved (04JAN2021)	NOT RELATED/OTHER: accidental self-inflicted injury	2	60	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13OCT2020	
Completed	VACCINATION	02DEC2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2001	19	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.6 cm	85.9 kg	32.5 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergies	Seasonal allergy	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15OCT2020 (1)	14:31
2	BNT162b2	06NOV2020 (23)	14:08

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Headache	Headache	06NOV2020 (23)	17:00	07NOV2020 (24)	22:00
2	GENRL	Injection site pain	Pain at injection site	07NOV2020 (24)		07NOV2020 (24)	
3	BLOOD	Lymphadenopathy	Left Axillary lymphadenopathy	07NOV2020 (24)		07NOV2020 (24)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	TC	N	Resolved (07NOV2020)	Study Treatment	2	1	N
2	1	1	N	N	Resolved (07NOV2020)	Study Treatment	2	2	N
3	1	1	N	N	Resolved (07NOV2020)	Study Treatment	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15OCT2020	
Completed	VACCINATION	09DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	100 kg	35.5 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	1996	Past
Acid Reflux	Gastrooesophageal reflux disease	1997	Present
Rhinitis	Rhinitis	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10SEP2020 (1)	15:06
2	BNT162b2	30SEP2020 (21)	13:34

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	Left axilla adenopathy	01OCT2020 (22)		02OCT2020 (23)	
2	MUSC	Myalgia	Myalgias	01OCT2020 (22)		02OCT2020 (23)	
3	GENRL	Pyrexia	Fever	01OCT2020 (22)	10:00	02OCT2020 (23)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	2	N	N	Resolved (02OCT2020)	Study Treatment	2	2	Y
2	2	2	TC	N	Resolved (02OCT2020)	Study Treatment	2	2	N
3	2	1	TC	N	Resolved (02OCT2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	29OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2004	16	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	58.51 kg	19.6 kg/m2	02DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Intermittent Asthma	Asthma	20APR2010	Present
Acne	Acne	22JAN2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02DEC2020 (1)	14:30

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	23DEC2020 (22)	11:20
3	BNT162b2	24FEB2021 (85)	14:15

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Chills	25FEB2021 (86)	11:00	25FEB2021 (86)	16:00
2	GENRL	Injection site pain	Left upper arm injection site pain	24FEB2021 (85)	22:00	26FEB2021 (87)	08:00
3	BLOOD	Lymphadenopathy	Lymph node swelling left armpit	24FEB2021 (85)	22:00	25FEB2021 (86)	08:00
4	GENRL	Pyrexia	Fever	25FEB2021 (86)	11:00	25FEB2021 (86)	16:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	2	N	N	Resolved (25FEB2021)	Study Treatment	3	2	N
2	3	1	N	N	Resolved (26FEB2021)	Study Treatment	3	1	N
3	2	1	N	N	Resolved (25FEB2021)	Study Treatment	3	1	Y
4	1	1	N	N	Resolved (25FEB2021)	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
MEN-ACYW (MENVEO) (meningococcal oligosaccharide ACYW-135)	MENINGOCOCCAL VACCINE A/C/Y/W CONJ (CRM197)	26JAN2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02DEC2020	
Completed	VACCINATION	26JAN2021	
Completed	REPEAT SCREENING 1	24FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	51	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	69.59 kg	22.6 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	1980	Present
tonsilitis	Tonsillitis	1999	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	11:26
2	BNT162b2	14SEP2020 (20)	10:31

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	Axillary Adenophathy, left side	26AUG2020 (1)	23:00	29AUG2020 (4)	20:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	1	TCN	N	Resolved (29AUG2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccine	INFLUENZA VACCINE	29SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	13OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	23	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	75.64 kg	26.9 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis	Rhinitis allergic	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15SEP2020 (1)	11:00
2	BNT162b2	06OCT2020 (22)	10:56

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Injection site pain	Left Arm injection site Pain	07OCT2020 (23)	11:00	08OCT2020 (24)	
2	BLOOD	Lymphadenopathy	Left Supraclavicular Adenopathy	07OCT2020 (23)		08OCT2020 (24)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	1	TC	N	Resolved (08OCT2020)	Study Treatment	2	2	N
2	2	2	TC	N	Resolved (08OCT2020)	Study Treatment	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15SEP2020	
Completed	VACCINATION	05NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	77	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	73 kg	25.2 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
exercise induced asthma	Asthma exercise induced	1950	Present
Acne	Acne	1960	Past
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	1960	Present
Headaches	Headache	1960	Present
Myopia	Myopia	1960	Present
Pollen Allergy	Seasonal allergy	1960	Present
Tonsillectomy	Tonsillectomy	1965	Past
tonsillitis	Tonsillitis	1965	Past
Acid Reflux	Gastrooesophageal reflux disease	1970	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hemorrhoidectomy	Haemorrhoid operation	1980	Past
Left Carpal Tunnel Syndrome	Carpal tunnel syndrome	1990	Past
Bilateral Cataracts	Cataract	1990	Past
Bilateral Cataracts surgery	Cataract operation	1990	Past
Non-organic fruit allergy	Food allergy	1990	Present
Hyperopia	Hypermetropia	1990	Present
Type 2 Diabetes	Type 2 diabetes mellitus	1992	Present
levaquin allergy	Drug hypersensitivity	1995	Present
Hemorrhoidectomy	Haemorrhoid operation	1995	Past
right Shoulder reconstruction	Shoulder arthroplasty	1997	Past
Hypertension	Hypertension	2000	Present
Depression	Depression	2005	Present
Bilateral Inguinal Hernia repair	Inguinal hernia repair	2005	Past
Insomnia	Insomnia	2005	Present
right shoulder reconstruction	Shoulder arthroplasty	2005	Past
Eczema	Eczema	2010	Present
hypercholesterolemia	Hypercholesterolaemia	2010	Present
Vitamin B12 deficiency	Vitamin B12 deficiency	2010	Present
Erectile dysfunction	Erectile dysfunction	2013	Present
urination problems	Micturition disorder	2013	Present
nocturia	Nocturia	2013	Present
Enlarged Prostate	Prostatomegaly	2013	Present
Transurethral resection of the prostate	Transurethral prostatectomy	2013	Past
basal cell carcinoma	Basal cell carcinoma	2014	Past
Low libido	Libido decreased	2016	Present
Right total knee replacement	Knee arthroplasty	2018	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Colon polyps	Large intestine polyp	2018	Past
Osteoarthritis	Osteoarthritis	JUL2018	Present
Right Carpal Tunnel Syndrome	Carpal tunnel syndrome	2019	Past
Cardiac catheterization	Catheterisation cardiac	27JAN2020	Past
Stent placement left anterior descending artery	Coronary arterial stent insertion	27JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07AUG2020 (1)	13:45
2	BNT162b2	28AUG2020 (22)	11:58

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	VASC	Hypertension	worsening hypertension	01JAN2021 (148)	08:00	ONGOING	
2	BLOOD	Lymphadenopathy	Left supraclavicular adenopathy	31AUG2020 (25)		ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		2	TC	N	Yes	NOT RELATED/OTHER: unknown etiology	2	127	N
2		1	TCN	N	Yes	Study Treatment	2	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	25SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.2 cm	93.1 kg	29.6 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cough	Cough	01JAN1982	Present
History of Alcoholism	Alcoholism	28MAR2000	Past
VASECTOMY	Vasectomy	19DEC2002	Past
Hypertension	Hypertension	01APR2003	Present
focal arthritis of dorsum right fifth Carpometacarpal joint	Arthritis	03DEC2008	Past
Compression injury dorsum right fifth Carpometacarpal joint	Joint injury	03DEC2008	Past
obstructive sleep apnea	Sleep apnoea syndrome	08JUN2011	Present
Moderate Persistent Asthma	Asthma	04SEP2015	Present
LIPID METABOLISM DISORDER	Lipid metabolism disorder	26MAR2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	11:30
2	Placebo	06NOV2020 (22)	09:04
3	BNT162b2	28JAN2021 (105)	14:18
4	BNT162b2	18FEB2021 (126)	14:06

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	BLOOD	Lymphadenopathy	swollen lymph node - right side of neck	11FEB2021 (119)	16:00	12FEB2021 (120)	23:00	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (12FEB2021)	NOT RELATED/OTHER: unknown	3	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	16OCT2020	
Completed	VACCINATION	04DEC2020	
Completed	REPEAT SCREENING 1	28JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168.5 cm	73.6 kg	25.9 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
eye glass wearer	Corrective lens user	1966	Present
contact wearer	Corrective lens user	1966	Present
myopia	Myopia	1966	Present
allergic rhinitis, seasonal	Seasonal allergy	1972	Present
migraine headaches	Migraine	1979	Present
Hashimoto disease	Autoimmune thyroiditis	1989	Present
hypothyroidism	Hypothyroidism	1989	Present
hysterectomy	Hysterectomy	2003	Present
cholecystectomy	Cholecystectomy	2006	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
gallstones	Cholelithiasis	2006	Past
elevated cholesterol, specific level unknown	Blood cholesterol increased	2015	Present
dizziness, related to travel by boat	Dizziness	2017	Present
lower back pain, undiagnosed etiology	Back pain	2018	Present
osteopenia	Osteopenia	2019	Present
vitamin D deficiency	Vitamin D deficiency	APR2020	Present
cataracts in both eyes, mild	Cataract	MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09SEP2020 (1)	14:33
2	Placebo	29SEP2020 (21)	15:10
3	BNT162b2	23DEC2020 (106)	08:57
4	BNT162b2	12JAN2021 (126)	11:29

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Headache	headache	30SEP2020 (22)	07:00	02OCT2020 (24)	
2	BLOOD	Lymphadenopathy	swollen axillary lymph nodes	30SEP2020 (22)		02OCT2020 (24)	

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
3	GENRL	Malaise	malaise	30SEP2020 (22)		01OCT2020 (23)	
4	MUSC	Myalgia	generalized myalgia	02OCT2020 (24)	02:00	02OCT2020 (24)	08:00

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	1	N	N	Resolved (02OCT2020)	Study Treatment	2	2	N
2	3	1	N	N	Resolved (02OCT2020)	Study Treatment	2	2	Y
3	2	1	N	N	Resolved (01OCT2020)	Study Treatment	2	2	N
4	1	2	N	N	Resolved (02OCT2020)	Study Treatment	2	4	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	28OCT2020	
Completed	REPEAT SCREENING 1	23DEC2020	
Completed	OPEN LABEL TREATMENT	09FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	35	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.8 cm	121.8 kg	40.3 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
nephrotic syndrome	Nephrotic syndrome	1984	Past
left kidney atrophy, congenital	Renal atrophy	1984	Present
left kidney repair	Renal surgery	1986	Past
allergic rhinitis, seasonal	Seasonal allergy	1990	Present
tonsillectomy	Tonsillectomy	1993	Past
anxiety	Anxiety	1998	Present
depression	Depression	1998	Present
shingles with no post herpetic neuropathy	Herpes zoster	2011	Past
recurrent heartburn	Dyspepsia	2012	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
high blood pressure	Hypertension	2012	Present
bunionectomy in right foot	Bunion operation	2019	Past
IBS-mixed	Irritable bowel syndrome	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09SEP2020 (1)	18:45
2	Placebo	01OCT2020 (23)	17:08
3	BNT162b2	05JAN2021 (119)	09:54
4	BNT162b2	25JAN2021 (139)	08:48

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INV	Body temperature increased	low grade temperature elevation (99.9)	25JAN2021 (139)	19:00	27JAN2021 (141)	
2	GENRL	Fatigue	fatigue	10SEP2020 (2)		12SEP2020 (4)	
3	NERV	Headache	headache	25JAN2021 (139)	19:00	27JAN2021 (141)	
4	GENRL	Injection site pain	injection site pain	05JAN2021 (119)	19:30	08JAN2021 (122)	

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
5	BLOOD	Lymphadenopathy	lymph node swelling right axillary and supra-clavicular	28JAN2021 (142)		01FEB2021 (146)	
6	GENRL	Pain	body aches	25JAN2021 (139)		27JAN2021 (141)	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	1	TC/TCN	N	Resolved (27JAN2021)	Study Treatment	4	1	N
2	3	2	N	N	Resolved (12SEP2020)	Study Treatment	1	2	N
3	3	2	N	N	Resolved (27JAN2021)	Study Treatment	4	1	N
4	4	2	TC	N	Resolved (08JAN2021)	Study Treatment	3	1	N
5	5	2	N	N	Resolved (01FEB2021)	Study Treatment	4	4	Y
6	3	2	TC	N	Resolved (27JAN2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
influenza vaccine, 0.5ml, IM	INFLUENZA VACCINE	16OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	02NOV2020	
Completed	REPEAT SCREENING 1	05JAN2021	
Completed	OPEN LABEL TREATMENT	24FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	102.9 kg	35.6 kg/m2	23OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
food allergy shellfish	Food allergy	1982	Present
obese	Obesity	1985	Present
obstructive sleep apnea	Sleep apnoea syndrome	2004	Present
drug allergies soma	Drug hypersensitivity	2008	Present
diabetes type 2	Type 2 diabetes mellitus	2010	Present
hyperlipidemia	Hyperlipidaemia	2012	Present
hyperopia bilateral	Hypermetropia	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23OCT2020 (1)	16:53
2	Placebo	11NOV2020 (20)	16:00
3	BNT162b2	27JAN2021 (97)	13:56
4	BNT162b2	17FEB2021 (118)	12:53

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PSYCH	Depression	DEPRESSION	19FEB2021 (120)	09:00	ONGOING			1
2	MUSC	Intervertebral disc disorder	Lumbar disc disease	08NOV2020 (17)	08:00	ONGOING			2
3	BLOOD	Lymphadenopathy	BILATERAL CERVICAL SWOLLEN LYMPH NODES	13NOV2020 (22)	09:00	15NOV2020 (24)	15:00	3	1
4	RESP	Oropharyngeal pain	SORE THROAT	13NOV2020 (22)	09:01	15NOV2020 (24)	15:00	3	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: situational depression	4	3	N
2	TC	N	Yes	NOT RELATED/OTHER: Lumbar disc disease	1	17	N
3	N	N	Resolved (15NOV2020)	NOT RELATED/OTHER: tHROAT PAIN	2	3	Y
4	N	N	Resolved (15NOV2020)	Study Treatment	2	3	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	23OCT2020	
Completed	VACCINATION	09DEC2020	
Completed	REPEAT SCREENING 1	27JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	22	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159.6 cm	68 kg	26.7 kg/m2	30OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Heart palpitation	Palpitations	JAN2016	Present
Surgery- Rhinoplasty	Rhinoplasty	AUG2016	Past
Anxiety	Anxiety	JUN2017	Present
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	JUN2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30OCT2020 (1)	12:46
2	BNT162b2	19NOV2020 (21)	11:51

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site pain	SORENESS AT INJECTION SITE	31OCT2020 (2)	08:00	04NOV2020 (6)	08:00
2	BLOOD	Lymphadenopathy	BILATERAL SWOLLEN CERVICAL LYMPH NODES	20NOV2020 (22)	08:00	21NOV2020 (23)	09:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	5	2	TC/TCN	N	Resolved (04NOV2020)	Study Treatment	1	2	N
2	2	2	TC/TCN	N	Resolved (21NOV2020)	Study Treatment	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30OCT2020	
Completed	VACCINATION	17DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1991	29	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.5 cm	55.9 kg	19 kg/m2	24SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
asthma	Asthma	1996	Past
nearsighted	Myopia	1996	Present
myopia	Myopia	1996	Present
seizures (epilepsy)	Epilepsy	NOV2013	Past
temporal lobectomy (right side)	Brain lobectomy	MAY2017	Past
gadolinium drug allergy	Drug hypersensitivity	2018	Present
migraines	Migraine	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24SEP2020 (1)	15:16
2	BNT162b2	13OCT2020 (20)	10:30

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	BLOOD	Lymphadenopathy	cervical lymphadenopathy (bilateral)	10OCT2020 (17)		20OCT2020 (27)		11	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (20OCT2020)	NOT RELATED/OTHER: throat irritation from air quality	1	17	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24SEP2020	
Completed	VACCINATION	13NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.59 cm	101.45 kg	31 kg/m2	06AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsilectomy	Tonsillectomy	30JUN1968	Past
Pet allergy	Allergy to animal	30JUN1970	Present
Hypertension	Hypertension	30JUN2018	Present
Basal cell carcinoma excision left shoulder	Skin neoplasm excision	31JAN2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	06AUG2020 (1)	16:20
2	BNT162b2	27AUG2020 (22)	15:18

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	Left Axillary lymph node swelling	13AUG2020 (8)	12:00	16AUG2020 (11)	12:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	1	N	N	Resolved (16AUG2020)	Study Treatment	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Seasonal Flu Vaccine	INFLUENZA VACCINE	30SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06AUG2020	
Completed	VACCINATION	25SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.31 cm	58.45 kg	24.5 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergies	Seasonal allergy	01AUG1996	Present
Umbilical hernia repair	Umbilical hernia repair	01AUG2012	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	12:33

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	14SEP2020 (22)	11:37
3	BNT162b2	15FEB2021 (176)	14:33
4	BNT162b2	08MAR2021 (197)	09:38

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	REPRO	Breast cyst	Breast Cyst	09MAR2021 (198)		ONGOING		
2	BLOOD	Lymphadenopathy	Lymphadenopathy above Left Clavicle	09MAR2021 (198)		ONGOING		
3	REPRO	Ovarian cyst	Ovarian Cyst	22FEB2021 (183)		ONGOING		
4	REPRO	Pelvic pain	Pelvic Pain	22FEB2021 (183)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Yes	NOT RELATED/OTHER: palpable nodule	4	2	N
2	1	N	N	Yes	Study Treatment	4	2	Y
3	2	N	N	Yes	NOT RELATED/OTHER: Pelvic pain	3	8	N
4	2	N	N	Yes	NOT RELATED/OTHER: New onset related to Mirena- IUD	3	8	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	13OCT2020	
Completed	REPEAT SCREENING 1	15FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.31 cm	54.18 kg	22.7 kg/m2	14OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sulfa Drug Allergy	Drug hypersensitivity	1990	Present
Psoriasis	Psoriasis	2000	Present
Panic Attacks	Panic attack	2005	Present
Hysterectomy	Hysterectomy	APR2008	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14OCT2020 (1)	10:56
2	Placebo	04NOV2020 (22)	13:21
3	BNT162b2	13JAN2021 (92)	14:33
4	BNT162b2	03FEB2021 (113)	14:40

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Diarrhoea	Diarrhea	14JAN2021 (93)	10:00	14JAN2021 (93)	10:00
2	BLOOD	Lymphadenopathy	enlarged lymph node axilla (R)	04FEB2021 (114)	08:00	10FEB2021 (120)	08:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	N	N	Resolved (14JAN2021)	Study Treatment	3	2	N
2	7	2	N	N	Resolved (10FEB2021)	Study Treatment	4	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14OCT2020	
Completed	VACCINATION	02DEC2020	
Completed	REPEAT SCREENING 1	13JAN2021	
Completed	OPEN LABEL TREATMENT	10MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	28	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	85.4 kg	29.6 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Headaches	Headache	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	16:43
2	BNT162b2	11SEP2020 (23)	13:49

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Injection site pain	injection site pain	11SEP2020 (23)	18:00	14SEP2020 (26)	08:00
2	BLOOD	Lymphadenopathy	swollen left axillary lymph node	12SEP2020 (24)	08:00	14SEP2020 (26)	08:00

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	1	N	N	Resolved (14SEP2020)	Study Treatment	2	1	N
2	3	1	N	N	Resolved (14SEP2020)	Study Treatment	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
influenza vaccination	INFLUENZA VACCINE	OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	98 kg	34.3 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	1975	Present
occasional headaches	Headache	1985	Present
left ACL repair	Ligament operation	1991	Past
Left ACL tear	Ligament rupture	1991	Past
asthma	Asthma	1995	Present
astigmatism	Astigmatism	1995	Present
occasional sleep disturbance	Sleep disorder	1998	Present
gallbladder removal	Cholecystectomy	2000	Past
gallstones	Cholelithiasis	2004	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
heart burn	Dyspepsia	2005	Present
SVT proxsymal	Supraventricular tachycardia	2014	Present
hysterectomy	Hysterectomy	SEP2015	Past
uterine fibroid	Uterine leiomyoma	SEP2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	09:57
2	Placebo	18SEP2020 (23)	14:36
3	BNT162b2	22DEC2020 (118)	09:02
4	BNT162b2	11JAN2021 (138)	11:26

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	SKIN	Cold sweat	cold sweats	12JAN2021 (139)	23:00	13JAN2021 (140)	06:00	2
2	GENRL	Fatigue	Fatigue	12JAN2021 (139)		17JAN2021 (144)		6
3	GENRL	Injection site pain	Injection Site Pain	22DEC2020 (118)	19:00	23DEC2020 (119)		2
4	PSYCH	Irritability	irritability	12JAN2021 (139)		15JAN2021 (142)		4
5	BLOOD	Lymphadenopathy	lymphadenopathy (left axillary, clavicle, elbow)	13JAN2021 (140)		17JAN2021 (144)		5

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
6	MUSC	Myalgia	muscle achiness	12JAN2021 (139)		15JAN2021 (142)		4
7	INJ&P	Thermal burn	Burn Injury, left hand	10JAN2021 (137)	17:00	15JAN2021 (142)		6

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (13JAN2021)	Study Treatment	4	2	N
2	1	N	N	Resolved (17JAN2021)	Study Treatment	4	2	N
3	1	N	N	Resolved (23DEC2020)	Study Treatment	3	1	N
4	1	N	N	Resolved (15JAN2021)	Study Treatment	4	2	N
5	2	N	N	Resolved (17JAN2021)	Study Treatment	4	3	Y
6	1	TC	N	Resolved (15JAN2021)	Study Treatment	4	2	N
7	1	TC	N	Resolved (15JAN2021)	NOT RELATED/OTHER: Heat trauma	3	20	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	22OCT2020	
Completed	REPEAT SCREENING 1	22DEC2020	
Completed	OPEN LABEL TREATMENT	08FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159.8 cm	72.6 kg	28.4 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Endometrial Ablation	Endometrial ablation	2012	Past
Post Menopausal	Postmenopause	2012	Present
Appendectomy	Appendicectomy	MAY2012	Past
Appendicitis	Appendicitis	MAY2012	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16SEP2020 (1)	15:19
2	Placebo	07OCT2020 (22)	15:10
3	BNT162b2	20JAN2021 (127)	15:10
4	BNT162b2	10FEB2021 (148)	15:35

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	chills	21JAN2021 (128)	12:00	22JAN2021 (129)	21:00
2	GENRL	Fatigue	Fatigue	21JAN2021 (128)	12:00	22JAN2021 (129)	21:00
3	NERV	Headache	headache	11FEB2021 (149)	07:00	12FEB2021 (150)	12:00
4	BLOOD	Lymphadenopathy	left axillary lymph node enlargement	23JAN2021 (130)	10:00	25JAN2021 (132)	05:00
5	GENRL	Pyrexia	Fever (100.9 F)	21JAN2021 (128)	12:00	22JAN2021 (129)	12:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (22JAN2021)	Study Treatment	3	2	N
2	2	1	N	N	Resolved (22JAN2021)	Study Treatment	3	2	N
3	2	1	N	N	Resolved (12FEB2021)	Study Treatment	4	2	N
4	3	1	N	N	Resolved (25JAN2021)	Study Treatment	3	4	Y
5	2	1	TC	N	Resolved (22JAN2021)	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccination	INFLUENZA VACCINE	22OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16SEP2020	
Completed	VACCINATION	11NOV2020	
Completed	REPEAT SCREENING 1	20JAN2021	
Completed	OPEN LABEL TREATMENT	11MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.5 cm	56.2 kg	21.8 kg/m2	18SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
diethylstilbestrol grandchild	Maternal drugs affecting foetus	1974	Present
amblyopia	Amblyopia	1978	Present
Right eye farsighted	Hypermetropia	1978	Present
left eye nearsighted	Myopia	1978	Present
migraines	Migraine	1990	Present
tipped cervix	Uterine malposition	1990	Present
gallbladder pain	Biliary colic	2013	Past
gallbladder removal	Cholecystectomy	2013	Past
allergy to zoloft	Drug hypersensitivity	2013	Present
depression	Depression	2014	Present
hyperhidrosis	Hyperhidrosis	2015	Present
gastroparesis	Impaired gastric emptying	JAN2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18SEP2020 (1)	09:20
2	BNT162b2	16OCT2020 (29)	15:37

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Back pain	Myalgia in Entire Back	17OCT2020 (30)	07:00	19OCT2020 (32)	07:00	3
2	MUSC	Back pain	Right Sided Upper Back Pain	17OCT2020 (30)	10:00	17OCT2020 (30)	11:00	1
3	INV	Body temperature increased	elevated body temperature, temperature 99.1	20SEP2020 (3)		20SEP2020 (3)		1
4	GENRL	Injection site pain	injection site soreness left arm	18SEP2020 (1)	13:30	20SEP2020 (3)		3
5	BLOOD	Lymphadenopathy	enlarged left interior neck lymph node	30SEP2020 (13)		ONGOING		
6	MUSC	Myalgia	muscle aches	18SEP2020 (1)	18:00	01OCT2020 (14)		14
7	GENRL	Injection site pain	Injection Site Pain	16OCT2020 (29)	16:00	19OCT2020 (32)	07:00	4

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (19OCT2020)	Study Treatment	2	2	N

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	2	N	N	Resolved (17OCT2020)	NOT RELATED/OTHER: Physical Exertion	2	2	N
3	1	N	N	Resolved (20SEP2020)	Study Treatment	1	3	N
4	2	N	N	Resolved (20SEP2020)	Study Treatment	1	1	N
5	1	N	N	Yes	Study Treatment	1	13	Y
6	1	N	N	Resolved (01OCT2020)	Study Treatment	1	1	N
7	1	N	N	Resolved (19OCT2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
Influenza Vaccine	INFLUENZA VACCINE	05NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18SEP2020	
Completed	VACCINATION	13NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1999	21	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178 cm	88.6 kg	28 kg/m2	27OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Klippel Feil Deformity	Klippel-Feil syndrome	(b) (6) 1999	Present
Allergy to Augmentin	Drug hypersensitivity	2001	Present
Seasonal Allergies	Seasonal allergy	2010	Present
R Foot Lisfranc Fracture	Lisfranc fracture	OCT2013	Past
R Foot Lisfranc Fracture Repair	Fracture treatment	11OCT2013	Past
L Knee Medial Meniscus Tear	Meniscus injury	2016	Past
L Knee Medial Meniscus Repair	Meniscus operation	28NOV2016	Past
Generalized Anxiety Disorder	Generalised anxiety disorder	2017	Present
Wisdom Teeth Removal	Wisdom teeth removal	MAY2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27OCT2020 (1)	14:28
2	Placebo	17NOV2020 (22)	14:30
3	BNT162b2	23DEC2020 (58)	10:45
4	BNT162b2	13JAN2021 (79)	09:16

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INV	Body temperature increased	elevated body temperature tmax 100.0F	14JAN2021 (80)	01:00	14JAN2021 (80)	09:00
2	GENRL	Chills	chills	14JAN2021 (80)	01:00	14JAN2021 (80)	09:00
3	GENRL	Fatigue	Fatigue	14JAN2021 (80)	01:00	14JAN2021 (80)	09:00
4	GENRL	Injection site pain	injection site pain	23DEC2020 (58)	15:00	25DEC2020 (60)	08:30
5	GENRL	Injection site pain	injection site soreness left deltoid	13JAN2021 (79)	14:00	14JAN2021 (80)	
6	BLOOD	Lymphadenopathy	enlarged lymph node left arm axillary	15JAN2021 (81)	08:00	17JAN2021 (83)	
7	GENRL	Malaise	malaise	14JAN2021 (80)	01:00	14JAN2021 (80)	09:00
8	MUSC	Myalgia	muscles aches	14JAN2021 (80)	01:00	14JAN2021 (80)	09:00

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	1	TC	N	Resolved (14JAN2021)	Study Treatment	4	2	N
2	1	2	TC	N	Resolved (14JAN2021)	Study Treatment	4	2	N
3	1	1	N	N	Resolved (14JAN2021)	Study Treatment	4	2	N
4	3	1	TC	N	Resolved (25DEC2020)	Study Treatment	3	1	N
5	2	1	TC	N	Resolved (14JAN2021)	Study Treatment	4	1	N
6	3	1	N	N	Resolved (17JAN2021)	Study Treatment	4	3	Y
7	1	2	TC	N	Resolved (14JAN2021)	Study Treatment	4	2	N
8	1	2	TC	N	Resolved (14JAN2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27OCT2020	
Completed	VACCINATION	15DEC2020	
Completed	REPEAT SCREENING 1	23DEC2020	
Completed	OPEN LABEL TREATMENT	15FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	66.91 kg	27.8 kg/m2	23SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
GERD	Gastrooesophageal reflux disease	2009	Present
essential hypertension	Essential hypertension	DEC2009	Present
sleep apnea	Sleep apnoea syndrome	MAR2015	Present
tummy tuck	Abdominoplasty	2018	Past
hysterectomy	Hysterectomy	2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23SEP2020 (1)	13:30
2	Placebo	12OCT2020 (20)	15:00
3	BNT162b2	16DEC2020 (85)	10:33
4	BNT162b2	05JAN2021 (105)	13:31

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	BLOOD	Lymphadenopathy	left axillary lymph node swelling	17DEC2020 (86)	06:00	19DEC2020 (88)		3
2	BLOOD	Lymphadenopathy	right cervical lymph node swelling	24DEC2020 (93)		25DEC2020 (94)		2
3	BLOOD	Lymphadenopathy	swollen left axillary lymph node	07JAN2021 (107)		10JAN2021 (110)		4
4	BLOOD	Lymphadenopathy	swollen right cervical lymph node	12JAN2021 (112)		19JAN2021 (119)		8

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (19DEC2020)	Study Treatment	3	2	Y
2	2	N	N	Resolved (25DEC2020)	Study Treatment	3	9	Y
3	2	N	N	Resolved (10JAN2021)	Study Treatment	4	3	Y
4	2	N	N	Resolved (19JAN2021)	NOT RELATED/OTHER: lymph adenitis	4	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	23SEP2020	
Completed	VACCINATION	10NOV2020	
Completed	REPEAT SCREENING 1	16DEC2020	
Completed	OPEN LABEL TREATMENT	23FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182 cm	96.7 kg	29.2 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Left Leg Drop Foot	Peroneal nerve palsy	2010	Present
Bilateral lower leg sciatica	Sciatica	2012	Present
Substance Abuse (opiates)	Drug abuse	2014	Present
DVT	Deep vein thrombosis	2018	Present
High blood pressure	Hypertension	2018	Present
Lumbar Degenerated Disk	Intervertebral disc degeneration	2018	Past
Chronic Regional Pain Syndrome	Pain	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15SEP2020 (1)	12:25

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Chest pain	Chest pain (cocaine induce)	15JAN2021 (123)	21:58	16JAN2021 (124)		2	1
2	GENRL	Drug withdrawal syndrome	Opioid dependence withdrawal	21JAN2021 (129)		26JAN2021 (134)		6	4
3	BLOOD	Lymphadenopathy	swollen lymph node in right axilla	05OCT2020 (21)	08:00	12OCT2020 (28)	08:00	8	1
4	MUSC	Pain in extremity	Right arm pain with motion	22SEP2020 (8)	18:00	25SEP2020 (11)	20:00	4	1
5	INFEC	Subcutaneous abscess	Abscess Right Armpit	05OCT2020 (21)	08:00	12OCT2020 (28)		8	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (16JAN2021)	NOT RELATED/OTHER: Substance abuse	1	123	Y
2	N	Y	Resolved (26JAN2021)	NOT RELATED/OTHER: medical	1	129	Y
3	TC	N	Resolved (12OCT2020)	NOT RELATED/OTHER: adenopathy	1	21	Y
4	N	N	Resolved (25SEP2020)	Study Treatment	1	8	N
5	N	N	Resolved (12OCT2020)	NOT RELATED/OTHER: possibly due to abscess infection	1	21	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15SEP2020	
	VACCINATION		
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	40	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
147.32 cm	69.45 kg	31.9 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sulfa Allergy	Drug hypersensitivity	1979	Present
Penicillin Allergy	Drug hypersensitivity	1979	Present
Egg Allergy	Food allergy	(b) (6) 1979	Present
Heartburn	Dyspepsia	2000	Present
Tuna Allergy	Food allergy	2007	Present
Lamb Meat Allergy	Food allergy	2007	Present
Cantelope Allergy	Food allergy	2007	Present
Irritable Bowel Syndrome	Irritable bowel syndrome	2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	18:11
2	BNT162b2	14SEP2020 (22)	17:52

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Injection site pain	Arm soreness (injection L site arm)	24AUG2020 (1)	22:00	25AUG2020 (2)		2
2	GENRL	Injection site pain	Pain at injection site	15SEP2020 (23)		16SEP2020 (24)		2
3	BLOOD	Lymphadenopathy	Swollen lymph nodes under left armpit	18SEP2020 (26)		01DEC2020 (100)		75
4	GASTR	Nausea	Nausea	15SEP2020 (23)		16SEP2020 (24)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (25AUG2020)	Study Treatment	1	1	N
2	1	N	N	Resolved (16SEP2020)	Study Treatment	2	2	N
3	1	N	N	Resolved (01DEC2020)	NOT RELATED/OTHER: Unknown	2	5	Y
4	1	N	N	Resolved (16SEP2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	12OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	130 kg	42.2 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Metronidazole allergy	Drug hypersensitivity	1999	Present
Psoriasis	Psoriasis	1999	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	09:12

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	24SEP2020 (22)	08:51
3	BNT162b2	02FEB2021 (153)	14:38
4	BNT162b2	24FEB2021 (175)	08:55

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Chills	03FEB2021 (154)		05FEB2021 (156)	
2	GENRL	Fatigue	Fatigue	25FEB2021 (176)		26FEB2021 (177)	
3	GENRL	Injection site pain	Injection Site pain	03FEB2021 (154)		05FEB2021 (156)	
4	BLOOD	Lymphadenopathy	Swollen lymph nodes (left armpit)	03FEB2021 (154)		05FEB2021 (156)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	1	N	N	Resolved (05FEB2021)	Study Treatment	3	2	N
2	2	1	N	N	Resolved (26FEB2021)	Study Treatment	4	2	N
3	3	1	N	N	Resolved (05FEB2021)	Study Treatment	3	2	N
4	3	1	N	N	Resolved (05FEB2021)	Study Treatment	3	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	22OCT2020	
Completed	REPEAT SCREENING 1	02FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	25	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.98 cm	90.55 kg	27.6 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
fractured right ankle	Ankle fracture	2011	Past
surgical repair right ankle	Ankle operation	2011	Past
surgical repair right clavicle	Bone operation	2012	Past
fractured right clavicle	Clavicle fracture	2012	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	16:51
2	Placebo	14SEP2020 (20)	17:09
3	BNT162b2	09MAR2021 (196)	14:16

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	GENRL	Fatigue	fatigue	10MAR2021 (197)	09:00	ONGOING
2	GENRL	Injection site pain	injection site pain.	10MAR2021 (197)	07:00	ONGOING
3	BLOOD	Lymphadenopathy	swollen lymph nodes (neck-both sides)	10MAR2021 (197)	10:00	ONGOING
4	MUSC	Myalgia	myalgia	10MAR2021 (197)	09:00	ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			1	TC	N	Yes	Study Treatment	3	2	N
2			1	TC	N	Yes	Study Treatment	3	2	N
3			1	TC	N	Yes	Study Treatment	3	2	Y
4			1	TC	N	Yes	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	09MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.12 cm	80.91 kg	32.3 kg/m2	21OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
cosmetic rhinoplasty	Rhinoplasty	1998	Past
myomectomy	Myomectomy	2004	Past
uterine fibroids	Uterine leiomyoma	2004	Past
Caesarean section	Caesarean section	2006	Past
incisional hernia	Incisional hernia	2008	Past
incisional hernia repair	Incisional hernia repair	2008	Past
Caesarean section	Caesarean section	2009	Past
thyroid cancer	Thyroid cancer	2010	Past
thyroidectomy	Thyroidectomy	2010	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
femoral hernia	Femoral hernia	2011	Past
femoral hernia repair	Femoral hernia repair	2011	Past
inguinal hernia	Inguinal hernia	2017	Past
inguinal hernia repair	Inguinal hernia repair	2017	Past
pneumonia	Pneumonia	2017	Past
benign right breast papilloma	Benign breast neoplasm	2018	Past
right breast duct excision	Mammary ductectomy	2018	Past
II/VI systolic ejection heart murmur diagnosed	Cardiac murmur	21OCT2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21OCT2020 (1)	12:32
2	Placebo	11NOV2020 (22)	10:30
3	BNT162b2	18DEC2020 (59)	08:50
4	BNT162b2	08JAN2021 (80)	08:48

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	EAR	Ear pain	Left Ear Pain	22JAN2021 (94)		ONGOING			2	TC	N

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
2	GENRL	Fatigue	Fatigue	22OCT2020 (2)	10:00	22OCT2020 (2)		1	1	N	N
3	BLOOD	Lymphadenopathy	Swollen Lymph Nodes (Left Jaw)	22JAN2021 (94)		ONGOING			2	TC	N
4	BLOOD	Lymphadenopathy	Swollen Lymph Nodes (Left Neck)	22JAN2021 (94)		ONGOING			2	TC	N
5	GENRL	Pyrexia	Fever (101.9 F)	21OCT2020 (1)	22:00	24OCT2020 (4)		4	2	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: Unknown - Possible Infection (ENT Consult Pending)	4	15	N
2	Resolved (22OCT2020)	Study Treatment	1	2	N
3	Yes	NOT RELATED/OTHER: Unknown - Possible Infection (ENT Consult Pending)	4	15	Y
4	Yes	NOT RELATED/OTHER: Unknown - Possible Infection (ENT Consult Pending)	4	15	Y
5	Resolved (24OCT2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21OCT2020	
Completed	VACCINATION	09DEC2020	
Completed	REPEAT SCREENING 1	18DEC2020	
Completed	OPEN LABEL TREATMENT	10FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	Black or African American	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.78 cm	75.6 kg	24.2 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
complex injury of left hand	Limb injury	17SEP2016	Past
reconstruction of forearm wound with fasciocutaneous flap	Soft tissue flap operation	17SEP2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	11:25

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	30SEP2020 (20)	16:10
3	BNT162b2	25FEB2021 (168)	15:58

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	BLOOD	Lymphadenopathy	CERVICAL LYMPHADENOPATHY	26FEB2021 (169)		ONGOING		
2	SKIN	Rash	FACIAL RASH	26FEB2021 (169)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Yes	Study Treatment	3	2	Y
2	1	N	N	Yes	NOT RELATED/OTHER: ABRASION FROM GLOVES	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	30OCT2020	
Completed	REPEAT SCREENING 1	25FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	64	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	129.09 kg	39.6 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasectomy	Vasectomy	1985	Past
Coronary Artery Stent Placement	Coronary arterial stent insertion	1994	Past
Coronary Artery Disease	Coronary artery disease	1994	Present
Hyperlipidemia	Hyperlipidaemia	1994	Present
Hypertension	Hypertension	1994	Present
Coronary Artery Stent Placement	Coronary arterial stent insertion	2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	16:06
2	BNT162b2	09SEP2020 (21)	17:27

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	RENAL	Haematuria	Hematuria	04SEP2020 (16)	07:00	14OCT2020 (56)		41	1	N	N
2	BLOOD	Lymphadenopathy	Lymphadenopathy left side of neck	03SEP2020 (15)		13SEP2020 (25)		11	2	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (14OCT2020)	NOT RELATED/OTHER: Unknown, subject advised to seek medical attention	1	16	N
2	Resolved (13SEP2020)	Study Treatment	1	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccine	INFLUENZA VACCINE	04FEB2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	14OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	27	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	89.4 kg	30.9 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Codeine Allergy	Drug hypersensitivity	1997	Present
Heartburn	Dyspepsia	2008	Present
Back pain radiculopathy to thighs, bilateral	Radiculopathy	12MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03AUG2020 (1)	13:54
2	BNT162b2	23NOV2020 (113)	11:00

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	1+right distal cervical lymph node enlarged	08NOV2020 (98)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	N	N	Yes	NOT RELATED/OTHER: Viral Syndrome	1	98	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	22DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	01MAR2021	LOST TO FOLLOW-UP

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	American Indian or Alaska Native	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	75.2 kg	26.6 kg/m2	08OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYSTERECTOMY	Hysterectomy	2000	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08OCT2020 (1)	16:24
2	Placebo	29OCT2020 (22)	15:37

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	07JAN2021 (92)	10:52
4	BNT162b2	28JAN2021 (113)	10:42

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	SWOLLEN LYMPH NODES	01FEB2021 (117)		04FEB2021 (120)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	1	N	N	Resolved (04FEB2021)	Study Treatment	4	5	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08OCT2020	
Completed	VACCINATION	30NOV2020	
Completed	REPEAT SCREENING 1	07JAN2021	
Completed	OPEN LABEL TREATMENT	03MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	101.14 kg	30.2 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	20APR2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03SEP2020 (1)	12:46
2	BNT162b2	25SEP2020 (23)	10:00

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Injection site pain	Injection Site pain	25SEP2020 (23)	10:30	26SEP2020 (24)	
2	BLOOD	Lymphadenopathy	Swollen Right Axillary lymph node	03SEP2020 (1)	13:00	12OCT2020 (40)	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	1	N	N	Resolved (26SEP2020)	Study Treatment	2	1	N
2	40	1	N	N	Resolved (12OCT2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
Seasonal Influenza Vaccine	INFLUENZA VACCINE	16OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	26OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166.37 cm	106 kg	38.2 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	DEC2013	Present
Obesity	Obesity	21DEC2014	Present
Gerd	Gastrooesophageal reflux disease	2015	Present
Seasonal Allergies	Seasonal allergy	21MAY2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16SEP2020 (1)	11:32
2	Placebo	06OCT2020 (21)	09:29
3	BNT162b2	06JAN2021 (113)	09:00
4	BNT162b2	27JAN2021 (134)	10:20

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Headache	Mild Headache	27JAN2021 (134)	14:00	28JAN2021 (135)	
2	BLOOD	Lymphadenopathy	Enlarged Left Axillary and subclavicular lymph nodes	06JAN2021 (113)	16:00	09JAN2021 (116)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (28JAN2021)	Study Treatment	4	1	N
2	4	1	N	N	Resolved (09JAN2021)	Study Treatment	3	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	16SEP2020	
Completed	VACCINATION	03NOV2020	
Completed	REPEAT SCREENING 1	06JAN2021	
Completed	OPEN LABEL TREATMENT	25FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	107.5 kg	37.6 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
polycystic ovarian syndrome	Polycystic ovaries	2000	Present
seasonal allergies	Seasonal allergy	2012	Present
asthma	Asthma	2015	Present
Gastro esophageal reflux disease	Gastrooesophageal reflux disease	2015	Present
anxiety	Anxiety	APR2018	Present
Essential Hypertension	Essential hypertension	AUG2018	Present
vitamin D Deficiency	Vitamin D deficiency	MAR2019	Present
Urinary tract infection	Urinary tract infection	13SEP2020	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	16SEP2020 (1)	12:16
2	BNT162b2	08OCT2020 (23)	09:24

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GENRL	Fatigue	Fatigue	09OCT2020 (24)	01:30	09OCT2020 (24)	06:00	1	1
2	GENRL	Injection site pain	Pain at injection Site	08OCT2020 (23)	21:00	11OCT2020 (26)		4	2
3	BLOOD	Lymphadenopathy	Enlarged Bilateral Inguinal Lymph Nodes	16DEC2020 (92)		06JAN2021 (113)		22	2
4	SKIN	Onycholysis	Toenail Onycholysis x3	14DEC2020 (90)		15JAN2021 (122)		33	2
5	GENRL	Peripheral swelling	Bilateral Lower extremity swelling	16DEC2020 (92)		16FEB2021 (154)		63	2
6	GENRL	Pyrexia	Fever of 99.9	08OCT2020 (23)	21:00	09OCT2020 (24)	00:00	2	1
7	CARD	Tachycardia	Tachycardia	31DEC2020 (107)		ONGOING			2
8	NERV	Tremor	Tremors	31DEC2020 (107)		ONGOING			2

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (09OCT2020)	Study Treatment	2	2	N

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	TC	N	Resolved (11OCT2020)	Study Treatment	2	1	N
3	N	N	Resolved (06JAN2021)	NOT RELATED/OTHER: unknown cause	2	70	Y
4	N	N	Resolved (15JAN2021)	NOT RELATED/OTHER: Unknown Cause	2	68	N
5	TC	N	Resolved (16FEB2021)	NOT RELATED/OTHER: Unknown cause at this time	2	70	N
6	TC	N	Resolved (09OCT2020)	Study Treatment	2	1	N
7	TC	N	Yes	NOT RELATED/OTHER: Cause unknown at this time	2	85	N
8	TC	N	Yes	NOT RELATED/OTHER: Cause Unknown	2	85	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Seasonal Influenza vaccine	INFLUENZA VACCINE	30OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16SEP2020	
Completed	VACCINATION	09NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.96 cm	122.73 kg	34.7 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	2004	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02SEP2020 (1)	09:29
2	BNT162b2	22SEP2020 (21)	10:19

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	BLOOD	Lymphadenopathy	bilateral axillary lymphadenopathy	25SEP2020 (24)		27SEP2020 (26)	
2	GENRL	Pyrexia	fever	23SEP2020 (22)		26SEP2020 (25)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	2	TC	N	Resolved (27SEP2020)	Study Treatment	2	4	Y
2	4	1	TC	N	Resolved (26SEP2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Flu Vaccine	INFLUENZA VACCINE	09OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	77.27 kg	31.1 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
migraine	Migraine	2000	Present
post menopausal	Postmenopause	2000	Present
depression	Depression	2004	Present
seasonal allergies	Seasonal allergy	2005	Present
attention deficit disorder	Attention deficit hyperactivity disorder	2006	Present
osteoarthritis	Osteoarthritis	2012	Present
sleep apnea	Sleep apnoea syndrome	2012	Present
hypercholesterolemia	Hypercholesterolaemia	2018	Present
hypertension	Hypertension	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14SEP2020 (1)	11:31
2	Placebo	05OCT2020 (22)	10:14
3	BNT162b2	26JAN2021 (135)	09:54
4	BNT162b2	22FEB2021 (162)	14:30

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site pain	injection site tenderness	26JAN2021 (135)	18:00	28JAN2021 (137)	
2	BLOOD	Lymphadenopathy	lymphadenopathy, rught axilla	14OCT2020 (31)	22:30	21OCT2020 (38)	10:30

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	1	N	N	Resolved (28JAN2021)	Study Treatment	3	1	N
2	8	1	N	N	Resolved (21OCT2020)	Study Treatment	2	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	09NOV2020	
Completed	REPEAT SCREENING 1	26JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	65.45 kg	24.7 kg/m2	25SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25SEP2020 (1)	09:53
2	Placebo	16OCT2020 (22)	08:31

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	22JAN2021 (120)	11:34
4	BNT162b2	10FEB2021 (139)	08:35

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	BLOOD	Anaemia	anemia	25FEB2021 (154)		ONGOING		
2	NEOPL	Breast cancer	left breast carcinoma	13JAN2021 (111)		ONGOING		
3	BLOOD	Lymphadenopathy	left axillary adenopathy with cortical thickening	27JAN2021 (125)		ONGOING		
4	BLOOD	Lymphadenopathy	right axillary adenopathy with cortical thickening	27JAN2021 (125)		ONGOING		
5	INJ&P	Seroma	seroma (left axilla)	26FEB2021 (155)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Yes	NOT RELATED/OTHER: unknown	4	16	N
2	3	N	Y	Yes	NOT RELATED/OTHER: Mitosis	2	90	Y
3	1	N	N	Yes	Study Treatment	3	6	Y
4	1	N	N	Yes	Study Treatment	3	6	Y
5	2	N	N	Yes	NOT RELATED/OTHER: axillary Lymph node biopsy	4	17	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25SEP2020	
Completed	VACCINATION	13NOV2020	
Completed	REPEAT SCREENING 1	22JAN2021	
Completed	OPEN LABEL TREATMENT	11MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	39	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	70 kg	23.4 kg/m2	14OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypothyroidism	Hypothyroidism	2010	Present
esophageal reflux	Gastrooesophageal reflux disease	2013	Present
factor II deficiency	Factor II deficiency	2014	Present
ectopic pregnancy	Ectopic pregnancy	2016	Past
right salpingectomy	Salpingectomy	2016	Past
left salpingectomy	Salpingectomy	2019	Past
seasonal allergies	Seasonal allergy	JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14OCT2020 (1)	10:51
2	Placebo	04NOV2020 (22)	10:08
3	BNT162b2	21DEC2020 (69)	11:18
4	BNT162b2	12JAN2021 (91)	13:44

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Chills	chills	12JAN2021 (91)	20:00	14JAN2021 (93)		3
2	NERV	Headache	Headache	21DEC2020 (69)	20:00	24DEC2020 (72)		4
3	NERV	Headache	headache	12JAN2021 (91)	20:00	14JAN2021 (93)		3
4	INFEC	Hordeolum	Left eye stye	19OCT2020 (6)		10NOV2020 (28)		23
5	GENRL	Injection site pain	tenderness at injection site	21DEC2020 (69)	20:00	22DEC2020 (70)		2
6	SKIN	Lichen sclerosus	lichen sclerosus	19JAN2021 (98)		ONGOING		
7	BLOOD	Lymphadenopathy	left axillary lymphadenopathy	13JAN2021 (92)	14:00	20JAN2021 (99)		8
8	GASTR	Nausea	nausea	21DEC2020 (69)	20:00	22DEC2020 (70)	20:00	2
9	GASTR	Nausea	nausea	12JAN2021 (91)	20:00	14JAN2021 (93)		3
10	GENRL	Pain	body ache	12JAN2021 (91)	20:00	14JAN2021 (93)		3
11	GENRL	Pain	body aches	21DEC2020 (69)	20:00	24DEC2020 (72)		4
12	GENRL	Pyrexia	fever	12JAN2021 (91)	20:00	14JAN2021 (93)		3

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	N	N	Resolved (14JAN2021)	Study Treatment	4	1	N
2	1	N	N	Resolved (24DEC2020)	Study Treatment	3	1	N
3	3	N	N	Resolved (14JAN2021)	Study Treatment	4	1	N
4	2	TC	N	Resolved (10NOV2020)	NOT RELATED/OTHER: microbes	1	6	N
5	1	N	N	Resolved (22DEC2020)	Study Treatment	3	1	N
6	1	TC	N	Yes	NOT RELATED/OTHER: unknown	4	8	N
7	1	N	N	Resolved (20JAN2021)	Study Treatment	4	2	Y
8	1	N	N	Resolved (22DEC2020)	Study Treatment	3	1	N
9	3	N	N	Resolved (14JAN2021)	Study Treatment	4	1	N
10	3	N	N	Resolved (14JAN2021)	Study Treatment	4	1	N
11	1	TC	N	Resolved (24DEC2020)	Study Treatment	3	1	N
12	1	TC	N	Resolved (14JAN2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14OCT2020	
Completed	VACCINATION	08DEC2020	
Completed	REPEAT SCREENING 1	21DEC2020	
Completed	OPEN LABEL TREATMENT	09FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
190 cm	96.1 kg	26.6 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial Hypertension	Hypertension	2015	Present
Hyperlipidemia	Hyperlipidaemia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15OCT2020 (1)	13:40

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	05NOV2020 (22)	14:51
3	BNT162b2	11JAN2021 (89)	14:09
4	BNT162b2	01FEB2021 (110)	14:20

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site pain	Pain at injection site	11JAN2021 (89)	20:00	13JAN2021 (91)	08:00
2	BLOOD	Lymphadenopathy	enlarged lymph nodes (right axillar)	02FEB2021 (111)		13FEB2021 (122)	08:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	2	N	N	Resolved (13JAN2021)	Study Treatment	3	1	N
2	12	2	N	N	Resolved (13FEB2021)	Study Treatment	4	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Vaxigrip	INFLUENZA VACCINE INACT SPLIT 3V	25SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15OCT2020	
Completed	VACCINATION	03DEC2020	
Completed	REPEAT SCREENING 1	11JAN2021	
Completed	OPEN LABEL TREATMENT	01MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	95.9 kg	35.7 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial Hypertension	Hypertension	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	19:05
2	Placebo	06NOV2020 (22)	09:08

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	12JAN2021 (89)	14:30
4	BNT162b2	02FEB2021 (110)	09:43

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site pain	Pain at injection site	12JAN2021 (89)	19:00	14JAN2021 (91)	23:00
2	BLOOD	Lymphadenopathy	Lymphadenopathia (axillar left)	04FEB2021 (112)		06FEB2021 (114)	20:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	2	N	N	Resolved (14JAN2021)	Study Treatment	3	1	N
2	3	2	N	N	Resolved (06FEB2021)	Study Treatment	4	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	16OCT2020	
Completed	VACCINATION	04DEC2020	
Completed	REPEAT SCREENING 1	12JAN2021	
Completed	OPEN LABEL TREATMENT	02MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	69.2 kg	23.1 kg/m2	19OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial Hypertension	Hypertension	2005	Present
av reentry tachykardie	Supraventricular tachycardia	JUN2011	Past
Hashimoto Thyreoiditis	Autoimmune thyroiditis	2015	Present
Uterus myoma	Uterine leiomyoma	2017	Past
Alopecia arreata	Alopecia areata	MAR2017	Present
Postmenopausal	Postmenopause	MAR2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19OCT2020 (1)	15:41
2	Placebo	10NOV2020 (23)	13:00
3	BNT162b2	12JAN2021 (86)	14:08
4	BNT162b2	02FEB2021 (107)	14:08

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	MUSC	Arthralgia	Pain at thumb base joint	04FEB2021 (109)		11FEB2021 (116)	
2	NERV	Headache	Headache	03FEB2021 (108)	20:00	11FEB2021 (116)	
3	GENRL	Injection site pain	Pain at injection site	12JAN2021 (86)	20:00	15JAN2021 (89)	
4	GENRL	Injection site pain	Pain at injection site	04FEB2021 (109)		11FEB2021 (116)	
5	BLOOD	Lymphadenopathy	Swelling lymph node (axillar right)	04FEB2021 (109)		11FEB2021 (116)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	8	2	N	N	Resolved (11FEB2021)	Study Treatment	4	3	N
2	9	2	N	N	Resolved (11FEB2021)	Study Treatment	4	2	N
3	4	2	N	N	Resolved (15JAN2021)	Study Treatment	3	1	N
4	8	2	N	N	Resolved (11FEB2021)	Study Treatment	4	3	N
5	8	2	N	N	Resolved (11FEB2021)	Study Treatment	4	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influvac tetra	INFLUENZA VACCINE INACT SAG 4V	25NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19OCT2020	
Completed	VACCINATION	08DEC2020	
Completed	REPEAT SCREENING 1	12JAN2021	
Completed	OPEN LABEL TREATMENT	02MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	68.18 kg	22.1 kg/m2	01SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01SEP2020 (1)	15:33
2	BNT162b2	22SEP2020 (22)	14:49

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Chills	chills	23SEP2020 (23)	08:00	24SEP2020 (24)	08:00
2	GENRL	Injection site pain	Pain at injection site	01SEP2020 (1)	18:00	02SEP2020 (2)	
3	BLOOD	Lymphadenopathy	swollen lymph node gland on neck	01SEP2020 (1)	17:00	03SEP2020 (3)	
4	GENRL	Pyrexia	Subjective Fever	01SEP2020 (1)	17:00	02SEP2020 (2)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	1	N	N	Resolved (24SEP2020)	Study Treatment	2	2	N
2	2	1	N	N	Resolved (02SEP2020)	Study Treatment	1	1	N
3	3	1	N	N	Resolved (03SEP2020)	Study Treatment	1	1	Y
4	2	1	N	N	Resolved (02SEP2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	43	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	77.27 kg	27.4 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasectomy	Vasectomy	2014	Past
Herniated Disc	Intervertebral disc protrusion	01OCT2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09SEP2020 (1)	17:20

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	30SEP2020 (22)	16:09
3	BNT162b2	14JAN2021 (128)	15:30
4	BNT162b2	04FEB2021 (149)	15:10

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	BLOOD	Lymphadenopathy	Swollen lymph nodes neck area (left side)	05FEB2021 (150)	12:00	ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			1	N	N	Yes	Study Treatment	4	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	28OCT2020	
Completed	REPEAT SCREENING 1	14JAN2021	
Completed	OPEN LABEL TREATMENT	05MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	31	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	63.64 kg	19 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Pernicious Anemia	Pernicious anaemia	21MAR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21SEP2020 (1)	15:20
2	BNT162b2	12OCT2020 (22)	12:42

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	MUSC	Arthralgia	opposite shoulder pain intermittent	22SEP2020 (2)	12:00	23SEP2020 (3)	10:00	2	1
2	GENRL	Fatigue	Fatigue	12OCT2020 (22)	22:00	14OCT2020 (24)	09:00	3	1
3	GENRL	Injection site pain	Muscle tenderness at injection site	12OCT2020 (22)	22:00	14OCT2020 (24)	09:00	3	1
4	BLOOD	Lymphadenopathy	Swollen submandibular lymph nodes	13OCT2020 (23)	20:00	15OCT2020 (25)		3	1
5	MUSC	Myalgia	muscle pain - abdominal	22SEP2020 (2)	20:00	23SEP2020 (3)	22:00	2	1
6	METAB	Polydipsia	Polydipsia	12OCT2020 (22)	22:00	15OCT2020 (25)		4	2
7	GENRL	Pyrexia	Low grade fever, 99.0	13OCT2020 (23)	12:00	14OCT2020 (24)	09:00	2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (23SEP2020)	NOT RELATED/OTHER: repetitive stress from work	1	2	N
2	N	N	Resolved (14OCT2020)	Study Treatment	2	1	N
3	TC	N	Resolved (14OCT2020)	Study Treatment	2	1	N
4	N	N	Resolved (15OCT2020)	Study Treatment	2	2	Y
5	N	N	Resolved (23SEP2020)	Study Treatment	1	2	N
6	N	N	Resolved (15OCT2020)	Study Treatment	2	1	N
7	N	N	Resolved (14OCT2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccine	INFLUENZA VACCINE	30OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Completed	VACCINATION	16NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	90.45 kg	27.8 kg/m2	14OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Strep Throat	Pharyngitis streptococcal	1999	Past
Tonsillectomy	Tonsillectomy	1999	Past
Spondylolysis	Spondylolysis	01JAN2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14OCT2020 (1)	16:13
2	BNT162b2	04NOV2020 (22)	12:49

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Chills	05NOV2020 (23)	02:00	06NOV2020 (24)	18:00
2	GENRL	Fatigue	Fatigue	15OCT2020 (2)	05:00	15OCT2020 (2)	14:00
3	NERV	Headache	Headache	05NOV2020 (23)	02:00	06NOV2020 (24)	18:00
4	GENRL	Injection site pain	Muscle tenderness at injection site	15OCT2020 (2)	08:00	18OCT2020 (5)	
5	GENRL	Injection site pain	Muscle tenderness at injection site	04NOV2020 (22)	14:00	06NOV2020 (24)	18:00
6	BLOOD	Lymphadenopathy	Right axillary lymph node swelling	05NOV2020 (23)	12:00	11NOV2020 (29)	
7	BLOOD	Lymphadenopathy	Swollen, tender left axillary lymph node	17OCT2020 (4)	05:00	22OCT2020 (9)	10:00
8	GENRL	Pyrexia	Low grade fever, 100.7	05NOV2020 (23)	02:00	06NOV2020 (24)	11:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	TC	N	Resolved (06NOV2020)	Study Treatment	2	2	N
2	1	1	N	N	Resolved (15OCT2020)	Study Treatment	1	2	N
3	2	2	TC	N	Resolved (06NOV2020)	Study Treatment	2	2	N
4	4	1	TC	N	Resolved (18OCT2020)	Study Treatment	1	2	N

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
5	3	1	TC	N	Resolved (06NOV2020)	Study Treatment	2	1	N
6	7	1	N	N	Resolved (11NOV2020)	Study Treatment	2	2	Y
7	6	1	N	N	Resolved (22OCT2020)	Study Treatment	1	4	Y
8	2	1	TC	N	Resolved (06NOV2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccine	INFLUENZA VACCINE	25NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14OCT2020	
Completed	VACCINATION	03DEC2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	37	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	105 kg	35.1 kg/m2	30OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30OCT2020 (1)	15:57
2	Placebo	20NOV2020 (22)	10:07

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	29DEC2020 (61)	14:25
4	BNT162b2	19JAN2021 (82)	09:55

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Arthralgia	joint pain	04NOV2020 (6)	20:00	05NOV2020 (7)	08:00	2
2	BLOOD	Lymphadenopathy	Axillary lymphadenopathy on the left.	20JAN2021 (83)		23JAN2021 (86)		4

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	N	Resolved (05NOV2020)	NOT RELATED/OTHER: ride motorcycle	1	6	N
2	2	N	N	Resolved (23JAN2021)	Study Treatment	4	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30OCT2020	
Completed	VACCINATION	18DEC2020	
Completed	REPEAT SCREENING 1	29DEC2020	
Completed	OPEN LABEL TREATMENT	16FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	84 kg	28.4 kg/m2	06NOV2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	06NOV2020 (1)	11:30
2	Placebo	27NOV2020 (22)	12:20

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	08FEB2021 (95)	10:40
4	BNT162b2	03MAR2021 (118)	10:45

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Diarrhoea	diarrhea	26NOV2020 (21)	17:00	27NOV2020 (22)	11:00	2
2	GENRL	Injection site pain	pain at the injection site	08FEB2021 (95)	18:00	10FEB2021 (97)	10:00	3
3	GENRL	Injection site pain	pain at the injection site	03MAR2021 (118)	17:00	05MAR2021 (120)	12:00	3
4	BLOOD	Lymphadenopathy	lymphadenomegaly in the right submandibular	06JAN2021 (62)		15JAN2021 (71)		10

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (27NOV2020)	NOT RELATED/OTHER: prepared foods	1	21	N
2	2	TC	N	Resolved (10FEB2021)	Study Treatment	3	1	N
3	2	N	N	Resolved (05MAR2021)	Study Treatment	4	1	N
4	1	TC	N	Resolved (15JAN2021)	NOT RELATED/OTHER: Bacteria	2	41	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	06NOV2020	
Completed	VACCINATION	28DEC2020	
Completed	REPEAT SCREENING 1	08FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1980	40	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
151.13 cm	59.18 kg	25.9 kg/m2	13NOV2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tonsillectomy	Tonsillectomy	1998	Past
L ankle reconstruction	Ankle arthroplasty	2001	Past
tachycardia	Tachycardia	2002	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13NOV2020 (1)	15:21
2	Placebo	04DEC2020 (22)	13:46
3	BNT162b2	21DEC2020 (39)	15:11
4	BNT162b2	11JAN2021 (60)	11:05

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	chills	22DEC2020 (40)	03:00	24DEC2020 (42)	05:00
2	BLOOD	Lymphadenopathy	lymphadenopathy	22DEC2020 (40)	05:00	29DEC2020 (47)	05:00
3	GENRL	Pain	body aches	22DEC2020 (40)	03:00	24DEC2020 (42)	05:00
4	GENRL	Pyrexia	fever	22DEC2020 (40)	03:00	24DEC2020 (42)	05:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	2	N	N	Resolved (24DEC2020)	Study Treatment	3	2	N
2	8	2	N	N	Resolved (29DEC2020)	Study Treatment	3	2	Y
3	3	2	N	N	Resolved (24DEC2020)	Study Treatment	3	2	N
4	3	2	N	N	Resolved (24DEC2020)	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13NOV2020	
Completed	VACCINATION	21DEC2020	
Completed	REPEAT SCREENING 1	21DEC2020	
Completed	OPEN LABEL TREATMENT	12FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	86.45 kg	28.1 kg/m2	18NOV2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
acne	Acne	1999	Past
seasonal allergies	Seasonal allergy	2005	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18NOV2020 (1)	16:28
2	BNT162b2	08DEC2020 (21)	15:05

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Chills	08DEC2020 (21)	18:05	09DEC2020 (22)	08:00
2	NERV	Headache	headache	09DEC2020 (22)	07:00	10DEC2020 (23)	07:00
3	GENRL	Injection site pain	Soreness at injection site	19NOV2020 (2)	08:00	19NOV2020 (2)	22:00
4	GENRL	Injection site pain	Soreness at injection site	08DEC2020 (21)	18:05	09DEC2020 (22)	08:00
5	BLOOD	Lymphadenopathy	Lymphadenopathy Left axillary	09DEC2020 (22)	06:00	14DEC2020 (27)	07:00
6	GENRL	Malaise	Malaise	09DEC2020 (22)	07:00	10DEC2020 (23)	07:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (09DEC2020)	Study Treatment	2	1	N
2	2	2	N	N	Resolved (10DEC2020)	Study Treatment	2	2	N
3	1	1	N	N	Resolved (19NOV2020)	Study Treatment	1	2	N
4	2	1	N	N	Resolved (09DEC2020)	Study Treatment	2	1	N
5	6	1	N	N	Resolved (14DEC2020)	Study Treatment	2	2	Y
6	2	2	N	N	Resolved (10DEC2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18NOV2020	
Completed	VACCINATION	11JAN2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179.07 cm	103 kg	32.1 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
diabetes type I	Type 1 diabetes mellitus	1989	Present
peripheral neuropathy	Neuropathy peripheral	2011	Present
migraines headaches	Migraine	DEC2011	Present
hypothyroidism	Hypothyroidism	2017	Present
Barrett's esophagus	Barrett's oesophagus	2019	Present
left ventricular hypertrophy	Left ventricular hypertrophy	2019	Present
abnormal central nervous system vascular	Nervous system disorder	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16SEP2020 (1)	13:00
2	Placebo	07OCT2020 (22)	12:36
3	BNT162b2	20DEC2020 (96)	10:11
4	BNT162b2	08JAN2021 (115)	10:02

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Abdominal pain	abdominal pain	31JAN2021 (138)		ONGOING	
2	GENRL	Asthenia	generalized weakness	09JAN2021 (116)	09:00	11JAN2021 (118)	09:00
3	GENRL	Injection site pain	injection site pain	09JAN2021 (116)	09:00	11JAN2021 (118)	09:00
4	BLOOD	Lymphadenopathy	Submandibular lymphadenopathy	01FEB2021 (139)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC	N	Yes	Study Treatment	4	24	N
2	3	1	N	N	Resolved (11JAN2021)	Study Treatment	4	2	N
3	3	1	TC	N	Resolved (11JAN2021)	Study Treatment	4	2	N
4		2	TC	N	Yes	Study Treatment	4	25	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	30OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16SEP2020	
Completed	VACCINATION	05NOV2020	
Completed	REPEAT SCREENING 1	20DEC2020	
Completed	OPEN LABEL TREATMENT	05FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1980	40	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.7 cm	63.1 kg	24.4 kg/m2	14AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14AUG2020 (1)	11:53
2	BNT162b2	04SEP2020 (22)	14:18

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	left axillary lymph node enlargement	06SEP2020 (24)		DEC2020 ()	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	N	N	Resolved (DEC2020)	Study Treatment	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	36	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.8 cm	63 kg	22.4 kg/m2	18AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	10:00
2	Placebo	08SEP2020 (22)	09:04

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	23JAN2021 (159)	11:45
4	BNT162b2	15FEB2021 (182)	09:55

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Headache	headache	16FEB2021 (183)		17FEB2021 (184)	
2	GENRL	Injection site pain	Pain at the injection site	23JAN2021 (159)	18:00	24JAN2021 (160)	
3	GENRL	Injection site pain	pain at the injection site	15FEB2021 (182)	16:00	17FEB2021 (184)	
4	BLOOD	Lymphadenopathy	lymphadenomegaly	16FEB2021 (183)		22FEB2021 (189)	
5	MUSC	Myalgia	muscle pain	16FEB2021 (183)		17FEB2021 (184)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	TC	N	Resolved (17FEB2021)	Study Treatment	4	2	N
2	2	2	N	N	Resolved (24JAN2021)	Study Treatment	3	1	N
3	3	1	TC	N	Resolved (17FEB2021)	Study Treatment	4	1	N
4	7	1	N	N	Resolved (22FEB2021)	Study Treatment	4	2	Y
5	2	1	TC	N	Resolved (17FEB2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	07OCT2020	
Completed	REPEAT SCREENING 1	23JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	54	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	79.4 kg	28.1 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Systemic arterial hypertension	Hypertension	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	14:42
2	BNT162b2	15SEP2020 (22)	12:14

Adverse Events						
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Injection site pain	Pain at injection site	26AUG2020 (2)		27AUG2020 (3)	
2	GENRL	Injection site pain	Pain at injection site	16SEP2020 (23)		20SEP2020 (27)	
3	BLOOD	Lymphadenopathy	left axillary lymphadenomegaly	16SEP2020 (23)		20SEP2020 (27)	
4	MUSC	Myalgia	Muscle pain	17SEP2020 (24)		18SEP2020 (25)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	1	TC	N	Resolved (27AUG2020)	Study Treatment	1	2	N
2	5	2	TC	N	Resolved (20SEP2020)	Study Treatment	2	2	N
3	5	2	TC	N	Resolved (20SEP2020)	Study Treatment	2	2	Y
4	2	1	N	N	Resolved (18SEP2020)	Study Treatment	2	3	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	37	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156.4 cm	68.5 kg	28 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypothyroidism	Hypothyroidism	2013	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	14:11
2	Placebo	16SEP2020 (22)	08:59

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
3	BNT162b2	25JAN2021 (153)	09:57
4	BNT162b2	16FEB2021 (175)	11:57

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Asthenia	Asthenia	16FEB2021 (175)	21:00	18FEB2021 (177)	
2	GASTR	Diarrhoea	Diarrhea	29AUG2020 (4)		29AUG2020 (4)	
3	GASTR	Diarrhoea	Diarrhea	31AUG2020 (6)		31AUG2020 (6)	
4	GENRL	Injection site pain	Pain at the injection site	16FEB2021 (175)	21:00	18FEB2021 (177)	
5	GENRL	Injection site pain	pain at the injection site	25JAN2021 (153)	21:00	29JAN2021 (157)	
6	BLOOD	Lymphadenopathy	axillary lymphadenopathy	26JAN2021 (154)		01FEB2021 (160)	
7	GENRL	Pyrexia	Fever 38.3 C	16FEB2021 (175)	21:00	18FEB2021 (177)	
8	GENRL	Pyrexia	fever (38.2 C)	26JAN2021 (154)		26JAN2021 (154)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	2	TC	N	Resolved (18FEB2021)	Study Treatment	4	1	N
2	1	1	N	N	Resolved (29AUG2020)	Study Treatment	1	4	N
3	1	1	N	N	Resolved (31AUG2020)	Study Treatment	1	6	N
4	3	2	TC	N	Resolved (18FEB2021)	Study Treatment	4	1	N
5	5	1	N	N	Resolved (29JAN2021)	Study Treatment	3	1	N

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
6	7	1	N	N	Resolved (01FEB2021)	Study Treatment	3	2	Y
7	3	2	TC	N	Resolved (18FEB2021)	Study Treatment	4	1	N
8	1	1	TC	N	Resolved (26JAN2021)	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	25JAN2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	51.9 kg	19.5 kg/m2	05SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05SEP2020 (1)	12:04
2	BNT162b2	24SEP2020 (20)	09:06

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	NERV	Headache	headache	05SEP2020 (1)	17:00	07SEP2020 (3)	
2	NERV	Headache	headache	24SEP2020 (20)	19:00	24SEP2020 (20)	
3	GENRL	Injection site pain	Pain at injection site	05SEP2020 (1)	17:00	07SEP2020 (3)	
4	BLOOD	Lymphadenopathy	enlargement of left axillary lymph node	25SEP2020 (21)		28OCT2020 (54)	
5	MUSC	Myalgia	muscle pain	24SEP2020 (20)	19:00	25SEP2020 (21)	
6	GENRL	Pain	Body pain	26SEP2020 (22)		26SEP2020 (22)	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	2	TC	N	Resolved (07SEP2020)	Study Treatment	1	1	N
2	1	1	N	N	Resolved (24SEP2020)	Study Treatment	2	1	N
3	3	2	N	N	Resolved (07SEP2020)	Study Treatment	1	1	N
4	34	1	N	N	Resolved (28OCT2020)	Study Treatment	2	2	Y
5	2	1	TC	N	Resolved (25SEP2020)	Study Treatment	2	1	N
6	1	1	N	N	Resolved (26SEP2020)	Study Treatment	2	3	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05SEP2020	
Completed	VACCINATION	22OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1993	27	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.8 cm	63.8 kg	21.9 kg/m2	14SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14SEP2020 (1)	12:00
2	BNT162b2	05OCT2020 (22)	12:30

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	axillary lymphadenopathy in the left arm	06OCT2020 (23)		08OCT2020 (25)	
2	GENRL	Pyrexia	fever (37,8 C)	05OCT2020 (22)	20:00	05OCT2020 (22)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	1	N	N	Resolved (08OCT2020)	Study Treatment	2	2	Y
2	1	1	TC	N	Resolved (05OCT2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	03NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
183 cm	80.5 kg	24 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
vasectomy	Vasectomy	2012	Past
dyslipidemia	Dyslipidaemia	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14SEP2020 (1)	13:50
2	BNT162b2	05OCT2020 (22)	12:38

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Headache	Headache	06OCT2020 (23)		07OCT2020 (24)	
2	GENRL	Injection site pain	Pain at injection site	06OCT2020 (23)		07OCT2020 (24)	
3	BLOOD	Lymphadenopathy	Axillary adenomegaly	06OCT2020 (23)		07OCT2020 (24)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	2	N	N	Resolved (07OCT2020)	Study Treatment	2	2	N
2	2	2	N	N	Resolved (07OCT2020)	Study Treatment	2	2	N
3	2	2	N	N	Resolved (07OCT2020)	Study Treatment	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	03NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	54	Multiple	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	71.2 kg	27.8 kg/m2	17SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
bilateral tubal ligation	Female sterilisation	2007	Past
Systemic arterial hypertension	Hypertension	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17SEP2020 (1)	10:37

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	07OCT2020 (21)	11:13
3	BNT162b2	13FEB2021 (150)	12:25
4	BNT162b2	05MAR2021 (170)	11:55

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site pain	Pain at the injection site	13FEB2021 (150)	18:00	14FEB2021 (151)	
2	BLOOD	Lymphadenopathy	Ipsilateral axillary lymph node enlargement	15FEB2021 (152)		17FEB2021 (154)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	2	TC	N	Resolved (14FEB2021)	Study Treatment	3	1	N
2	3	2	TC	N	Resolved (17FEB2021)	Study Treatment	3	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17SEP2020	
Completed	VACCINATION	07NOV2020	
Completed	REPEAT SCREENING 1	13FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	99.2 kg	34.3 kg/m2	17SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17SEP2020 (1)	13:11
2	Placebo	07OCT2020 (21)	13:00

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
3	BNT162b2	25JAN2021 (131)	13:24
4	BNT162b2	16FEB2021 (153)	13:40

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Chills	Chills	26JAN2021 (132)		28JAN2021 (134)	
2	GENRL	Fatigue	Fatigue	26JAN2021 (132)		28JAN2021 (134)	
3	GENRL	Fatigue	fatigue	17FEB2021 (154)		19FEB2021 (156)	
4	GENRL	Injection site pain	Pain at injection site	17SEP2020 (1)	19:00	19SEP2020 (3)	
5	BLOOD	Lymphadenopathy	(left) axillary lymph node enlargement	17FEB2021 (154)		19FEB2021 (156)	
6	MUSC	Myalgia	muscle pain	17FEB2021 (154)		19FEB2021 (156)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	1	N	N	Resolved (28JAN2021)	Study Treatment	3	2	N
2	3	1	N	N	Resolved (28JAN2021)	Study Treatment	3	2	N
3	3	2	TC	N	Resolved (19FEB2021)	Study Treatment	4	2	N
4	3	1	N	N	Resolved (19SEP2020)	Study Treatment	1	1	N
5	3	2	TC	N	Resolved (19FEB2021)	Study Treatment	4	2	Y
6	3	2	TC	N	Resolved (19FEB2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17SEP2020	
Completed	VACCINATION	05NOV2020	
Completed	REPEAT SCREENING 1	25JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	41	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	80.6 kg	27.2 kg/m2	19SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
deviation of nasal septum	Nasal septum deviation	1985	Past
septoplasty	Nasal septal operation	2001	Past
left inguinal hernia	Inguinal hernia	2015	Past
left inguinal herniorrhaphy	Inguinal hernia repair	2015	Past
anxiety disorder	Anxiety disorder	2016	Present
dyslipidemia	Dyslipidaemia	SEP2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19SEP2020 (1)	11:05
2	BNT162b2	09OCT2020 (21)	10:57

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	Left axillary lymph node enlargement	10OCT2020 (22)		15OCT2020 (27)	
2	MUSC	Myalgia	Muscle pain	10OCT2020 (22)		11OCT2020 (23)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	6	2	TC	N	Resolved (15OCT2020)	Study Treatment	2	2	Y
2	2	2	TC	N	Resolved (11OCT2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19SEP2020	
Completed	VACCINATION	11NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1987	33	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	73 kg	25.6 kg/m2	03OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03OCT2020 (1)	10:04
2	BNT162b2	26OCT2020 (24)	10:04

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Asthenia	Asthenia	26OCT2020 (24)	18:00	27OCT2020 (25)	13:00
2	GENRL	Injection site pain	Pain at injection site	26OCT2020 (24)	18:00	27OCT2020 (25)	13:00
3	BLOOD	Lymphadenopathy	Left axillary adenomegaly	29OCT2020 (27)		03NOV2020 (32)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (27OCT2020)	Study Treatment	2	1	N
2	2	1	N	N	Resolved (27OCT2020)	Study Treatment	2	1	N
3	6	1	N	N	Resolved (03NOV2020)	Study Treatment	2	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03OCT2020	
Completed	VACCINATION	27NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	65	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	71.6 kg	28 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	1979	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16OCT2020 (1)	11:58
2	BNT162b2	04NOV2020 (20)	11:18

Adverse Events						
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Injection site erythema	Redness at injection site	16OCT2020 (1)	20:00	25OCT2020 (10)	
2	GENRL	Injection site oedema	Edema at injection site	16OCT2020 (1)	20:00	25OCT2020 (10)	
3	GENRL	Injection site pain	Pain at injection site	04NOV2020 (20)	20:00	08NOV2020 (24)	
4	GENRL	Injection site pain	Pain at local injection	16OCT2020 (1)	20:00	25OCT2020 (10)	
5	BLOOD	Lymphadenopathy	(Left) axillary lymph node enlargement	16OCT2020 (1)	20:00	25OCT2020 (10)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	10	2	N	N	Resolved (25OCT2020)	Study Treatment	1	1	N
2	10	2	N	N	Resolved (25OCT2020)	Study Treatment	1	1	N
3	5	1	N	N	Resolved (08NOV2020)	Study Treatment	2	1	N
4	10	2	N	N	Resolved (25OCT2020)	Study Treatment	1	1	N
5	10	2	N	N	Resolved (25OCT2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
Completed	VACCINATION	08DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	22	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	62.5 kg	21.6 kg/m2	17OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17OCT2020 (1)	10:24
2	Placebo	07NOV2020 (22)	10:35

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	23JAN2021 (99)	14:10
4	BNT162b2	20FEB2021 (127)	12:15

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Fatigue	fatigue	21FEB2021 (128)		21FEB2021 (128)	
2	BLOOD	Lymphadenopathy	left axillary lymph node enlargement	24JAN2021 (100)		27JAN2021 (103)	
3	MUSC	Myalgia	myalgia	24JAN2021 (100)		27JAN2021 (103)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	N	N	Resolved (21FEB2021)	Study Treatment	4	2	N
2	4	1	TC	N	Resolved (27JAN2021)	Study Treatment	3	2	Y
3	4	1	TC	N	Resolved (27JAN2021)	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17OCT2020	
Completed	VACCINATION	23DEC2020	
Completed	REPEAT SCREENING 1	23JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	57 kg	22.8 kg/m2	17OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
anxiety disorder	Anxiety disorder	1998	Present
hypothyroidism	Hypothyroidism	2012	Present
menopausa	Menopause	2015	Present
D hypovitaminosis	Vitamin D deficiency	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17OCT2020 (1)	11:23
2	Placebo	06NOV2020 (21)	09:04
3	BNT162b2	17FEB2021 (124)	11:10
4	BNT162b2	09MAR2021 (144)	12:30

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	BLOOD	Lymphadenopathy	Left axillary lymphadenopathy	11MAR2021 (146)		ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			2	N	N	Yes	Study Treatment	4	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17OCT2020	
Completed	VACCINATION	08DEC2020	
Completed	REPEAT SCREENING 1	17FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	108 kg	35.7 kg/m2	15AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Migraine	Migraine	01JAN2001	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15AUG2020 (1)	11:03
2	BNT162b2	03SEP2020 (20)	09:35

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	BLOOD	Lymphadenopathy	Left axillary adenopathy	05SEP2020 (22)	09:00	20SEP2020 (37)	12:00	16
2	NERV	Tension headache	Tension headache	05OCT2020 (52)	10:00	15OCT2020 (62)	12:00	11

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	TC/TCN	N	Resolved (20SEP2020)	Study Treatment	2	3	Y
2	2	TC	N	Resolved (15OCT2020)	NOT RELATED/OTHER: tensional	2	33	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	48	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
189 cm	100.93 kg	28.3 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
non-hodgkin lymphoma	Non-Hodgkin's lymphoma	01AUG1992	Past
swallowing disorder	Dysphagia	13MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	18:30

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	07SEP2020 (22)	18:55
3	BNT162b2	23FEB2021 (191)	11:40

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Gastrooesophageal reflux disease	gastroesophageal reflux	21OCT2020 (66)	15:00	13JAN2021 (150)	21:00	85
2	INFEC	Helicobacter infection	Helicobacter Pylori infection	21OCT2020 (66)	15:00	01FEB2021 (169)	20:40	104
3	BLOOD	Lymphadenopathy	Cervical lymphadenopathy	23DEC2020 (129)	10:00	23FEB2021 (191)	20:00	63
4	BLOOD	Lymphadenopathy mediastinal	mediastinal lymphadenopathy	23DEC2020 (129)	10:00	23FEB2021 (191)	20:00	63

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Resolved (13JAN2021)	NOT RELATED/OTHER: Unknown	2	45	N
2	2	TC	N	Resolved (01FEB2021)	NOT RELATED/OTHER: Unknown	2	45	N
3	2	N	N	Resolved (23FEB2021)	NOT RELATED/OTHER: Unknown	2	108	Y
4	2	N	N	Resolved (23FEB2021)	NOT RELATED/OTHER: unknown	2	108	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
Completed	REPEAT SCREENING 1	23FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	82 kg	26.8 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypercholesterolemia	Hypercholesterolaemia	01JAN2018	Present
Hypertriglyceridemia	Hypertriglyceridaemia	01JAN2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	18:45
2	BNT162b2	08SEP2020 (23)	17:25

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	right axillary adenopathy	10SEP2020 (25)	10:00	12SEP2020 (27)	10:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	1	N	N	Resolved (12SEP2020)	Study Treatment	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	25	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178 cm	107 kg	33.8 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Smoking	Tobacco user	01MAY2008	Present
Seasonal allergy	Seasonal allergy	01APR2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18AUG2020 (1)	17:35
2	BNT162b2	08SEP2020 (22)	14:55

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	BLOOD	Lymphadenopathy	left inguinal adenopathy	20OCT2020 (64)	10:30	03NOV2020 (78)	09:00	15

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (03NOV2020)	NOT RELATED/OTHER: unknown	2	43	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	06OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	47	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	101.25 kg	38.1 kg/m2	20AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	18:20
2	Placebo	22SEP2020 (34)	19:05
3	BNT162b2	25FEB2021 (190)	18:19

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	BLOOD	Lymphadenopathy	Adenopathy in the left supraclavicular area	27FEB2021 (192)	09:00	07MAR2021 (200)	21:00
2	MUSC	Myalgia	Myalgia on internal area of left arm	26FEB2021 (191)	08:00	08MAR2021 (201)	08:00

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	9	2	TC	N	Resolved (07MAR2021)	Study Treatment	3	3	Y
2	11	2	TC	N	Resolved (08MAR2021)	Study Treatment	3	2	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Other_AEI_SAE/profile Date of Generation: 07APR2021 (21:52)

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	08OCT2020	
Completed	REPEAT SCREENING 1	25FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	21	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159 cm	65.5 kg	25.9 kg/m2	21AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	14:18
2	BNT162b2	10SEP2020 (21)	14:05

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	BLOOD	Lymphadenopathy	Left axillary adenopathy	27AUG2020 (7)	12:00	30SEP2020 (41)	15:00	35

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (30SEP2020)	NOT RELATED/OTHER: Unknown	1	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	70	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
181 cm	115 kg	35.1 kg/m2	23AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	23AUG2020 (1)	15:35
2	BNT162b2	15SEP2020 (24)	17:05

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	VASC	Hypertension	Arterial hypertension	24OCT2020 (63)	20:00	25OCT2020 (64)	22:00	2
2	BLOOD	Lymphadenopathy	LEFT INFRACLAVICULAR ADENOPATHY, 5 mm IN DIAMETER.	17SEP2020 (26)	18:00	24SEP2020 (33)	09:00	8

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (25OCT2020)	NOT RELATED/OTHER: unknown	2	40	N
2	1	N	N	Resolved (24SEP2020)	NOT RELATED/OTHER: UNKNOWN	2	3	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23AUG2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	66 kg	23.7 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sjogren syndrome	Sjogren's syndrome	07JUL1977	Present
insomnia	Insomnia	07JUL1990	Present
Right hip replacement surgery	Hip arthroplasty	19DEC2018	Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	24AUG2020 (1)	17:45
2	BNT162b2	13SEP2020 (21)	15:58

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	RESP	Emphysema	Panlobar emphysema	09OCT2020 (47)		ONGOING			1
2	BLOOD	Lymphadenopathy	Bilateral axillary adenopathy	09OCT2020 (47)	12:00	ONGOING			1
3	BLOOD	Lymphadenopathy mediastinal	ENLARGEMENT OF MEDIASTINAL LYMPH NODES	09OCT2020 (47)	12:00	11DEC2020 (110)	18:00	64	1
4	RESP	Pneumonitis	Non-specific Pneumonitis	29SEP2020 (37)	15:30	10OCT2020 (48)		12	2
5	INFEC	Sialoadenitis	Left submaxillary sialadenitis	03NOV2020 (72)	08:00	09NOV2020 (78)	20:00	7	2

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Yes	NOT RELATED/OTHER: Unknown	2	27	N
2	N	N	Yes	NOT RELATED/OTHER: Non-specific Pneumonitis.	2	27	Y
3	TC	N	Resolved (11DEC2020)	NOT RELATED/OTHER: Non-specific Pneumonitis	2	27	N
4	N	Y	Resolved (10OCT2020)	NOT RELATED/OTHER: unknown	2	17	Y
5	TC	N	Resolved (09NOV2020)	NOT RELATED/OTHER: Sjogren's syndrome	2	52	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	26NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	75 kg	28.2 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hashimoto`s thyroiditis	Autoimmune thyroiditis	01JAN2005	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	20:47
2	BNT162b2	15SEP2020 (23)	11:23

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	BLOOD	Lymphadenopathy	left supraclavicular and axillary adenomegaly	16SEP2020 (24)	09:00	23SEP2020 (31)	11:00	8

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC	N	Resolved (23SEP2020)	NOT RELATED/OTHER: Unknown	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1987	32	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
171 cm	88 kg	30.1 kg/m2	25AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	25AUG2020 (1)	12:50
2	BNT162b2	16SEP2020 (23)	09:42

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	BLOOD	Lymphadenopathy	right axillary adenopathy	18SEP2020 (25)	12:00	22SEP2020 (29)	17:00	5

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (22SEP2020)	NOT RELATED/OTHER: Unknown	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	14OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	25	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	60 kg	21.8 kg/m2	25AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	18:00
2	BNT162b2	13SEP2020 (20)	15:30

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	BLOOD	Lymphadenopathy	Left axillary adenopathy	01SEP2020 (8)	12:00	17SEP2020 (24)	20:00	17

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	N	N	Resolved (17SEP2020)	NOT RELATED/OTHER: Unknown	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	14OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	65.9 kg	26.4 kg/m2	26AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	11:35
2	BNT162b2	16SEP2020 (22)	12:31

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	EAR	Ear pain	left otalgia	27AUG2020 (2)	18:00	29AUG2020 (4)	16:00	3
2	BLOOD	Lymphadenopathy	Left cervical adenopathy	27AUG2020 (2)	18:00	02OCT2020 (38)	10:00	37

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (29AUG2020)	NOT RELATED/OTHER: unknown	1	2	N
2	1	N	N	Resolved (02OCT2020)	NOT RELATED/OTHER: unknown	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	87 kg	33.2 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	01OCT2004	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	15:55

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	16SEP2020 (22)	14:20
3	BNT162b2	06MAR2021 (193)	14:09

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	BLOOD	Lymphadenopathy	Painful left axillary adenopathy	19SEP2020 (25)	21:20	22SEP2020 (28)	21:30	4

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (22SEP2020)	NOT RELATED/OTHER: unknown	2	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	20OCT2020	
Completed	REPEAT SCREENING 1	06MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1979	41	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
159 cm	51 kg	20.2 kg/m2	26AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	26AUG2020 (1)	19:35
2	BNT162b2	16SEP2020 (22)	16:46

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	BLOOD	Lymphadenopathy	Supraclavicular adenopathy (left)	29AUG2020 (4)	08:00	23OCT2020 (59)	08:00	56
2	RESP	Tonsillar hypertrophy	swollen tonsils	18SEP2020 (24)	10:30	08OCT2020 (44)	10:00	21

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	TC	N	Resolved (23OCT2020)	NOT RELATED/OTHER: unknown	1	4	Y
2	1	TC	N	Resolved (08OCT2020)	NOT RELATED/OTHER: Unknown	2	3	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	16OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1966	53	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
168 cm	87.1 kg	30.9 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Arterial hypertension	Hypertension	01JUN2012	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	27AUG2020 (1)	16:15
2	BNT162b2	16SEP2020 (21)	15:25

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	BLOOD	Lymphadenopathy	left submandibular adenopathy.	03OCT2020 (38)	12:00	13OCT2020 (48)	08:00	11

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (13OCT2020)	NOT RELATED/OTHER: Unknown	2	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	23OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1955	65	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
149 cm	48.7 kg	21.9 kg/m2	28AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	28AUG2020 (1)	21:15
2	BNT162b2	16SEP2020 (20)	17:54

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	BLOOD	Lymphadenopathy	Left cervical adenopathy	21SEP2020 (25)	09:01	24SEP2020 (28)	08:00	4

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (24SEP2020)	NOT RELATED/OTHER: Unknown	2	6	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	16OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
153 cm	70.55 kg	30.1 kg/m2	29AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29AUG2020 (1)	10:31
2	BNT162b2	17SEP2020 (20)	13:04

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	BLOOD	Lymphadenopathy	Adenopathy in low left cervical region.	19SEP2020 (22)	10:30	23SEP2020 (26)	09:00	5

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (23SEP2020)	NOT RELATED/OTHER: unknown	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
194 cm	135.8 kg	36.1 kg/m2	29AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Gastroesophageal reflux	Gastrooesophageal reflux disease	01AUG2013	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29AUG2020 (1)	18:55
2	BNT162b2	17SEP2020 (20)	16:05

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	MUSC	Arthralgia	Arthralgias	22SEP2020 (25)	13:00	28DEC2020 (122)	11:00	98
2	BLOOD	Lymphadenopathy	Left axillary adenopathy	19SEP2020 (22)	17:00	28DEC2020 (122)	11:00	101

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	N	N	Resolved (28DEC2020)	NOT RELATED/OTHER: unknown	2	6	N
2	1	N	N	Resolved (28DEC2020)	NOT RELATED/OTHER: unknown	2	3	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1980	40	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	65 kg	26 kg/m2	31AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	09:30
2	BNT162b2	19SEP2020 (20)	10:15

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	BLOOD	Lymphadenopathy	Left axillary adenomegaly	20SEP2020 (21)	09:00	25SEP2020 (26)	10:00	6

Adverse Events							
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC	N	Resolved (25SEP2020)	NOT RELATED/OTHER: unknown	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	23OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	48	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	102.65 kg	34.3 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bronchial asthma	Asthma	01JUL1987	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	10:30
2	BNT162b2	19SEP2020 (20)	10:42

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Fatigue	Fatigue	19SEP2020 (20)	21:00	20SEP2020 (21)	17:00	2
2	BLOOD	Lymphadenopathy	Left axillar adenomegaly	20SEP2020 (21)	10:00	26SEP2020 (27)	18:00	7
3	MUSC	Myalgia	generalized myalgia	19SEP2020 (20)	21:00	20SEP2020 (21)	17:00	2

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	TC	N	Resolved (20SEP2020)	NOT RELATED/OTHER: Unknown	2	1	N
2	2	TC	N	Resolved (26SEP2020)	Study Treatment	2	2	Y
3	1	TC	N	Resolved (20SEP2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	52.27 kg	21 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Dyslipidemia	Dyslipidaemia	2015	Present
Allergic Rhinitis	Rhinitis allergic	2015	Present
Contraception	Contraception	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21SEP2020 (1)	14:50
2	Placebo	13OCT2020 (23)	13:15
3	BNT162b2	22DEC2020 (93)	09:37
4	BNT162b2	12JAN2021 (114)	09:31

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	BLOOD	Lymphadenopathy	Bilateral swollen mandibular lymph nodes	15JAN2021 (117)	08:00	ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			2	N	N	Yes	Study Treatment	4	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Fluarix 0.5ml IM	INFLUENZA VACCINE INACT SPLIT 3V	28OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Completed	VACCINATION	12NOV2020	
Completed	REPEAT SCREENING 1	22DEC2020	
Completed	OPEN LABEL TREATMENT	12FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	129.09 kg	39.6 kg/m2	20OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
TOURETTE'S SYNDROME	Tourette's disorder	1973	Present
amenorrhea	Amenorrhoea	2019	Present
Afib-rate controlled	Atrial fibrillation	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20OCT2020 (1)	13:08
2	BNT162b2	11NOV2020 (23)	13:39

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Chills	chills	12NOV2020 (24)	12:00	15NOV2020 (27)	08:00	4	1
2	GENRL	Injection site pain	injection site pain	12NOV2020 (24)	12:00	15NOV2020 (27)	08:00	4	1
3	BLOOD	Lymphadenopathy	Cervical lymphadenopathy, left side	01NOV2020 (13)	06:00	ONGOING			2
4	MUSC	Myalgia	body aches, myalgia	12NOV2020 (24)	20:20	15NOV2020 (27)	08:00	4	1
5	NEOPL	Oropharyngeal squamous cell carcinoma	squamous cell carcinoma of oropharynx	23OCT2020 (4)		ONGOING			3
6	GENRL	Pyrexia	pyrexia	12NOV2020 (24)	12:00	15NOV2020 (27)	08:00	4	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (15NOV2020)	Study Treatment	2	2	N
2	TC	N	Resolved (15NOV2020)	Study Treatment	2	2	N
3	TC	N	Yes	NOT RELATED/OTHER: tooth fracture	1	13	Y
4	TC	N	Resolved (15NOV2020)	Study Treatment	2	2	N
5	TC/TCN	Y	Yes	NOT RELATED/OTHER: human papilloma virus	1	4	Y
6	TC	N	Resolved (15NOV2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Cisplatin	CISPLATIN	01FEB2021	ONGOING	INTRAVENOUS

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20OCT2020	
Completed	VACCINATION	10DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1987	33	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
153 cm	76 kg	32.5 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	2003	Present
Polycystic ovary syndrome	Polycystic ovaries	2005	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12AUG2020 (1)	10:41
2	BNT162b2	02SEP2020 (22)	09:31

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Cystitis	Cystitis	07OCT2020 (57)		14OCT2020 (64)		8	2
2	BLOOD	Lymphadenopathy	Left Axillary lymphadenopathy	03SEP2020 (23)		06SEP2020 (26)		4	1
3	INFEC	Oral candidiasis	Oral thrush	06SEP2020 (26)		11SEP2020 (31)		6	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (14OCT2020)	NOT RELATED/OTHER: Bacterial urinary infection	2	36	N
2	N	N	Resolved (06SEP2020)	Study Treatment	2	2	Y
3	N	N	Resolved (11SEP2020)	Study Treatment	2	5	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
151.5 cm	77.1 kg	33.6 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Systemic arterial hypertension	Hypertension	1993	Present
allergic rhinitis	Rhinitis allergic	2000	Present
Osteoarthritis	Osteoarthritis	2005	Present
Hysterectomy	Hysterectomy	2006	Past
Benign thyroid nodules	Benign neoplasm of thyroid gland	OCT2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	10:46
2	Placebo	04SEP2020 (22)	09:19
3	BNT162b2	29JAN2021 (169)	09:47
4	BNT162b2	19FEB2021 (190)	09:50

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Fatigue	Fatigue	20FEB2021 (191)		22FEB2021 (193)	
2	GENRL	Fatigue	Prostration	20FEB2021 (191)		22FEB2021 (193)	
3	GENRL	Injection site pain	Injection site pain	30JAN2021 (170)		02FEB2021 (173)	
4	BLOOD	Lymphadenopathy	Left axillary lymph node enlargement	20FEB2021 (191)		22FEB2021 (193)	
5	MUSC	Myalgia	Myalgia	30JAN2021 (170)		02FEB2021 (173)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	1	TC	N	Resolved (22FEB2021)	Study Treatment	4	2	N
2	3	1	TC	N	Resolved (22FEB2021)	Study Treatment	4	2	N
3	4	1	N	N	Resolved (02FEB2021)	Study Treatment	3	2	N
4	3	1	N	N	Resolved (22FEB2021)	Study Treatment	4	2	Y
5	4	1	TC	N	Resolved (02FEB2021)	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	02OCT2020	
Completed	REPEAT SCREENING 1	29JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	109 kg	37.7 kg/m2	17AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	21:23
2	Placebo	08SEP2020 (23)	16:27

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	22JAN2021 (159)	11:10
4	BNT162b2	10FEB2021 (178)	10:46

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Chills	Chills	22JAN2021 (159)	18:00	23JAN2021 (160)		2	1
2	GENRL	Fatigue	Fatigue	22JAN2021 (159)	18:00	23JAN2021 (160)		2	1
3	GENRL	Fatigue	Fatigue	10FEB2021 (178)	22:00	12FEB2021 (180)		3	2
4	GENRL	Injection site pain	Injection site pain	22JAN2021 (159)	18:00	24JAN2021 (161)		3	2
5	GENRL	Injection site pain	Injection site pain	10FEB2021 (178)	22:00	12FEB2021 (180)		3	2
6	INJ&P	Ligament sprain	Left ankle sprain	24SEP2020 (39)		30SEP2020 (45)		7	2
7	BLOOD	Lymphadenopathy	Ipsilateral axillary lymphadenopathy	22JAN2021 (159)	18:00	24JAN2021 (161)		3	2
8	MUSC	Myalgia	Myalgia	10FEB2021 (178)	22:00	12FEB2021 (180)		3	2
9	GENRL	Pyrexia	Fever	10FEB2021 (178)	22:00	12FEB2021 (180)		3	2
10	INFEC	Tooth infection	Dental inflammation	28SEP2020 (43)		12OCT2020 (57)		15	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (23JAN2021)	Study Treatment	3	1	N
2	N	N	Resolved (23JAN2021)	Study Treatment	3	1	N

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	N	N	Resolved (12FEB2021)	Study Treatment	4	1	N
4	N	N	Resolved (24JAN2021)	Study Treatment	3	1	N
5	N	N	Resolved (12FEB2021)	Study Treatment	4	1	N
6	TC	N	Resolved (30SEP2020)	NOT RELATED/OTHER: Physical activity	2	17	N
7	N	N	Resolved (24JAN2021)	Study Treatment	3	1	Y
8	N	N	Resolved (12FEB2021)	Study Treatment	4	1	N
9	N	N	Resolved (12FEB2021)	Study Treatment	4	1	N
10	TC	N	Resolved (12OCT2020)	NOT RELATED/OTHER: Bacterial tooth abscess	2	21	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
Completed	REPEAT SCREENING 1	22JAN2021	
Completed	OPEN LABEL TREATMENT	10MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	23	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	59.9 kg	23.4 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
dysmenorrhea	Dysmenorrhoea	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	13:10
2	Placebo	10SEP2020 (22)	18:28

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
3	BNT162b2	01FEB2021 (166)	09:17
4	BNT162b2	22FEB2021 (187)	09:57

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Fatigue	Fatigue	22FEB2021 (187)	20:00	23FEB2021 (188)		2
2	NERV	Headache	Headache	09SEP2020 (21)		09SEP2020 (21)		1
3	NERV	Headache	Headache	03FEB2021 (168)		06FEB2021 (171)		4
4	NERV	Headache	Headache	22FEB2021 (187)	20:00	23FEB2021 (188)		2
5	GENRL	Injection site pain	Injection site pain	01FEB2021 (166)	23:00	02FEB2021 (167)		2
6	BLOOD	Lymphadenopathy	Left axillary lymphadenopathy	02FEB2021 (167)		04FEB2021 (169)		3
7	GENRL	Pyrexia	Fever	22FEB2021 (187)	20:00	23FEB2021 (188)		2

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	TC	N	Resolved (23FEB2021)	Study Treatment	4	1	N
2	1	TC	N	Resolved (09SEP2020)	NOT RELATED/OTHER: Stress	1	21	N
3	1	TC	N	Resolved (06FEB2021)	Study Treatment	3	3	N
4	1	TC	N	Resolved (23FEB2021)	Study Treatment	4	1	N
5	1	N	N	Resolved (02FEB2021)	Study Treatment	3	1	N

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
6	1	N	N	Resolved (04FEB2021)	Study Treatment	3	2	Y
7	1	TC	N	Resolved (23FEB2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	08OCT2020	
Completed	REPEAT SCREENING 1	01FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	33	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	89 kg	33.9 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
headache	Headache	11AUG2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	19:17
2	Placebo	09SEP2020 (21)	14:21

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	22JAN2021 (156)	17:16
4	BNT162b2	10FEB2021 (175)	14:02

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	REPRO	Dysmenorrhoea	dysmenorrhea	05SEP2020 (17)		05SEP2020 (17)		1	1
2	GENRL	Injection site pain	Injection site pain	23JAN2021 (157)		23JAN2021 (157)		1	1
3	GENRL	Injection site pain	Injection site pain	11FEB2021 (176)		12FEB2021 (177)		2	1
4	BLOOD	Lymphadenopathy	Lymph node enlargement in the left armpit	11FEB2021 (176)		13FEB2021 (178)		3	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	N	Resolved (05SEP2020)	NOT RELATED/OTHER: menstrual period	1	17	N
2	N	N	Resolved (23JAN2021)	Study Treatment	3	2	N
3	TC	N	Resolved (12FEB2021)	Study Treatment	4	2	N
4	TC	N	Resolved (13FEB2021)	Study Treatment	4	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	09OCT2020	
Completed	REPEAT SCREENING 1	22JAN2021	
Completed	OPEN LABEL TREATMENT	10MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
155 cm	73.3 kg	30.5 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Shellfish allergy	Food allergy	2013	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	09:33
2	Placebo	14SEP2020 (22)	10:21

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	25JAN2021 (155)	15:29
4	BNT162b2	15FEB2021 (176)	13:49

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Headache	Headache	26JAN2021 (156)		27JAN2021 (157)	
2	GENRL	Injection site pain	Injection site pain	26JAN2021 (156)		29JAN2021 (159)	
3	GENRL	Injection site pain	Injection site pain	16FEB2021 (177)		19FEB2021 (180)	
4	BLOOD	Lymphadenopathy	Left axillary lymph node enlargement	26JAN2021 (156)		29JAN2021 (159)	
5	BLOOD	Lymphadenopathy	Left axillary lymphadenopathy	16FEB2021 (177)		19FEB2021 (180)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	TC	N	Resolved (27JAN2021)	Study Treatment	3	2	N
2	4	1	N	N	Resolved (29JAN2021)	Study Treatment	3	2	N
3	4	1	N	N	Resolved (19FEB2021)	Study Treatment	4	2	N
4	4	1	N	N	Resolved (29JAN2021)	Study Treatment	3	2	Y
5	4	1	N	N	Resolved (19FEB2021)	Study Treatment	4	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	25JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.5 cm	69.7 kg	25.4 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cholecystectomy	Cholecystectomy	MAY2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	09:07
2	Placebo	15SEP2020 (22)	09:00

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	25JAN2021 (154)	11:10
4	BNT162b2	15FEB2021 (175)	09:07

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Chills	25JAN2021 (154)	20:00	26JAN2021 (155)	
2	GENRL	Injection site pain	Injection site pain	25JAN2021 (154)	20:00	26JAN2021 (155)	
3	GENRL	Injection site pain	Injection site pain	16FEB2021 (176)		18FEB2021 (178)	
4	BLOOD	Lymphadenopathy	Left axillary lymphadenopathy	16FEB2021 (176)		20FEB2021 (180)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (26JAN2021)	Study Treatment	3	1	N
2	2	1	N	N	Resolved (26JAN2021)	Study Treatment	3	1	N
3	3	1	N	N	Resolved (18FEB2021)	Study Treatment	4	2	N
4	5	1	N	N	Resolved (20FEB2021)	Study Treatment	4	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	13OCT2020	
Completed	REPEAT SCREENING 1	25JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.5 cm	63.9 kg	23.6 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Headache	Headache	20AUG2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	09:57
2	BNT162b2	15SEP2020 (22)	09:50

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Chills	Chills	15SEP2020 (22)	18:00	18SEP2020 (25)		4
2	GENRL	Fatigue	Fatigue	15SEP2020 (22)	18:00	18SEP2020 (25)		4
3	NERV	Headache	Headache	15SEP2020 (22)	18:00	18SEP2020 (25)		4
4	GENRL	Injection site pain	Injection site pain	15SEP2020 (22)	12:00	21SEP2020 (28)		7
5	GENRL	Injection site swelling	Injection site swelling	15SEP2020 (22)	12:00	21SEP2020 (28)		7
6	BLOOD	Lymphadenopathy	Reactive axillary lymph node in the left arm	16SEP2020 (23)		26SEP2020 (33)		11
7	INFEC	Mumps	Left mumps	FEB2021 ()		ONGOING		
8	MUSC	Myalgia	Myalgia	15SEP2020 (22)	18:00	18SEP2020 (25)		4
9	GASTR	Nausea	Nausea	15SEP2020 (22)	18:00	18SEP2020 (25)		4
10	GENRL	Pyrexia	Fever	15SEP2020 (22)	18:00	18SEP2020 (25)		4
11	GENRL	Injection site pain	Injection site pain	25AUG2020 (1)	09:58	26AUG2020 (2)		2

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC	N	Resolved (18SEP2020)	Study Treatment	2	1	N
2	2	TC	N	Resolved (18SEP2020)	Study Treatment	2	1	N
3	2	TC	N	Resolved (18SEP2020)	Study Treatment	2	1	N
4	2	TC	N	Resolved (21SEP2020)	Study Treatment	2	1	N
5	2	TC	N	Resolved (21SEP2020)	Study Treatment	2	1	N
6	2	TC	N	Resolved (26SEP2020)	Study Treatment	2	2	Y

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
7	1	N	N	Yes	NOT RELATED/OTHER: Sjogren syndrome	2		N
8	2	TC	N	Resolved (18SEP2020)	Study Treatment	2	1	N
9	2	TC	N	Resolved (18SEP2020)	Study Treatment	2	1	N
10	2	TC	N	Resolved (18SEP2020)	Study Treatment	2	1	N
11	1	N	N	Resolved (26AUG2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	13OCT2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	28	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	55.6 kg	22.6 kg/m2	25AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	15:36
2	Placebo	15SEP2020 (22)	13:24

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	25JAN2021 (154)	11:14
4	BNT162b2	15FEB2021 (175)	09:50

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	Left axillary lymph node enlargement	16FEB2021 (176)		18FEB2021 (178)	
2	MUSC	Myalgia	Myalgia	16FEB2021 (176)		18FEB2021 (178)	
3	GENRL	Pyrexia	Fever	16FEB2021 (176)		18FEB2021 (178)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	1	N	N	Resolved (18FEB2021)	Study Treatment	4	2	Y
2	3	1	N	N	Resolved (18FEB2021)	Study Treatment	4	2	N
3	3	1	N	N	Resolved (18FEB2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	16OCT2020	
Completed	REPEAT SCREENING 1	25JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	55	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	76.5 kg	28.4 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic rhinitis	Rhinitis allergic	1990	Present
Hemorrhoidectomy	Haemorrhoid operation	1995	Past
Menopause	Menopause	2018	Present
Lower Limb Varicose Veins	Varicose vein	MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	18:37
2	Placebo	22SEP2020 (21)	14:58
3	BNT162b2	01FEB2021 (153)	12:06
4	BNT162b2	22FEB2021 (174)	10:48

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Diarrhoea	Diarrhea	25SEP2020 (24)		30SEP2020 (29)	
2	GENRL	Fatigue	Fatigue	23FEB2021 (175)		24FEB2021 (176)	
3	GENRL	Injection site pain	Injection site pain	01FEB2021 (153)	18:00	05FEB2021 (157)	
4	BLOOD	Lymphadenopathy	Left axillary lymph node enlargement	22FEB2021 (174)	17:00	26FEB2021 (178)	
5	GENRL	Pyrexia	Fever	26SEP2020 (25)		26SEP2020 (25)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	6	1	TC	N	Resolved (30SEP2020)	Study Treatment	2	4	N
2	2	1	N	N	Resolved (24FEB2021)	Study Treatment	4	2	N
3	5	1	N	N	Resolved (05FEB2021)	Study Treatment	3	1	N
4	5	1	N	N	Resolved (26FEB2021)	Study Treatment	4	1	Y
5	1	1	N	N	Resolved (26SEP2020)	Study Treatment	2	5	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	20OCT2020	
Completed	REPEAT SCREENING 1	01FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	28	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	65.5 kg	25.6 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Endometriosis	Endometriosis	2007	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	19:27
2	Placebo	22SEP2020 (21)	11:33

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	27JAN2021 (148)	13:21
4	BNT162b2	17FEB2021 (169)	11:53

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Headache	Headache	18FEB2021 (170)		20FEB2021 (172)	
2	GENRL	Injection site pain	Injection site pain	04SEP2020 (3)		04SEP2020 (3)	
3	BLOOD	Lymphadenopathy	Right axillary lymph node enlargement	18FEB2021 (170)		20FEB2021 (172)	
4	GENRL	Pyrexia	Fever	18FEB2021 (170)		20FEB2021 (172)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	1	N	N	Resolved (20FEB2021)	Study Treatment	4	2	N
2	1	1	N	N	Resolved (04SEP2020)	Study Treatment	1	3	N
3	3	1	N	N	Resolved (20FEB2021)	Study Treatment	4	2	Y
4	3	1	TC	N	Resolved (20FEB2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	20OCT2020	
Completed	REPEAT SCREENING 1	27JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182 cm	98.7 kg	29.8 kg/m2	17SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	1981	Past
Allergic rhinitis	Rhinitis allergic	MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17SEP2020 (1)	20:23
2	BNT162b2	06OCT2020 (20)	09:42

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site pain	Injection site pain	18SEP2020 (2)		20SEP2020 (4)	
2	GENRL	Injection site pain	Injection site pain	06OCT2020 (20)	23:00	09OCT2020 (23)	
3	BLOOD	Lymphadenopathy	Axillary lymph nodes enlargement in left arm	06OCT2020 (20)	23:00	09OCT2020 (23)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	1	N	N	Resolved (20SEP2020)	Study Treatment	1	2	N
2	4	1	TC	N	Resolved (09OCT2020)	Study Treatment	2	1	N
3	4	1	TC	N	Resolved (09OCT2020)	Study Treatment	2	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17SEP2020	
Completed	VACCINATION	03NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	75.8 kg	26.5 kg/m2	18SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Systemic arterial hypertension	Hypertension	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18SEP2020 (1)	17:22
2	Placebo	09OCT2020 (22)	18:38

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	25JAN2021 (130)	17:24
4	BNT162b2	15FEB2021 (151)	15:57

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Fatigue	Fatigue	16FEB2021 (152)		17FEB2021 (153)	
2	NERV	Headache	Headache	15FEB2021 (151)	17:00	16FEB2021 (152)	
3	BLOOD	Lymphadenopathy	Left axillary lymphadenopathy	17FEB2021 (153)		19FEB2021 (155)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (17FEB2021)	Study Treatment	4	2	N
2	2	1	TC	N	Resolved (16FEB2021)	Study Treatment	4	1	N
3	3	1	TC	N	Resolved (19FEB2021)	Study Treatment	4	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18SEP2020	
Completed	VACCINATION	06NOV2020	
Completed	REPEAT SCREENING 1	25JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	31	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159 cm	79.1 kg	31.3 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Right eye pterygium	Pterygium	2000	Present
Surgery of anal fistula	Anorectal operation	2012	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21SEP2020 (1)	09:19
2	BNT162b2	13OCT2020 (23)	09:50

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Diarrhoea	Diarrhea	22SEP2020 (2)		22SEP2020 (2)	
2	GENRL	Fatigue	Fatigue	13OCT2020 (23)	21:00	15OCT2020 (25)	
3	NERV	Headache	Headache	21SEP2020 (1)	15:00	22SEP2020 (2)	
4	NERV	Headache	Headache	13OCT2020 (23)	21:00	15OCT2020 (25)	
5	GENRL	Injection site pain	Injection site pain	21SEP2020 (1)	15:00	22SEP2020 (2)	
6	GENRL	Injection site pain	Injection site pain	13OCT2020 (23)	21:00	15OCT2020 (25)	
7	BLOOD	Lymphadenopathy	Reactional Left axillary lymph node	14OCT2020 (24)		15OCT2020 (25)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	N	N	Resolved (22SEP2020)	Study Treatment	1	2	N
2	3	2	TC	N	Resolved (15OCT2020)	Study Treatment	2	1	N
3	2	1	N	N	Resolved (22SEP2020)	Study Treatment	1	1	N
4	3	2	TC	N	Resolved (15OCT2020)	Study Treatment	2	1	N
5	2	1	N	N	Resolved (22SEP2020)	Study Treatment	1	1	N
6	3	2	TC	N	Resolved (15OCT2020)	Study Treatment	2	1	N
7	2	1	N	N	Resolved (15OCT2020)	Study Treatment	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21SEP2020	
Completed	VACCINATION	10NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	42	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	75.4 kg	27.4 kg/m2	30SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic rhinitis	Rhinitis allergic	1988	Present
Unilateral salpingectomy	Salpingectomy	2010	Past
Lactose intolerance	Lactose intolerance	2017	Present
Anxiety disorder	Anxiety disorder	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30SEP2020 (1)	11:17
2	BNT162b2	23OCT2020 (24)	10:35

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	BLOOD	Lymphadenopathy	Left axillary lymph node enlargement	25OCT2020 (26)		27OCT2020 (28)		3	1
2	GASTR	Odynophagia	Odinophagy	13OCT2020 (14)		16OCT2020 (17)		4	1
3	GENRL	Pyrexia	Fever	24OCT2020 (25)		25OCT2020 (26)		2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (27OCT2020)	Study Treatment	2	3	Y
2	N	N	Resolved (16OCT2020)	NOT RELATED/OTHER: Infection of upper airways	1	14	N
3	N	N	Resolved (25OCT2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30SEP2020	
Completed	VACCINATION	20NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171 cm	72.5 kg	24.8 kg/m2	30SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30SEP2020 (1)	16:22
2	Placebo	23OCT2020 (24)	14:58

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	03FEB2021 (127)	15:23
4	BNT162b2	24FEB2021 (148)	15:03

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Fatigue	Fatigue	25FEB2021 (149)		28FEB2021 (152)	
2	GENRL	Injection site pain	Injection site pain	25FEB2021 (149)		28FEB2021 (152)	
3	BLOOD	Lymphadenopathy	Left axillary lymphadenopathy	26FEB2021 (150)		03MAR2021 (155)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	1	N	N	Resolved (28FEB2021)	Study Treatment	4	2	N
2	4	1	N	N	Resolved (28FEB2021)	Study Treatment	4	2	N
3	6	1	N	N	Resolved (03MAR2021)	Study Treatment	4	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30SEP2020	
Completed	VACCINATION	20NOV2020	
Completed	REPEAT SCREENING 1	03FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	38	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184 cm	91 kg	26.9 kg/m2	02OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic rhinitis	Rhinitis allergic	1986	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02OCT2020 (1)	10:47
2	BNT162b2	26OCT2020 (25)	10:25

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Fatigue	Fatigue	26OCT2020 (25)	18:00	27OCT2020 (26)	08:00
2	BLOOD	Lymphadenopathy	Left axillary lymph node enlargement	28OCT2020 (27)		29OCT2020 (28)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	2	TC	N	Resolved (27OCT2020)	Study Treatment	2	1	N
2	2	1	N	N	Resolved (29OCT2020)	Study Treatment	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02OCT2020	
Completed	VACCINATION	23NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	62 kg	24.8 kg/m2	02OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Breast nodule removal	Breast conserving surgery	2007	Past
Hypothyroidism	Hypothyroidism	15FEB2020	Present
Total thyroidectomy	Thyroidectomy	15FEB2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02OCT2020 (1)	10:56
2	Placebo	21OCT2020 (20)	15:21
3	BNT162b2	05FEB2021 (127)	12:04
4	BNT162b2	26FEB2021 (148)	11:27

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Fatigue	Fatigue	06FEB2021 (128)		07FEB2021 (129)	
2	NERV	Headache	Headache	03OCT2020 (2)		03OCT2020 (2)	
3	NERV	Headache	Headache	06FEB2021 (128)		07FEB2021 (129)	
4	BLOOD	Lymphadenopathy	Left armpit lifoadenomegaly	06FEB2021 (128)		07FEB2021 (129)	
5	MUSC	Myalgia	Myalgia	06FEB2021 (128)		07FEB2021 (129)	
6	GENRL	Pyrexia	Fever	06FEB2021 (128)		07FEB2021 (129)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (07FEB2021)	Study Treatment	3	2	N
2	1	1	N	N	Resolved (03OCT2020)	Study Treatment	1	2	N
3	2	1	N	N	Resolved (07FEB2021)	Study Treatment	3	2	N
4	2	1	N	N	Resolved (07FEB2021)	Study Treatment	3	2	Y

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	2	1	N	N	Resolved (07FEB2021)	Study Treatment	3	2	N
6	2	1	TC	N	Resolved (07FEB2021)	Study Treatment	3	2	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02OCT2020	
Completed	VACCINATION	18NOV2020	
Completed	REPEAT SCREENING 1	05FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	90 kg	32.3 kg/m2	14OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sulfa allergy	Drug hypersensitivity	1984	Present
Non-steroidal anti-inflammatory allergy	Drug hypersensitivity	1984	Present
Dipyrone allergy	Drug hypersensitivity	1984	Present
Allergy Acetyl salicylic acid	Drug hypersensitivity	1984	Present
Allergic rhinitis	Rhinitis allergic	1984	Present
Psoriasis	Psoriasis	1985	Present
Prosthesis insertion in left arm	Prosthesis implantation	2016	Past
Uterine fibroid	Uterine leiomyoma	2019	Past
Hysterectomy	Hysterectomy	OCT2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14OCT2020 (1)	15:54
2	BNT162b2	04NOV2020 (22)	12:50

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	chills	05NOV2020 (23)		06NOV2020 (24)	
2	GENRL	Fatigue	Fatigue	05NOV2020 (23)		06NOV2020 (24)	
3	BLOOD	Lymphadenopathy	Left armpit lymph node enlargement	15OCT2020 (2)		16OCT2020 (3)	
4	GENRL	Medical device pain	Pain in prosthesis in the left hand	15OCT2020 (2)		30OCT2020 (17)	
5	GENRL	Medical device pain	Pain in prosthesis in the left hand	05NOV2020 (23)		07NOV2020 (25)	
6	GENRL	Pyrexia	Fever	05NOV2020 (23)		06NOV2020 (24)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (06NOV2020)	Study Treatment	2	2	N
2	2	1	N	N	Resolved (06NOV2020)	Study Treatment	2	2	N
3	2	1	N	N	Resolved (16OCT2020)	Study Treatment	1	2	Y

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	16	1	N	N	Resolved (30OCT2020)	Study Treatment	1	2	N
5	3	1	N	N	Resolved (07NOV2020)	Study Treatment	2	2	N
6	2	1	N	N	Resolved (06NOV2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14OCT2020	
Completed	VACCINATION	03DEC2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	39	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	85 kg	30.1 kg/m2	05OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05OCT2020 (1)	12:12
2	BNT162b2	26OCT2020 (22)	10:58

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	BLOOD	Lymphadenopathy	Left axilla Lymphadenopathy	27OCT2020 (23)		04NOV2020 (31)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	9	1	N	N	Resolved (04NOV2020)	Study Treatment	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05OCT2020	
Completed	VACCINATION	23NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	109 kg	40.5 kg/m2	08OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Temporal lobe Epilepsy	Temporal lobe epilepsy	2001	Present
Bilateral tubal ligation Sterilized	Female sterilisation	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	08OCT2020 (1)	09:38
2	BNT162b2	28OCT2020 (21)	11:09

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	MUSC	Arthralgia	Generalized Joint pain	29OCT2020 (22)		29OCT2020 (22)	
2	MUSC	Arthralgia	Generalized Joint pain	30OCT2020 (23)		ONGOING	
3	GASTR	Diarrhoea	Diarrhea	09OCT2020 (2)		10OCT2020 (3)	
4	GENRL	Fatigue	Fatigue	13OCT2020 (6)	15:00	14OCT2020 (7)	05:00
5	NERV	Headache	Headaches	29OCT2020 (22)		29OCT2020 (22)	
6	GENRL	Injection site pain	Injection Pain	13OCT2020 (6)	15:00	14OCT2020 (7)	
7	BLOOD	Lymphadenopathy	Left axillary lymphadenopathy	29OCT2020 (22)		02NOV2020 (26)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	2	N	N	Resolved (29OCT2020)	Study Treatment	2	2	N
2		2	TC	N	Yes	Study Treatment	2	3	N
3	2	1	N	N	Resolved (10OCT2020)	Study Treatment	1	2	N
4	2	1	N	N	Resolved (14OCT2020)	Study Treatment	1	6	N
5	1	2	TC	N	Resolved (29OCT2020)	Study Treatment	2	2	N

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
6	2	1	N	N	Resolved (14OCT2020)	Study Treatment	1	6	N
7	5	1	N	N	Resolved (02NOV2020)	Study Treatment	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08OCT2020	
Completed	VACCINATION	30NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	70.31 kg	25.8 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin allergy	Drug hypersensitivity	1976	Present
myopia	Myopia	1990	Present
heartburn	Dyspepsia	2017	Present
anxiety	Anxiety	2018	Present
depression	Depression	2018	Present
left breast biopsy	Biopsy breast	SEP2019	Past
left breast tumor	Breast neoplasm	SEP2019	Past
urinary tract infections intermittent	Urinary tract infection	OCT2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	15:24
2	Placebo	29SEP2020 (22)	14:42
3	BNT162b2	30JAN2021 (145)	12:42
4	BNT162b2	20FEB2021 (166)	12:20

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site pain	Soreness at injection site	31JAN2021 (146)		01FEB2021 (147)	
2	BLOOD	Lymphadenopathy	Bilateral swollen lymph nodes	21FEB2021 (167)		22FEB2021 (168)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (01FEB2021)	Study Treatment	3	2	N
2	2	2	TC	N	Resolved (22FEB2021)	Study Treatment	4	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	27OCT2020	
Completed	REPEAT SCREENING 1	30JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	26	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.28 cm	61.18 kg	19.6 kg/m2	28AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	13:52
2	Placebo	17SEP2020 (21)	13:10

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
3	BNT162b2	31DEC2020 (126)	10:14
4	BNT162b2	22JAN2021 (148)	16:02

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Fatigue	fatigue	28AUG2020 (1)	18:05	29AUG2020 (2)	18:03
2	GENRL	Fatigue	fatigue	23JAN2021 (149)	07:00	23JAN2021 (149)	12:00
3	NERV	Headache	headache	01JAN2021 (127)	08:00	01JAN2021 (127)	12:00
4	GENRL	Injection site pain	soreness at the injection site	01JAN2021 (127)	08:00	01JAN2021 (127)	12:00
5	BLOOD	Lymphadenopathy	lymph node swelling in left armpit	22JAN2021 (148)	18:00	23JAN2021 (149)	07:00
6	GENRL	Malaise	malaise	23JAN2021 (149)	07:00	23JAN2021 (149)	12:00

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	2	N	N	Resolved (29AUG2020)	Study Treatment	1	1	N
2	1	1	TC	N	Resolved (23JAN2021)	Study Treatment	4	2	N
3	1	1	TC	N	Resolved (01JAN2021)	Study Treatment	3	2	N
4	1	1	TC	N	Resolved (01JAN2021)	Study Treatment	3	2	N
5	2	1	TC	N	Resolved (23JAN2021)	Study Treatment	4	1	Y
6	1	1	N	N	Resolved (23JAN2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccination	INFLUENZA VACCINE	01OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	16OCT2020	
Completed	REPEAT SCREENING 1	31DEC2020	
Completed	OPEN LABEL TREATMENT	26FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	42	Black or African American	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.1 cm	76.2 kg	24.9 kg/m2	17SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17SEP2020 (1)	12:23
2	Placebo	06OCT2020 (20)	11:08

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	21DEC2020 (96)	10:38
4	BNT162b2	12JAN2021 (118)	11:20

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Fatigue	fatigue	21DEC2020 (96)	12:00	24DEC2020 (99)	12:00
2	NERV	Headache	headache	12JAN2021 (118)	20:00	14JAN2021 (120)	08:00
3	GENRL	Injection site erythema	redness at injection site	21DEC2020 (96)	12:00	22DEC2020 (97)	00:00
4	GENRL	Injection site pain	pain at the injection site	21DEC2020 (96)	12:00	22DEC2020 (97)	00:00
5	BLOOD	Lymphadenopathy	bilateral enlarged lymph nodes in neck	22DEC2020 (97)	06:00	23DEC2020 (98)	06:00
6	GENRL	Malaise	malaise	21DEC2020 (96)	12:00	22DEC2020 (97)	00:00
7	GENRL	Pain	achiness - generalized	18SEP2020 (2)	10:00	18SEP2020 (2)	18:00
8	GENRL	Pain	body aches generalized	12JAN2021 (118)	20:00	14JAN2021 (120)	08:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	1	N	N	Resolved (24DEC2020)	Study Treatment	3	1	N
2	3	1	TC	N	Resolved (14JAN2021)	Study Treatment	4	1	N
3	2	1	N	N	Resolved (22DEC2020)	Study Treatment	3	1	N
4	2	1	N	N	Resolved (22DEC2020)	Study Treatment	3	1	N

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	2	1	N	N	Resolved (23DEC2020)	Study Treatment	3	2	Y
6	2	1	N	N	Resolved (22DEC2020)	Study Treatment	3	1	N
7	1	1	N	N	Resolved (18SEP2020)	Study Treatment	1	2	N
8	3	1	TC/TCN	N	Resolved (14JAN2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Influenza vaccine	INFLUENZA VACCINE	29OCT2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17SEP2020	
Completed	VACCINATION	03NOV2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	REPEAT SCREENING 1	21DEC2020	
Completed	OPEN LABEL TREATMENT	08FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	49	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.7 cm	122.9 kg	42.2 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Back surgery	Spinal operation	2009	Past
Hypertension (Chronic)	Hypertension	11DEC2017	Present
Obesity	Obesity	11DEC2017	Present
Low Back Pain	Back pain	04APR2018	Present
Iron Deficiency Anemia	Iron deficiency anaemia	04APR2018	Present
Cystoscopy	Cystoscopy	07DEC2018	Past
Laparoscopic Hysterectomy	Hysterectomy	07DEC2018	Past
Laparoscopic Salpingectomy	Salpingectomy	07DEC2018	Past
Reactive Airway Disease (Chronic)	Bronchial hyperreactivity	07APR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21SEP2020 (1)	11:38
2	BNT162b2	13OCT2020 (23)	10:15

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	Sore and swollen underarm lymph node (both arms)	14OCT2020 (24)		15OCT2020 (25)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (15OCT2020)	Study Treatment	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flulaval Quadrivalent Influenza Vaccination	INFLUENZA VACCINE INACT SPLIT 4V	16NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Completed	VACCINATION	16NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	Native Hawaiian or Other Pacific Islander	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.6 cm	67.1 kg	23.9 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Central Serous Choroidopathy	Chorioretinopathy	17FEB2009	Present
Dyslipidemia	Dyslipidaemia	06MAR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21SEP2020 (1)	14:07
2	BNT162b2	12OCT2020 (22)	16:14

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	Swollen left superficial cervical lymph node	22SEP2020 (2)	07:00	23SEP2020 (3)	07:00
2	GENRL	Pyrexia	Fever	13OCT2020 (23)		14OCT2020 (24)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (23SEP2020)	Study Treatment	1	2	Y
2	2	1	N	N	Resolved (14OCT2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21SEP2020	
Completed	VACCINATION	12NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
192 cm	79.2 kg	21.5 kg/m2	23SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23SEP2020 (1)	17:30
2	Placebo	16OCT2020 (24)	09:49
3	BNT162b2	09MAR2021 (168)	13:15

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Application site rash	Rash in the arm contralateral to the application of the research product	23SEP2020 (1)	20:00	23SEP2020 (1)	23:00	1
2	BLOOD	Lymphadenopathy	Right axillary adenopathy	10MAR2021 (169)	15:59	ONGOING		

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (23SEP2020)	Study Treatment	1	1	N
2	1	N	N	Yes	NOT RELATED/OTHER: unknown	3	2	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23SEP2020	
Completed	VACCINATION	13NOV2020	
Completed	REPEAT SCREENING 1	09MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	76.8 kg	26.6 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety disorder	Anxiety disorder	13JUN2018	Present
Depressive disorder	Depression	25AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25SEP2020 (1)	17:25
2	BNT162b2	14OCT2020 (20)	16:30

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	left axillary adenopathy	15OCT2020 (21)	08:00	18OCT2020 (24)	08:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	1	N	N	Resolved (18OCT2020)	Study Treatment	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
Completed	VACCINATION	11NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
189.5 cm	101.1 kg	28.2 kg/m2	29JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
pectus excavatum	Pectus excavatum	1964	Past
Hernia, inguinal, left	Inguinal hernia	1979	Past
osteoarthritis	Osteoarthritis	1994	Present
Hernia, inguinal, right	Inguinal hernia	1997	Past
Torn Anterior cruciate ligament	Ligament rupture	DEC2000	Past
appendicitis	Appendicitis	JUN2004	Past
bilateral cataracts	Cataract	2013	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29JUL2020 (1)	13:15
2	BNT162b2	19AUG2020 (22)	13:00

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Chest pain	Chest Pain	10JAN2021 (166)	12:09	15JAN2021 (171)		6	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (15JAN2021)	NOT RELATED/OTHER: cardiac ischemia	2	145	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
flu vaccine	INFLUENZA VACCINE	14SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29JUL2020	
Completed	VACCINATION	21SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	62.6 kg	23 kg/m2	30JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
dyslipidemia	Dyslipidaemia	2000	Present
hypertension	Hypertension	2000	Present
seasonal allergies	Seasonal allergy	2017	Present
osteoarthritis	Osteoarthritis	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30JUL2020 (1)	12:04
2	Placebo	18AUG2020 (20)	11:19
3	BNT162b2	20JAN2021 (175)	12:15
4	BNT162b2	08FEB2021 (194)	12:21

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	SKIN	Dermatitis	Dermatitis of trunk	25AUG2020 (27)		03SEP2020 (36)		10	2
2	SKIN	Dermatitis contact	poison ivy	11AUG2020 (13)		31AUG2020 (33)		21	2
3	INJ&P	Fall	fall	12DEC2020 (136)		12DEC2020 (136)		1	2
4	INJ&P	Foot fracture	R 5th metatarsal fracture	12DEC2020 (136)		ONGOING			2
5	INJ&P	Radius fracture	L radial head fracture	12DEC2020 (136)		ONGOING			2
6	MUSC	Trigger finger	R pinky finger trigger finger	01JAN2021 (156)		ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (03SEP2020)	NOT RELATED/OTHER: poison ivy	2	8	N
2	TC	N	Resolved (31AUG2020)	NOT RELATED/OTHER: exposure to poison ivy	1	13	N
3	N	N	Resolved (12DEC2020)	NOT RELATED/OTHER: fall	2	117	N
4	TC/TCN	Y	Yes	NOT RELATED/OTHER: Participant tripped and fell down	2	117	Y

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	TC/TCN	Y	Yes	NOT RELATED/OTHER: Participant tripped and fell down	2	117	Y
6	TCN	N	Yes	NOT RELATED/OTHER: R pinky finger trigger finger	2	137	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30JUL2020	
Completed	VACCINATION	22SEP2020	
Completed	REPEAT SCREENING 1	20JAN2021	
Completed	OPEN LABEL TREATMENT	08MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	70 kg	24.1 kg/m2	12JUN2020 (-12)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Wears Glasses	Corrective lens user	1982	Present
Deviated Septum - Nasal Surgery	Nasal septal operation	2010	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24JUN2020 (1)	11:32
2	BNT162b2	15JUL2020 (22)	09:46

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Neuritis	neuritis	29JUL2020 (36)		ONGOING		
2	MUSC	Pain in extremity	right arm pain	29JUL2020 (36)	09:40	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Yes	NOT RELATED/OTHER: related to study blood draw	2	15	Y
2	2	N	N	Yes	NOT RELATED/OTHER: unknown	2	15	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12JUN2020	
Completed	VACCINATION	19AUG2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	71.82 kg	22 kg/m2	30JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	2000	Present
Osteoarthritis	Osteoarthritis	2000	Present
Interstitial Lung Disease	Interstitial lung disease	2017	Present
Seasonal Allergies	Seasonal allergy	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30JUL2020 (1)	13:55
2	Placebo	20AUG2020 (22)	13:04

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INV	Autoantibody positive	positive autoantibody status	20OCT2020 (83)		ONGOING			3
2	RESP	Interstitial lung disease	worsening of interstitial lung disease	17OCT2020 (80)		ONGOING			4
3	RESP	Respiratory failure	respiratory failure	11JAN2021 (166)		ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	N	Yes	NOT RELATED/OTHER: possible scleroderma	2	62	N
2	TC/TCN	Y	Yes	NOT RELATED/OTHER: worsening of interstitial lung disease	2	59	Y
3	TC	Y	Yes	NOT RELATED/OTHER: interstitial lung disease	2	145	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30JUL2020	
Completed	VACCINATION	21SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	70	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	86.82 kg	26.6 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	1959	Past
appendicitis	Appendicitis	1959	Past
high blood pressure	Hypertension	2009	Present
gastrointestinal reflux disorder	Duodenogastric reflux	2013	Present
Type II diabetes	Type 2 diabetes mellitus	2015	Present
benign prostatic hypertrophy	Benign prostatic hyperplasia	2017	Present
environmental allergies - hives	Urticaria	2019	Present
right eye cataract	Cataract	FEB2019	Past
right eye cataract removal	Cataract operation	FEB2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	05AUG2020 (1)	15:19
2	Placebo	26AUG2020 (22)	14:57
3	BNT162b2	15JAN2021 (164)	09:38
4	BNT162b2	03FEB2021 (183)	10:40

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PSYCH	Panic attack	suspected panic attack	28DEC2020 (146)		29DEC2020 (147)		2	3
2	GASTR	Small intestinal obstruction	small bowel obstruction	08AUG2020 (4)	00:17	10AUG2020 (6)	00:13	3	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (29DEC2020)	NOT RELATED/OTHER: suspected panic attack	2	125	Y
2	TC/TCN	Y	Resolved (10AUG2020)	NOT RELATED/OTHER: SAE - unplanned bowel obstruction	1	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	23SEP2020	
Completed	REPEAT SCREENING 1	15JAN2021	
Completed	OPEN LABEL TREATMENT	03MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	41	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	81.82 kg	24.4 kg/m2	13AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13AUG2020 (1)	15:21
2	Placebo	03SEP2020 (22)	11:43

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	17DEC2020 (127)	14:53
4	BNT162b2	06JAN2021 (147)	14:25

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CONG	Congenital ureteropelvic junction obstruction	Congenital right ureteropelvic junction obstruction	01DEC2020 (111)		27JAN2021 (168)		58	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (27JAN2021)	NOT RELATED/OTHER: ureteropelvic junction obstruction	2	90	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Quadrivalent Influenza Vaccine	INFLUENZA VACCINE INACT SPLIT 4V	OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	05OCT2020	
Completed	REPEAT SCREENING 1	17DEC2020	
Completed	OPEN LABEL TREATMENT	05FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	123.18 kg	37.8 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
left hip replacement	Hip arthroplasty	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14AUG2020 (1)	12:50
2	BNT162b2	04SEP2020 (22)	11:42

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	VASC	Deep vein thrombosis	bilateral lower extremity DVT	27DEC2020 (136)		12FEB2021 (183)		48	3
2	CONG	Protein S deficiency	S protein deficiency	28DEC2020 (137)		ONGOING			2
3	RESP	Pulmonary embolism	pulmonary embolism	28DEC2020 (137)		11JAN2021 (151)		15	3

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	Y	Resolved (12FEB2021)	NOT RELATED/OTHER: unknown	2	115	Y
2	TC	N	Yes	NOT RELATED/OTHER: protein S deficiency	2	116	N
3	TC	Y	Resolved (11JAN2021)	NOT RELATED/OTHER: DVT	2	116	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	91.36 kg	31.5 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
TUBAL LIGATION	Female sterilisation	1975	Past
APPENDECTOMY	Appendicectomy	1990	Past
ACUTE APPENDICITIS	Appendicitis	1990	Past
HYPERLIPIDEMIA	Hyperlipidaemia	1990	Present
HYPERTENSION	Hypertension	1990	Present
HYPOTHYROID	Hypothyroidism	1990	Present
HIATAL HERNIA	Hiatus hernia	1995	Present
POST MENOPAUSAL	Postmenopause	1997	Present
gastroesophageal reflux disease	Gastrooesophageal reflux disease	2009	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
VITAMIN B12 DEFICIENCY	Vitamin B12 deficiency	2015	Present
RIGHT ANKLE REPLACEMENT	Ankle arthroplasty	2019	Past
RIGHT ANKLE FRACTURE	Ankle fracture	2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	13AUG2020 (1)	09:55
2	BNT162b2	01SEP2020 (20)	11:32

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Aortic aneurysm	AORTIC ANEURYSM	20NOV2020 (100)		28JAN2021 (169)		70	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (28JAN2021)	NOT RELATED/OTHER: occult condition, pre-existing	2	81	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	29SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	54	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	137.55 kg	48.8 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HIGH BLOOD PRESSURE	Hypertension	1980	Present
DEPRESSION	Depression	1985	Present
MORPHINE ALLERGY	Drug hypersensitivity	1985	Present
ANXIETY	Anxiety	2004	Present
HYSTERECTOMY	Hysterectomy	2008	Past
UTERINE FIBROIDS	Uterine leiomyoma	2008	Past
MENOPAUSE	Menopause	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	13AUG2020 (1)	12:04
2	BNT162b2	04SEP2020 (23)	10:58

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Non-cardiac chest pain	INTERMITTENT NON CARDIAC CHEST PAIN	09SEP2020 (28)		17SEP2020 (36)		9

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	Y	Resolved (17SEP2020)	NOT RELATED/OTHER: IDIOPATHIC	2	6	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	64.55 kg	26.8 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
controlled squamous cell carcinoma skin on chin	Squamous cell carcinoma of skin	1993	Present
MENOPAUSE	Menopause	2002	Present
HIGH BLOOD PRESSURE	Hypertension	2004	Present
LEFT BREAST CANCER	Breast cancer	2005	Past
LEFT BREAST LUMPECTOMY	Breast conserving surgery	2010	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	09:34
2	Placebo	02SEP2020 (20)	15:50
3	BNT162b2	18JAN2021 (158)	14:49
4	BNT162b2	08FEB2021 (179)	15:38

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	NEOPL	Breast cancer	LEFT BREAST CANCER	04SEP2020 (22)		12JAN2021 (152)	00:00	131	2	TC

Adverse Events					
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (12JAN2021)	NOT RELATED/OTHER: PRE-EXISTING OCCULT MALIGNANCY	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	02OCT2020	
Completed	REPEAT SCREENING 1	18JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
183.64 cm	93.91 kg	27.8 kg/m2	19OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Alcohol Use Disorder	Alcohol use disorder	1973	Present
VASECTOMY	Vasectomy	2005	Past
CERVICAL FUSION	Spinal fusion surgery	2013	Past
RIGHT INGUINAL HERNIA REPAIR	Inguinal hernia repair	2016	Past
OSTEOARTHRITIS	Osteoarthritis	2017	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2018	Present
HIGH CHOLESTEROL	Blood cholesterol increased	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19OCT2020 (1)	08:47

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	RESP	Acute respiratory failure	Acute Respiratory Failure	08NOV2020 (21)	00:43	ONGOING			4	N	Y
2	CARD	Cardiac arrest	CARDIAC ARREST	08NOV2020 (21)	00:43	08NOV2020 (21)		1	4	TC	Y
3	INJ&P	Overdose	Overdose	08NOV2020 (21)	00:43	08NOV2020 (21)		1	4	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: unknown	1	21	Y
2	Resolved (08NOV2020)	NOT RELATED/OTHER: possible intentional overdose, or. poor choice of alcohol and drug abuse.	1	21	Y
3	Resolved (08NOV2020)	NOT RELATED/OTHER: multi-drug ingestion	1	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19OCT2020	
Withdrawn	VACCINATION	14DEC2020	LOST TO FOLLOW-UP
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	14DEC2020	LOST TO FOLLOW-UP

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2003	17	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	46.09 kg	18 kg/m2	08JAN2021 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
IMPERFORATE ANUS	Anal atresia	2003	Past
appendectomy	Appendicectomy	2003	Past
cholecystectomy	Cholecystectomy	2003	Past
INTESTINAL STOMA	Enterostomy	2003	Past
RESECTION OF NECROTIC BOWEL	Intestinal resection	2003	Past
short bowel syndrome	Short-bowel syndrome	2003	Present
OSTOMY REVERSAL	Stoma closure	2003	Past
VOLVULUS	Volvulus	2003	Past
CONSTIPATION	Constipation	2013	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	08JAN2021 (1)	11:50
2	BNT162b2	28JAN2021 (21)	11:38

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Abdominal pain	ABDOMINAL PAIN	29JAN2021 (22)		01FEB2021 (25)		4

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (01FEB2021)	NOT RELATED/OTHER: CONSTIPATION	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
TETANUS VACCINE	TETANUS VACCINE	04DEC2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08JAN2021	
	VACCINATION		
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.01 cm	60.55 kg	21.7 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Ehlers-Danlos Syndrome	Ehlers-Danlos syndrome	1966	Present
Postural Orthostatic Tachycardia Syndrome	Postural orthostatic tachycardia syndrome	1966	Present
Environmental Allergies	Hypersensitivity	1969	Present
Recurrent Urinary Tract Infection	Urinary tract infection	1974	Present
Migraines with Aura	Migraine with aura	1979	Present
Recurrent Sinusitis	Sinusitis	1980	Past
Asthma (Moderate)	Asthma	1985	Present
Complete Hysterectomy	Hysterectomy	1989	Past
Postmenopausal	Postmenopause	1989	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Post Partum Hemorrhage	Postpartum haemorrhage	1989	Past
Premarin Allergy (Hives)	Urticaria	1989	Present
Attention Deficit Hyperactivity Disorder	Attention deficit hyperactivity disorder	01FEB1989	Present
Macrodantin Allergy (Hives)	Urticaria	1990	Present
Restless Leg Syndrome	Restless legs syndrome	2000	Present
History of Recurrent Actinic Keratosis	Actinic keratosis	06SEP2011	Present
Basal Cell Carcinoma (Forehead)	Basal cell carcinoma	11SEP2011	Past
Rosacea (mild)	Rosacea	12SEP2011	Present
Chronic Fatigue Syndrome	Chronic fatigue syndrome	14AUG2012	Present
Insomnia	Insomnia	13SEP2013	Present
Mild Anxiety	Anxiety	19MAY2014	Present
Lumbar Disc Degeneration	Intervertebral disc degeneration	14AUG2014	Present
Tinnitus Left Ear	Tinnitus	12MAR2015	Present
Bilateral Eye Cataracts	Cataract	20OCT2016	Past
Recurrent Muscle Spasms (Whole Body)	Muscle spasms	10MAR2017	Present
Gastrointestinal Bleed	Gastrointestinal haemorrhage	27NOV2017	Past
Urethral Sling	Urinary bladder suspension	2018	Present
Osteoporosis	Osteoporosis	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	13:34
2	BNT162b2	15SEP2020 (23)	15:51

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	CARD	Atrial fibrillation	ATRIAL FIBRILLATION INTERMITTENT	06OCT2020 (44)		12OCT2020 (50)		7	2
2	NERV	Headache	Headache	24AUG2020 (1)	14:30	25AUG2020 (2)	07:00	2	2
3	INFEC	Urinary tract infection	URINARY TRACT INFECTION	03OCT2020 (41)		12OCT2020 (50)		10	3

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN	Y	Resolved (12OCT2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	22	Y
2	TC	N	Resolved (25AUG2020)	Study Treatment	1	1	N
3	TC	N	Resolved (12OCT2020)	NOT RELATED/OTHER: BACTERIAL INFECTION	2	19	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINE	INFLUENZA VACCINE	02OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2004	16	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	63.77 kg	24.9 kg/m2	27OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	2011	Present
Seasonal Allergies	Seasonal allergy	2011	Present
Migraines	Migraine	2017	Present
Anxiety	Anxiety	2018	Present
Depression	Depression	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27OCT2020 (1)	17:59
2	Placebo	19NOV2020 (24)	17:41

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Asthma	Acute Asthma Exacerbation	03FEB2021 (100)		10FEB2021 (107)		8	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (10FEB2021)	NOT RELATED/OTHER: strep pharyngitis	2	77	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccine	INFLUENZA VACCINE	10OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13OCT2020	
Completed	VACCINATION	29DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	77	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154 cm	64.3 kg	27.1 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Uterine fibroid polyp	Uterine polyp	1992	Past
Hysterectomy	Hysterectomy	DEC1992	Past
Hypercholesterolemia	Hypercholesterolaemia	2005	Present
Bladder prolapse	Bladder prolapse	2006	Past
Cystocele repair	Cystocele repair	2006	Past
Basal cell carcinoma	Basal cell carcinoma	2010	Present
Barrett's esophagus	Barrett's oesophagus	17MAR2017	Past
Chronic gastritis	Chronic gastritis	17MAR2017	Present
Bursitis of right hip	Bursitis	2019	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic kidney disease stage 3	Chronic kidney disease	2019	Present
Left ventricular hypertrophy	Left ventricular hypertrophy	27FEB2019	Present
Basal cell carcinoma of skin in situ	Basal cell carcinoma	OCT2019	Past
Plastic repair of pinna	Otoplasty	OCT2019	Past
Hypothyroidism	Hypothyroidism	FEB2020	Present
Type 2 diabetes mellitus	Type 2 diabetes mellitus	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13AUG2020 (1)	14:49
2	Placebo	03SEP2020 (22)	14:27
3	BNT162b2	25FEB2021 (197)	11:44

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GASTR	Duodenal ulcer	Duodenal ulcer	17DEC2020 (127)		11FEB2021 (183)		57	2	TC	N
2	GASTR	Gastric ulcer	Gastric ulcer	11DEC2020 (121)		ONGOING			2	TC	N

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
3	GASTR	Gastrointestinal haemorrhage	Gastrointestinal Bleed	09DEC2020 (119)		07JAN2021 (148)		30	3	TC/TCN	Y
4	INJ&P	Tendon rupture	right gluteus medius tendon tear	27SEP2020 (46)		03DEC2020 (113)		68	2	TCN	N

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (11FEB2021)	NOT RELATED/OTHER: surgical stress	2	106	N
2	Yes	NOT RELATED/OTHER: surgical stress	2	100	N
3	Resolved (07JAN2021)	NOT RELATED/OTHER: GI bleed after surgery. Gastric and duodenal ulcers.	2	98	Y
4	Resolved (03DEC2020)	NOT RELATED/OTHER: injury	2	25	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	01OCT2020	
Completed	REPEAT SCREENING 1	25FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187 cm	91.4 kg	26.1 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergy	Seasonal allergy	1987	Present
Asthma	Asthma	1990	Present
Vasectomy	Vasectomy	2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	15:11
2	Placebo	17SEP2020 (23)	14:33

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Chronic myeloid leukaemia	chronic myelogenous leukemia	24SEP2020 (30)		ONGOING			4
2	BLOOD	Leukocytosis	leukocytosis	24SEP2020 (30)		19OCT2020 (55)		26	3
3	BLOOD	Thrombocytosis	thrombocytosis	24SEP2020 (30)		26OCT2020 (62)		33	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Yes	NOT RELATED/OTHER: Genetic change in stem cells	2	8	Y
2	N	N	Resolved (19OCT2020)	NOT RELATED/OTHER: Chronic myelogenous leukemia	2	8	N
3	N	N	Resolved (26OCT2020)	NOT RELATED/OTHER: Chronic myelogenous leukemia	2	8	N

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Dasatinib	DASATINIB	06OCT2020	ONGOING	ORAL

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
SARS-CoV-2 vaccination Pfizer	TOZINAMERAN	30DEC2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	30DEC2020	PROTOCOL DEVIATION

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.2 cm	93.3 kg	32.2 kg/m2	12OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergy	Seasonal allergy	1992	Present
Hysterectomy	Hysterectomy	2003	Past
Obesity	Obesity	2003	Present
Salpingo-oophorectomy unilateral	Salpingo-oophorectomy unilateral	2003	Past
Asthma	Asthma	06JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12OCT2020 (1)	15:31
2	Placebo	02NOV2020 (22)	13:44

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Pneumonia	left lower lobe pneumonia	19FEB2021 (131)		ONGOING			3
2	INFEC	Sepsis	sepsis	19FEB2021 (131)		06MAR2021 (146)		16	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Yes	NOT RELATED/OTHER: Legionella bacteria	2	110	Y
2	TC/TCN	Y	Resolved (06MAR2021)	NOT RELATED/OTHER: Legionella bacteria	2	110	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12OCT2020	
Completed	VACCINATION	30NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	60	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	103.18 kg	34.5 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Epilepsy	Epilepsy	2007	Present
Hypertension	Hypertension	2013	Present
Diabetes Type II	Type 2 diabetes mellitus	2013	Present
Vitamin B12 deficiency	Vitamin B12 deficiency	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	14:58
2	Placebo	08SEP2020 (22)	12:30
3	BNT162b2	20JAN2021 (156)	12:32
4	BNT162b2	10FEB2021 (177)	10:18

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Dyspnoea	Shortness of breath	MAR2021 ()		ONGOING		
2	GENRL	Injection site pain	Injection site pain	20JAN2021 (156)	17:00	24JAN2021 (160)		5

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Yes	NOT RELATED/OTHER: unknown	4		Y
2	1	N	N	Resolved (24JAN2021)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	06OCT2020	
Completed	REPEAT SCREENING 1	20JAN2021	
Completed	OPEN LABEL TREATMENT	10MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
189.23 cm	103.73 kg	28.9 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Percocet allergy	Drug hypersensitivity	1998	Present
Seasonal allergies	Seasonal allergy	2010	Present
Hypertension	Hypertension	2018	Present
Tinea Versicolor	Tinea versicolour	MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	15:31
2	BNT162b2	21SEP2020 (22)	14:54

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Optic neuritis	Optic neuritis left eye	09DEC2020 (101)		22DEC2020 (114)		14

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (22DEC2020)	NOT RELATED/OTHER: unknown	2	80	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Quadrivalent flu prophylaxis intramuscular vaccine 0.5 ml once	INFLUENZA VACCINE INACT SPLIT 4V	08OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	109.55 kg	38.9 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Thimerosal allergy	Drug hypersensitivity	1974	Present
High cholesterol	Blood cholesterol increased	2019	Present
Elevated PSA	Prostatic specific antigen increased	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	14:32
2	Placebo	24SEP2020 (22)	10:57
3	BNT162b2	13JAN2021 (133)	13:03
4	BNT162b2	04FEB2021 (155)	12:20

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Prostate cancer	Prostate cancer	30SEP2020 (28)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	TCN	Y	Yes	NOT RELATED/OTHER: Unknown	2	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flucelvax influenza prophylaxis intramuscular vaccine 0.5 ml once	INFLUENZA VACCINE INACT SAG 3V	19OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	22OCT2020	
Completed	REPEAT SCREENING 1	13JAN2021	
Completed	OPEN LABEL TREATMENT	04MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.99 cm	92.09 kg	30.4 kg/m2	14OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	1980	Present
Diabetes type II	Type 2 diabetes mellitus	2000	Present
High cholesterol	Blood cholesterol increased	2014	Present
Coronary artery disease	Coronary artery disease	2015	Present
Sebaceous cyst of scalp	Dermal cyst	SEP2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14OCT2020 (1)	11:44
2	Placebo	05NOV2020 (23)	15:06
3	BNT162b2	21JAN2021 (100)	13:58
4	BNT162b2	11FEB2021 (121)	12:20

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Cellulitis	CELLULITIS UPPER BACK	26OCT2020 (13)		02NOV2020 (20)		8	3
2	INFEC	Subcutaneous abscess	SCALP ABCESS	26OCT2020 (13)		27OCT2020 (14)		2	3
3	INJ&P	Wound	Surgical wound scalp	27OCT2020 (14)		21JAN2021 (100)		87	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (02NOV2020)	NOT RELATED/OTHER: SCALP ABCESS	1	13	Y
2	TC/TCN	Y	Resolved (27OCT2020)	NOT RELATED/OTHER: HISTORY SCALP CYST	1	13	Y
3	TC/TCN	N	Resolved (21JAN2021)	NOT RELATED/OTHER: Post I&D scalp abcess	1	14	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14OCT2020	
Completed	VACCINATION	03DEC2020	
Completed	REPEAT SCREENING 1	21JAN2021	
Completed	OPEN LABEL TREATMENT	11MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	75.45 kg	29.4 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Benign Thryoid Nodule	Benign neoplasm of thyroid gland	1975	Present
Partial Thyroidectomy	Thyroidectomy	1975	Past
Depression	Depression	1987	Present
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	1990	Present
Post Menopausal	Postmenopause	1998	Present
Hypercholesterolemia	Hypercholesterolaemia	2010	Present
Insomnia	Insomnia	2015	Present
Posterior Septal Resection	Nasal septal operation	2017	Past
Osteoarthritis	Osteoarthritis	2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Abnormal discharge uterine cervix	Cervical discharge	2019	Past
Hysterectomy	Hysterectomy	2019	Past
tubular adenoma of ascending colon	Colon adenoma	JUN2020	Present
Hypertension	Hypertension	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27AUG2020 (1)	14:09
2	BNT162b2	15SEP2020 (20)	11:15

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Colon adenoma	TUBULAR ADENOMA OF ASCENDING COLON	15DEC2020 (111)		17DEC2020 (113)		3	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (17DEC2020)	NOT RELATED/OTHER: NEW GROWTH	2	92	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
SHINGRIX #1	VARICELLA ZOSTER VACCINE RGE (CHO)	17OCT2020
SHINGRIX #2	VARICELLA ZOSTER VACCINE RGE (CHO)	12JAN2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	13OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	110.55 kg	41.7 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
MTHFR GENE MUTATION	Methylenetetrahydrofolate reductase gene mutation	(b) (6) 1957	Present
ENVIRONMENTAL ALLERGIES	Hypersensitivity	1958	Present
LACTOSE INTOLERANCE	Lactose intolerance	1970	Present
MORPHINE INTOLERANCE	Drug intolerance	1986	Present
ASPIRIN INTOLERANCE	Drug intolerance	1986	Present
HYSTERECTOMY	Hysterectomy	1986	Past
GLUTEN INTOLERANCE	Gluten sensitivity	2003	Present
ANXIETY	Anxiety	JUN2011	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DEPRESSION	Depression	JUN2011	Present
HYPOTHYROIDISM	Hypothyroidism	JUN2011	Present
MILD ASTHMA	Asthma	2018	Present
OSTEOARTHRITIS (GENERALIZED)	Osteoarthritis	JUN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	13:44
2	Placebo	22SEP2020 (23)	16:22

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	REPRO	Breast mass	right breast lump	02SEP2020 (3)		ONGOING	
2	NEOPL	Intraductal proliferative breast lesion	Right Breast Ductal Carcinoma In Situ	02SEP2020 (3)		ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		1	N	N	Yes	NOT RELATED/OTHER: cancer	1	3	N
2		1	TCN	Y	Yes	NOT RELATED/OTHER: spontaneous onset	1	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	76	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	74.82 kg	22.3 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPOTHYROIDISM	Hypothyroidism	1985	Present
DEPRESSION	Depression	1990	Present
BENIGN PROSTATIC HYPERPLASIA	Benign prostatic hyperplasia	1995	Present
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	1995	Present
HYPERLIPIDEMIA	Hyperlipidaemia	1995	Present
BILATERAL IMPACTED CERUM OF EARS-INTERMITTENT	Cerumen impaction	2000	Present
INSOMNIA	Insomnia	2000	Present
ACTINIC KERATOSIS	Actinic keratosis	2010	Present
HISTORY OF DIVERTICULITIS-NO SYMPTOMS	Diverticulitis	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
diverticulosis	Diverticulum	2010	Present
LEFT SHOULDER PAIN	Arthralgia	19AUG2011	Present
SLEEP APNEA	Sleep apnoea syndrome	31MAR2012	Present
LEFT HIP PAIN	Arthralgia	2014	Present
HISTORY OF SPINAL MENINGITIS-NO SYMPTOMS TODAY	Meningitis	2014	Past
LOW BACK PAIN	Back pain	2015	Present
AUGMENTIN INTOLERANCE	Drug intolerance	2017	Present
OSCILLPSIA	Oscillopsia	2017	Present
ARTHRITIS OF CARPOMETACARPAL JOINT LEFT THUMB	Arthritis	2019	Present
TRIGGER FINGER LEFT HAND	Trigger finger	2019	Past
Clostridium difficile Infection	Clostridium difficile infection	10APR2019	Past
atherosclerosis of aorta	Aortic arteriosclerosis	23APR2019	Present
coronary artery disease	Coronary artery disease	23APR2019	Present
MYOCARDIAL INFARCTION	Myocardial infarction	23APR2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	11:51
2	Placebo	22SEP2020 (20)	10:00
3	BNT162b2	15FEB2021 (166)	09:28
4	BNT162b2	08MAR2021 (187)	09:22

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	INFEC	Diverticulitis	worsening of diverticulitis	31DEC2020 (120)		02JAN2021 (122)		3	2

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN	Y	Resolved (02JAN2021)	NOT RELATED/OTHER: underlying illness	2	101	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
influenza vaccine	INFLUENZA VACCINE	08OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	20OCT2020	
Completed	REPEAT SCREENING 1	15FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	72	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	61.36 kg	23.2 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Insomnia	Insomnia	2010	Present
Sleep Apnea	Sleep apnoea syndrome	2010	Present
Osteoarthritis Left Knee	Osteoarthritis	2014	Past
Osteoporosis	Osteoporosis	2016	Present
Left Knee Arthroplasty	Knee arthroplasty	2017	Past
Basal Cell Carcinoma Nose	Basal cell carcinoma	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	14:16
2	Placebo	21SEP2020 (22)	13:15
3	BNT162b2	13JAN2021 (136)	15:48
4	BNT162b2	02FEB2021 (156)	11:50

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Chills	Chills	02FEB2021 (156)	21:30	03FEB2021 (157)		2
2	NERV	Dizziness	Dizziness	24JAN2021 (147)		24JAN2021 (147)		1
3	GENRL	Injection site pain	Left arm localized soreness at injection site	02SEP2020 (3)		03SEP2020 (4)		2
4	GENRL	Pyrexia	Fever	03FEB2021 (157)		03FEB2021 (157)		1
5	INJ&P	Skin laceration	Laceration on Head	03FEB2021 (157)	00:02	11FEB2021 (165)		9
6	EAR	Vertigo	Vertigo	03FEB2021 (157)	00:00	05FEB2021 (159)	13:55	3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	N	Resolved (03FEB2021)	Study Treatment	4	1	N
2	1	N	N	Resolved (24JAN2021)	NOT RELATED/OTHER: Unknown	3	12	N
3	1	N	N	Resolved (03SEP2020)	Study Treatment	1	3	N
4	1	N	N	Resolved (03FEB2021)	Study Treatment	4	2	N

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	2	TC/TCN	N	Resolved (11FEB2021)	NOT RELATED/OTHER: Vertigo	4	2	N
6	3	TC/TCN	Y	Resolved (05FEB2021)	NOT RELATED/OTHER: Unknown	4	2	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
Seasonal Influenza Vaccine	INFLUENZA VACCINE	16OCT2020

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	20OCT2020	
Completed	REPEAT SCREENING 1	13JAN2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	02MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1940	80	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	77.27 kg	25.1 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bilateral hearing loss	Deafness bilateral	1964	Present
VASECTOMY	Vasectomy	1977	Past
PROSTATE CANCER	Prostate cancer	DEC1987	Past
PROSTATECTOMY	Prostatectomy	DEC1987	Past
GENERALIZED OSTEOARTHRITIS	Osteoarthritis	2005	Present
SEASONAL ALLERGIES	Seasonal allergy	2010	Present
LEFT KNEE REPLACEMENT	Knee arthroplasty	2014	Past
HYPERLIPIDEMIA	Hyperlipidaemia	2017	Present
Mitral Valve Prolapse	Mitral valve prolapse	2017	Present
SQUAMOUS CELL CARCINOMA ON FACE	Squamous cell carcinoma of skin	2018	Past
Heart Arrhythmia	Arrhythmia	2019	Present
Loop Recorder Implant	Electrocardiogram ambulatory	OCT2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	11:01
2	Placebo	21SEP2020 (20)	13:13
3	BNT162b2	13JAN2021 (134)	16:01
4	BNT162b2	02FEB2021 (154)	11:51

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Atrial fibrillation	PAROXYSMAL ATRIAL FIBRILLATION	09DEC2020 (99)		11DEC2020 (101)		3
2	MUSC	Back pain	BACK PAIN	03FEB2021 (155)		ONGOING		
3	GENRL	Chills	BODY CHILLS	03FEB2021 (155)		06FEB2021 (158)		4
4	SKIN	Hyperhidrosis	BODY SWEATS	03FEB2021 (155)		06FEB2021 (158)		4

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (11DEC2020)	NOT RELATED/OTHER: New diagnosis	2	80	Y
2	2	N	N	Yes	NOT RELATED/OTHER: Unknown	4	2	N

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	2	N	N	Resolved (06FEB2021)	Study Treatment	4	2	N
4	2	N	N	Resolved (06FEB2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Seasonal Influenza Vaccine	INFLUENZA VACCINE	16OCT2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	20OCT2020	
Completed	REPEAT SCREENING 1	13JAN2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	02MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	57.6 kg	23.4 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
RIGHT RENAL STENT INSERTION	Renal surgery	FEB2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05AUG2020 (1)	10:40
2	BNT162b2	26AUG2020 (22)	15:05

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Vascular stent occlusion	OBSTRUCTED RENAL STENT (ARTERY)	01SEP2020 (28)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	N	Y	Yes	NOT RELATED/OTHER: RENAL STENT	2	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	30SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1991	29	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
153.4 cm	52.5 kg	22.3 kg/m2	06AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HISTORY OF SEIZURES	Seizure	2004	Past
LEFT TORN LABRUM	Cartilage injury	SEP2009	Past
LEFT TORN LABRUM REPAIR	Chondroplasty	2011	Past
ENVIRONMENTAL ALLERGIES	Hypersensitivity	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	06AUG2020 (1)	11:25
2	Placebo	27AUG2020 (22)	13:30
3	BNT162b2	02FEB2021 (181)	14:45
4	BNT162b2	25FEB2021 (204)	14:15

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	VASC	Deep vein thrombosis	LEFT ARM DEEP VEIN THROMBOSIS	20DEC2020 (137)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC	Y	Yes	NOT RELATED/OTHER: UNKOWN	2	116	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	06AUG2020	
Completed	VACCINATION	24SEP2020	
Completed	REPEAT SCREENING 1	02FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	28	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
183 cm	86 kg	25.7 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SEASONAL ALLERGIES	Seasonal allergy	1992	Present
VAPING	Electronic cigarette user	2016	Present
ELEVATED TRIGLYCERIDES	Blood triglycerides increased	2018	Present
GENITAL HERPES	Genital herpes	10AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	13AUG2020 (1)	10:36
2	BNT162b2	02SEP2020 (21)	14:10

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Pulmonary embolism	Pulmonary Embolism Bilateral	14DEC2020 (124)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Yes	NOT RELATED/OTHER: Vaping and sedentary lifestyle	2	104	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	30SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	75	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174.9 cm	72.2 kg	23.6 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
RIGHT KNEE OSTEOARTHRITIS	Osteoarthritis	1990	Past
LEFT KNEE OSTEOARTHRITIS	Osteoarthritis	1990	Past
LEFT KNEE REPLACEMENT	Knee arthroplasty	2000	Past
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2005	Present
HIATAL HERNIA	Hiatus hernia	2005	Present
RIGHT KNEE REPLACEMENT	Knee arthroplasty	2009	Past
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2014	Present
HYPERTENSION	Hypertension	2015	Present
INGUINAL HERNIA	Inguinal hernia	2016	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SMALL BOWEL PERFORATION	Small intestinal perforation	2016	Past
SMALL BOWEL RESECTION	Small intestinal resection	2016	Past
INGUINAL HERNIA REPAIR	Inguinal hernia repair	2017	Past
CONSTIPATION	Constipation	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	13AUG2020 (1)	12:35
2	BNT162b2	07OCT2020 (56)	15:10

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	GASTR	Abdominal adhesions	abdominal adhesions	29AUG2020 (17)		30AUG2020 (18)		2	3	TC
2	RENAL	Acute kidney injury	acute renal failure	29AUG2020 (17)		16SEP2020 (35)		19	3	N
3	RESP	Acute respiratory failure	acute hypoxic respiratory failure	30AUG2020 (18)		11SEP2020 (30)		13	3	N
4	BLOOD	Anaemia	anemia	30AUG2020 (18)		16SEP2020 (35)		18	3	N
5	CARD	Cardiac failure congestive	CONGESTIVE HEART FAILURE	30AUG2020 (18)		16SEP2020 (35)		18	3	N
6	METAB	Hypokalaemia	hypokalemia	30AUG2020 (18)		16SEP2020 (35)		18	3	N

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
7	METAB	Hyponatraemia	HYPONATREMIA	29AUG2020 (17)		07SEP2020 (26)		10	2	TC
8	CARD	Left ventricular hypertrophy	MILD CONCENTRIC LEFT VENTRICULAR HYPERTROPHY	16SEP2020 (35)		ONGOING			1	N
9	BLOOD	Leukopenia	LEUKOPENIA	29AUG2020 (17)		07SEP2020 (26)		10	2	TCN
10	PSYCH	Mental status changes	altered mental status	29AUG2020 (17)		16SEP2020 (35)		19	3	N
11	RESP	Pneumonia aspiration	ASPIRATION PNEUMONIA	30AUG2020 (18)		16SEP2020 (35)		18	2	TCN
12	INFEC	Sepsis	sepsis	29AUG2020 (17)		16SEP2020 (35)		19	3	N
13	GASTR	Small intestinal obstruction	SMALL BOWEL OBSTRUCTION	29AUG2020 (17)		30AUG2020 (18)		2	2	TCN
14	INFEC	Urinary tract infection	URINARY TRACT INFECTION	13JAN2021 (154)		22JAN2021 (163)		10	1	TC

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (30AUG2020)	NOT RELATED/OTHER: PREVIOUS SURGERY	1	17	Y
2	N	Resolved (16SEP2020)	NOT RELATED/OTHER: prior surgery	1	17	N
3	Y	Resolved (11SEP2020)	NOT RELATED/OTHER: prior surgery	1	18	Y
4	N	Resolved (16SEP2020)	NOT RELATED/OTHER: prior surgery	1	18	N
5	N	Resolved (16SEP2020)	NOT RELATED/OTHER: prior surgery	1	18	N
6	N	Resolved (16SEP2020)	NOT RELATED/OTHER: prior surgery	1	18	N
7	N	Resolved (07SEP2020)	NOT RELATED/OTHER: BOWEL OBSTRUCTION	1	17	N
8	N	Yes	NOT RELATED/OTHER: UNKNOWN	1	35	N
9	N	Resolved (07SEP2020)	NOT RELATED/OTHER: BOWEL OBSTRUCTION	1	17	N
10	N	Resolved (16SEP2020)	NOT RELATED/CONCOMITANT NON-DRUG TREATMENT	1	17	N

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
11	Y	Resolved (16SEP2020)	NOT RELATED/OTHER: ADHESIONS	1	18	Y
12	N	Resolved (16SEP2020)	NOT RELATED/OTHER: prior surgery	1	17	N
13	Y	Resolved (30AUG2020)	NOT RELATED/OTHER: ADHESIONS	1	17	Y
14	N	Resolved (22JAN2021)	NOT RELATED/OTHER: UNKNOWN	2	99	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	04NOV2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.6 cm	65.7 kg	23.4 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
MIGRAINE HEADACHES	Migraine	2000	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2017	Present
TARLOV CYST	Perineurial cyst	DEC2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	10:21
2	BNT162b2	08SEP2020 (23)	14:07

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RENAL	Nephrolithiasis	kidney stones	04JAN2021 (141)		05JAN2021 (142)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	Y	Resolved (05JAN2021)	NOT RELATED/OTHER: kidney stone	2	119	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	06OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.9 cm	96.8 kg	27.4 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ACL TEAR RIGHT KNEE	Ligament rupture	1978	Past
RIGHT KNEE ACL REPAIR	Ligament operation	1980	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01SEP2020 (1)	10:50
2	BNT162b2	22SEP2020 (22)	09:55

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	VASC	Arterial occlusive disease	ARTERY OCCLUSION	13MAR2021 (194)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Yes	NOT RELATED/OTHER: DISEASE PROCESS	2	173	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	70	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.8 cm	77.1 kg	23.1 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ASTHMA	Asthma	1951	Present
VITILIGO	Vitiligo	1978	Present
CORONARY ARTERY DISEASE	Coronary artery disease	2005	Present
HYPOTHYROIDISM	Hypothyroidism	2016	Present
STENT CARDIAC INSERTION	Coronary arterial stent insertion	14FEB2016	Past
MYOCARDIAL INFARCTION	Myocardial infarction	14FEB2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10SEP2020 (1)	13:05
2	BNT162b2	30SEP2020 (21)	14:36

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Acute myocardial infarction	STEMI	08NOV2020 (60)		10NOV2020 (62)		3	3
2	GENRL	Fatigue	FATIGUE	11SEP2020 (2)	07:00	11SEP2020 (2)	19:00	1	1
3	GENRL	Injection site pain	INJECTION SITE PAIN TO LEFT ARM	10SEP2020 (1)	07:00	11SEP2020 (2)	08:00	2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (10NOV2020)	NOT RELATED/OTHER: CORONARY ARTERY DISEASE	2	40	Y
2	N	N	Resolved (11SEP2020)	Study Treatment	1	2	N
3	N	N	Resolved (11SEP2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	28OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166.5 cm	94.6 kg	34.1 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
asthma	Asthma	1968	Present
seasonal allergies	Seasonal allergy	1972	Present
herniated disc C-5	Intervertebral disc protrusion	2003	Past
surgical fusion of C5	Spinal fusion surgery	2003	Past
endometriosis	Endometriosis	2008	Past
cholecystectomy	Cholecystectomy	2009	Past
cholecystitis	Cholecystitis	2009	Past
total abdominal hysterectomy	Hysterectomy	2009	Past
bilateral oophorectomy	Oophorectomy bilateral	2009	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
bilateral salpingectomy	Salpingectomy	2009	Past
rheumatoid arthritis in remission	Rheumatoid arthritis	2010	Present
irritable bowel syndrome	Irritable bowel syndrome	2014	Present
obesity	Obesity	2016	Present
hypertension	Hypertension	2017	Present
hypercholesterolemia	Hypercholesterolaemia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16SEP2020 (1)	11:18
2	BNT162b2	05OCT2020 (20)	15:14

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Asthma	acute exacerbation of asthma	16DEC2020 (92)		20DEC2020 (96)		5
2	GENRL	Chills	CHILLS	06OCT2020 (21)	09:00	07OCT2020 (22)	22:00	2
3	GENRL	Injection site pain	INJECTION PAIN	05OCT2020 (20)	22:00	06OCT2020 (21)	20:00	2
4	GENRL	Injection site pain	INJECTION SITE PAIN	17SEP2020 (2)	23:20	20SEP2020 (5)	08:00	4
5	GENRL	Pain	BODY PAIN	05OCT2020 (20)	22:00	06OCT2020 (21)	22:00	2
6	GENRL	Pyrexia	LOW GRADE FEVER	06OCT2020 (21)	09:00	07OCT2020 (22)	22:00	2

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC	Y	Resolved (20DEC2020)	NOT RELATED/OTHER: Asthma	2	73	Y
2	1	N	N	Resolved (07OCT2020)	Study Treatment	2	2	N
3	2	N	N	Resolved (06OCT2020)	Study Treatment	2	1	N
4	1	N	N	Resolved (20SEP2020)	Study Treatment	1	2	N
5	1	N	N	Resolved (06OCT2020)	Study Treatment	2	1	N
6	1	TC	N	Resolved (07OCT2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16SEP2020	
Completed	VACCINATION	02NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2003	16	Black or African American	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
155 cm	102.7 kg	42.7 kg/m2	07OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
CHARCOT MARIE TOOTH	Hereditary motor and sensory neuropathy	2005	Present
ASTHMA	Asthma	2008	Present
ATTENTION DEFICIT HYPERACTIVITY DISORDER	Attention deficit hyperactivity disorder	2008	Present
ACHILLES TENDON RIGHT AND LEFT RELEASE	Tenoplasty	2011	Past
ACHILLES TENDON RIGHT AND LEFT RELEASE	Tenoplasty	2013	Past
OBESITY	Obesity	2019	Present
ANKLE FRACTURE RIGHT	Ankle fracture	11SEP2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07OCT2020 (1)	12:09
2	BNT162b2	27OCT2020 (21)	14:25

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	VASC	Deep vein thrombosis	RIGHT LOWER EXTREMITY DEEP VEIN THROMBOSIS	15NOV2020 (40)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC	Y	Yes	NOT RELATED/OTHER: FRACTURE	2	20	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07OCT2020	
Completed	VACCINATION	24NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.4 cm	75.3 kg	21.9 kg/m2	07OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DIABETIC PERIPHERAL NEUROPATHY	Diabetic neuropathy	2016	Present
TYPE 2 DIABETES MELLITUS	Type 2 diabetes mellitus	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07OCT2020 (1)	11:16

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	27OCT2020 (21)	10:56
3	BNT162b2	12FEB2021 (129)	11:10
4	BNT162b2	03MAR2021 (148)	15:48

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	METAB	Diabetic ketoacidosis	DIABETIC KETOACIDOSIS	18JAN2021 (104)		21JAN2021 (107)		4

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (21JAN2021)	NOT RELATED/OTHER: DIABETES	2	84	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07OCT2020	
Completed	VACCINATION	24NOV2020	
Completed	REPEAT SCREENING 1	12FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	59	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	60.2 kg	24.1 kg/m2	13OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
BINGE EATING DISORDER	Binge eating	1989	Past
SUBTOTAL ABDOMINAL HYSTERECTOMY	Hysterectomy	1994	Past
GASTRIC BYPASS	Gastric bypass	2018	Past
HERNIATED DISC C4-C6	Intervertebral disc protrusion	JAN2020	Past
HERNIATED DISC FUSION C4-C6	Intervertebral disc operation	JUN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13OCT2020 (1)	10:59
2	Placebo	09NOV2020 (28)	10:59
3	BNT162b2	15JAN2021 (95)	11:10
4	BNT162b2	04FEB2021 (115)	14:13

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	RENAL	Nephrolithiasis	KKIDNEY STONES	19FEB2021 (130)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC	Y	Yes	NOT RELATED/OTHER: UNKNOWN	4	16	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13OCT2020	
Completed	VACCINATION	07DEC2020	
Completed	REPEAT SCREENING 1	15JAN2021	
Completed	OPEN LABEL TREATMENT	08MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.2 cm	85.85 kg	31.5 kg/m2	14OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ALLERGIC TO SULFA	Drug hypersensitivity	1993	Present
ANXIETY DISORDER	Anxiety disorder	2000	Present
PARTIAL HYSTERECTOMY	Hysterectomy	FEB2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14OCT2020 (1)	11:03
2	Placebo	02NOV2020 (20)	16:08
3	BNT162b2	24FEB2021 (134)	15:53

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Chills	CHILLS	04NOV2020 (22)	11:00	05NOV2020 (23)	22:00	2
2	HEPAT	Cholecystitis	CHOLECYSTITIS	07MAR2021 (145)		10MAR2021 (148)		4
3	GENRL	Fatigue	FATIGUE	04NOV2020 (22)	11:00	05NOV2020 (23)	22:00	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (05NOV2020)	Study Treatment	2	3	N
2	2	TC	Y	Resolved (10MAR2021)	NOT RELATED/OTHER: UNKNOWN	3	12	Y
3	1	N	N	Resolved (05NOV2020)	Study Treatment	2	3	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14OCT2020	
Completed	VACCINATION	03DEC2020	
Completed	REPEAT SCREENING 1	24FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.6 cm	95.9 kg	34.1 kg/m2	21OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OBESITY	Obesity	1965	Present
OBSTRUCTIVE SLEEP APNEA	Sleep apnoea syndrome	1989	Present
MAJOR DEPRESSIVE DISORDER	Major depression	1990	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	1999	Present
POSTMENOPAUSAL	Postmenopause	1999	Present
SEASONAL ALLERGIES	Seasonal allergy	1999	Present
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2009	Present
HYPERTENSION	Hypertension	2009	Present
TYPE II DIABETES	Type 2 diabetes mellitus	2009	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
LOWER BACK PAIN (LUMBAR)	Back pain	2013	Present
GOUT	Gout	2016	Present
GENERALIZED ANXIETY DISORDER	Generalised anxiety disorder	JUL2016	Present
STENT PLACEMENT IN RIGHT CORONARY ARTERY	Coronary arterial stent insertion	01MAY2018	Past
PERCUTANEOUS CURONARY INTERVENTION	Percutaneous coronary intervention	01MAY2018	Past
MYOCARDIAL INFARCTION	Myocardial infarction	23JUN2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21OCT2020 (1)	11:22
2	Placebo	12NOV2020 (23)	15:03
3	BNT162b2	25JAN2021 (97)	14:50

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	COVID-19 pneumonia	COVID-19 PNEUMONIA	02FEB2021 (105)		06FEB2021 (109)		5
2	NERV	Syncope	SYNCOPAL EPISODE	30JAN2021 (102)		01FEB2021 (104)		3

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC	Y	Resolved (06FEB2021)	NOT RELATED/OTHER: UNKNOWN	3	9	Y
2	3	TC	Y	Resolved (01FEB2021)	NOT RELATED/OTHER: UNKNOWN	3	6	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21OCT2020	
Completed	VACCINATION	10DEC2020	
Completed	REPEAT SCREENING 1	25JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1945	75	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	94.55 kg	34.6 kg/m2	02OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Excessive urination	Polyuria	1955	Present
Insomnia	Insomnia	1990	Present
HIV	HIV test positive	1991	Present
Depression	Depression	2000	Present
Hypothyroidism	Hypothyroidism	2002	Present
Prostate cancer	Prostate cancer	2002	Past
Generalized anxiety disorder	Generalised anxiety disorder	2005	Present
COPD	Chronic obstructive pulmonary disease	2009	Present
Congestive Heart Failure	Cardiac failure congestive	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Diabetic Neuropathy	Diabetic neuropathy	2010	Present
Asthma	Asthma	2012	Present
Hypertension	Hypertension	2013	Present
Type 2 Diabetes	Type 2 diabetes mellitus	2013	Present
Alcoholic cirrhosis	Cirrhosis alcoholic	2015	Present
Sleep Apnea	Sleep apnoea syndrome	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02OCT2020 (1)	12:44
2	BNT162b2	27OCT2020 (26)	13:49

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Oedema peripheral	Peripheral edema	03FEB2021 (125)		05MAR2021 (155)		31	2
2	INFEC	Pneumonia	Pneumonia	20JAN2021 (111)		27JAN2021 (118)		8	3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (05MAR2021)	NOT RELATED/OTHER: Exisiting neuropathy	2	100	N
2	TC	Y	Resolved (27JAN2021)	NOT RELATED/OTHER: Un-related to vaccine	2	86	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02OCT2020	
Completed	VACCINATION	24NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	86.45 kg	28.1 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arthritis	Arthritis	SEP2010	Present
B12 Deficiency	Vitamin B12 deficiency	SEP2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04AUG2020 (1)	11:33
2	BNT162b2	27AUG2020 (24)	09:25

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Arthritis	worsening arthritis of right hip	10OCT2020 (68)		23DEC2020 (142)		75

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	Y	Resolved (23DEC2020)	NOT RELATED/OTHER: arthritis	2	45	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Completed	VACCINATION	24SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1993	27	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	74.18 kg	27.2 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	MAR2006	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	10:34
2	Placebo	04SEP2020 (22)	09:27

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	23DEC2020 (132)	09:25
4	BNT162b2	11JAN2021 (151)	12:30

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Brachial plexopathy	left brachial nerve plexopathy	11JAN2021 (151)	09:51	28JAN2021 (168)		18	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (28JAN2021)	NOT RELATED/OTHER: vaccine administration procedure	4	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	06OCT2020	
Completed	REPEAT SCREENING 1	23DEC2020	
Completed	OPEN LABEL TREATMENT	09FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	61.18 kg	23.8 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
bipolar disorder	Bipolar disorder	OCT1998	Present
seasonal allergies	Seasonal allergy	MAR2005	Present
hysterectomy	Hysterectomy	NOV2006	Past
anxiety	Anxiety	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	10:44
2	Placebo	09SEP2020 (24)	16:20
3	BNT162b2	20JAN2021 (157)	16:43
4	BNT162b2	12FEB2021 (180)	15:59

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Intraductal proliferative breast lesion	ductal carcinoma in situ, right breast	26OCT2020 (71)		09DEC2020 (115)		45

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TCN	Y	Resolved (09DEC2020)	NOT RELATED/OTHER: cancer	2	48	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	09OCT2020	
Completed	REPEAT SCREENING 1	20JAN2021	
Completed	OPEN LABEL TREATMENT	12MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	47	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.01 cm	103.64 kg	37.1 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	JUN1985	Present
depression	Depression	JUN1987	Present
polycystic ovary syndrome	Polycystic ovaries	JUN1987	Present
hypothyroidism	Hypothyroidism	JUN1995	Present
mitral regurgitation	Mitral valve incompetence	JUN2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	09:48
2	Placebo	02OCT2020 (22)	10:12
3	BNT162b2	16DEC2020 (97)	10:34
4	BNT162b2	06JAN2021 (118)	10:55

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Atrial fibrillation	atrial fibrillation	09OCT2020 (29)	13:00	12OCT2020 (32)	10:00	4	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (12OCT2020)	NOT RELATED/OTHER: cardiac dysrhythmia	2	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	30OCT2020	
Completed	REPEAT SCREENING 1	16DEC2020	
Completed	OPEN LABEL TREATMENT	03FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2002	17	Multiple	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.58 cm	60.18 kg	22.4 kg/m2	18SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	MAY2008	Present
asthma	Asthma	30JUN2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18SEP2020 (1)	10:00
2	BNT162b2	07OCT2020 (20)	09:38

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Chills	chills	18SEP2020 (1)	20:30	20SEP2020 (3)	11:30	3	2
2	INJ&P	Concussion	concussion	31OCT2020 (44)		ONGOING			2
3	INJ&P	Facial bones fracture	facial fractures	31OCT2020 (44)		ONGOING			3
4	GENRL	Pyrexia	fever	18SEP2020 (1)	20:30	20SEP2020 (3)	11:30	3	1
5	INJ&P	Road traffic accident	motor vehicle accident	31OCT2020 (44)		31OCT2020 (44)		1	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (20SEP2020)	Study Treatment	1	1	N
2	N	N	Yes	NOT RELATED/OTHER: motor vehicle accident	2	25	N
3	TC	Y	Yes	NOT RELATED/OTHER: motor vehicle accident	2	25	Y
4	TC	N	Resolved (20SEP2020)	Study Treatment	1	1	N
5	N	N	Resolved (31OCT2020)	NOT RELATED/OTHER: motor vehicle accident	2	25	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18SEP2020	
Completed	VACCINATION	06NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	80.45 kg	24.7 kg/m2	06AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
broken right lower jaw	Jaw fracture	2008	Past
right lower jaw surgery	Jaw operation	2008	Past
Hair Loss	Alopecia	2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	06AUG2020 (1)	12:29
2	Placebo	27AUG2020 (22)	09:20
3	BNT162b2	20JAN2021 (168)	14:47
4	BNT162b2	10FEB2021 (189)	16:01

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	VASC	Deep vein thrombosis	Deep Vein Thrombosis, left leg	27NOV2020 (114)		ONGOING		
2	RESP	Pulmonary embolism	Pulmonary Embolism, bilateral, segmental and sub segmental	14DEC2020 (131)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Yes	NOT RELATED/OTHER: Trauma, sports related	2	93	Y
2	4	TC	Y	Yes	NOT RELATED/OTHER: DVT of left leg, FH, marker	2	110	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06AUG2020	
Completed	VACCINATION	28SEP2020	
Completed	REPEAT SCREENING 1	20JAN2021	
Completed	OPEN LABEL TREATMENT	11MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	71	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	70.73 kg	28.5 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Iodine Allergy	Iodine allergy	1970	Present
Codeine Allergy	Drug hypersensitivity	1988	Present
Facial injuries	Face injury	1988	Past
Jaw surgery	Jaw operation	1988	Past
Nasal surgery	Nasal operation	1988	Past
Generalized Osteoarthritis	Osteoarthritis	1988	Present
Seasonal Allergic Rhinitis	Seasonal allergy	1988	Present
Vertigo	Vertigo	1988	Present
Asthma	Asthma	1990	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hysterectomy	Hysterectomy	1990	Past
Postmenopausal	Postmenopause	1990	Present
Uterine fibroids	Uterine leiomyoma	1990	Past
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	1994	Past
Hypothyroidism	Hypothyroidism	1994	Present
Hypertension	Hypertension	1999	Present
Hyperlipidemia	Hyperlipidaemia	2000	Present
Barrett's esophagus	Barrett's oesophagus	2004	Present
Nissen fundoplication - Surgery	Oesophagogastric fundoplasty	2004	Past
Acquired deformities of second toe of right foot	Foot deformity	2007	Present
Partial Left knee replacement	Knee arthroplasty	14MAY2007	Past
Sleep apnea	Sleep apnoea syndrome	2008	Present
Osteoporosis	Osteoporosis	JUN2008	Present
Vitamin D deficiency	Vitamin D deficiency	2009	Present
Lumbar radiculopathy	Lumbar radiculopathy	2010	Present
Fatigue	Fatigue	2012	Present
Prediabetes	Glucose tolerance impaired	2012	Past
Intermittent lower extremities edema	Oedema peripheral	2016	Present
Telangiectasias on lower extremities	Telangiectasia	2016	Present
Vitamin B12 deficiency	Vitamin B12 deficiency	2016	Present
Right trigger finger release	Tendon sheath incision	09DEC2016	Past
Right stenosing tenosynovitis	Tenosynovitis stenosans	09DEC2016	Past
Acute bronchitis	Bronchitis	15DEC2016	Past
Foot fracture	Foot fracture	2017	Past
Surgery - Foot fracture repair	Fracture treatment	2017	Past
Colonic polyps	Large intestine polyp	28APR2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Neck strain	Muscle strain	14JUN2017	Past
Right Jaw pain	Pain in jaw	14JUN2017	Past
Penicillin Allergy	Drug hypersensitivity	2018	Present
Pre-syncope	Presyncope	2018	Past
Acute rhinitis	Rhinitis	11DEC2018	Past
Left hand inflammatory arthropathy	Arthropathy	MAR2019	Past
Acute bronchitis	Bronchitis	19MAR2019	Past
Concussion	Concussion	28MAY2019	Past
Frontal Scalp contusion	Contusion	28MAY2019	Past
Closed nasal bone fracture	Facial bones fracture	28MAY2019	Past
Periorbital hematoma	Periorbital haematoma	28MAY2019	Past
Urinary tract infection	Urinary tract infection	14AUG2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12AUG2020 (1)	11:09
2	BNT162b2	01SEP2020 (21)	12:18

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	INV	Cardiac stress test abnormal	CARDIAC STRESS TEST ABNORMAL, HOSPITALIZED	08SEP2020 (28)		ONGOING			3	N	Y

Adverse Events				
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Yes	NOT RELATED/OTHER: Believed related to chronic conditions including hypertension and hyperlipidemia	2	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	14JAN2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1940	80	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.75 cm	86.23 kg	34.1 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Drug allergy - penicillin	Drug hypersensitivity	1950	Present
Drug allergy - macrodantin	Drug hypersensitivity	1950	Present
Endometriosis	Endometriosis	1960	Past
Tonsillectomy	Tonsillectomy	1961	Past
Tonsillitis	Tonsillitis	1961	Past
Allergic rhinitis	Rhinitis allergic	1972	Present
Familial tremors	Familial tremor	1974	Present
Recurrent joint pain, neck, shoulders, ankles, elbows, hips, knees, wrists	Arthralgia	1980	Present
Arthroscopy left knee	Arthroscopy	1980	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anal fistula	Anal fistula	1981	Past
Anal fistulectomy	Anal fistula repair	1981	Past
Chronic Obstructive Pulmonary Disease	Chronic obstructive pulmonary disease	1984	Present
Myopia - bilateral	Myopia	1984	Present
Presbyopia	Presbyopia	1984	Present
Obesity	Obesity	1985	Present
CPAP	Continuous positive airway pressure	1989	Present
Sleep apnea	Sleep apnoea syndrome	1989	Present
duodenal ulcer	Duodenal ulcer	1990	Past
heartburn	Dyspepsia	1990	Present
esophageal ulcer	Oesophageal ulcer	1990	Past
Tension headaches	Tension headache	1993	Present
Cholecystectomy	Cholecystectomy	1994	Past
cholelithiasis	Cholelithiasis	1994	Past
Hypercholesterolemia	Hypercholesterolaemia	1994	Present
Carpal tunnel release surgery, bilateral	Carpal tunnel decompression	1996	Past
Carpal tunnel syndrome, bilateral	Carpal tunnel syndrome	1996	Past
Osteoarthritis, bilateral hands and knees	Osteoarthritis	1997	Present
Tennis elbow	Epicondylitis	1998	Past
Gout	Gout	1998	Present
Trigger release surgery, left fourth finger	Tendon sheath incision	1999	Past
Left fourth trigger finger	Trigger finger	1999	Past
Diabetic neuropathy, bilateral lower extremities	Diabetic neuropathy	2000	Present
Diabetic neuropathy bilateral hands	Diabetic neuropathy	2000	Present
Anxiety	Anxiety	2001	Present
Depression	Depression	2001	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Rosacea	Rosacea	26NOV2001	Present
Psoriasis	Psoriasis	2002	Present
Diabetes mellitus type 2	Type 2 diabetes mellitus	2002	Present
Urinary incontinence	Urinary incontinence	2002	Present
Fracture L. 5th toe	Foot fracture	2003	Past
Recurrent back pain - lumbar	Back pain	2004	Present
Heart murmur	Cardiac murmur	2004	Present
Hypertension	Hypertension	2004	Present
Hypothyroidism	Hypothyroidism	2004	Present
mitral valve regurgitation	Mitral valve incompetence	2005	Present
Uterine lesion - benign	Uterine disorder	2005	Past
Excision, uterine lesion	Uterine operation	2006	Past
Tendonitis, left wrist	Tendonitis	JAN2006	Past
Left wrist tendonitis repair	Tenoplasty	JAN2006	Past
Left knee arthroplasty	Knee arthroplasty	2007	Past
cyst, right ankle, benign	Arthropathy	2009	Past
Pneumonia	Pneumonia	MAR2009	Past
Fracture, right foot	Foot fracture	2010	Past
External hemorrhoids	Haemorrhoids	2010	Present
chronic constipation	Constipation	APR2010	Present
Cyst excision, right ankle	Ankle operation	JUL2010	Past
Fracture, right shoulder	Upper limb fracture	JUL2010	Past
Stress fracture, right ankle	Stress fracture	AUG2010	Past
Iron deficiency anemia	Iron deficiency anaemia	SEP2010	Past
bronchitis	Bronchitis	12NOV2010	Past
Dry mouth	Dry mouth	2012	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteopenia	Osteopenia	2012	Present
Shoulder implant, right - insertion	Shoulder arthroplasty	2013	Past
Shoulder implant infection, right	Device related infection	2014	Past
Insomnia	Insomnia	2014	Present
Fibromyalgia	Fibromyalgia	APR2014	Present
Shoulder implant removal, right	Shoulder arthroplasty	APR2014	Past
Cataracts - bilateral	Cataract	2016	Past
Osteoporosis	Osteoporosis	2016	Present
atrial fibrillation	Atrial fibrillation	01NOV2017	Present
implantable loop recorder	Implantable cardiac monitor insertion	01NOV2017	Present
Chest Pain	Chest pain	2018	Present
Left rotator cuff tear	Rotator cuff syndrome	JAN2018	Past
Left rotator cuff repair surgery	Rotator cuff repair	01MAR2018	Past
Bilateral leg cramps	Muscle spasms	APR2018	Present
Chronic kidney disease stage III	Chronic kidney disease	25APR2018	Present
edema- bilateral lower extremities	Oedema peripheral	25APR2018	Present
nasal polyps	Nasal polyps	MAY2018	Present
Peripheral Vascular Disease	Peripheral vascular disorder	MAY2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	10:15
2	BNT162b2	01SEP2020 (22)	08:18

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GASTR	Diarrhoea	Diarrhea	17AUG2020 (7)	00:00	27AUG2020 (17)	00:00	11	2
2	GASTR	Diarrhoea	Diarrhea	27AUG2020 (17)		29AUG2020 (19)		3	4
3	PSYCH	Mental status changes	Mental State Status Change	02OCT2020 (53)		02OCT2020 (53)		1	2

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (27AUG2020)	NOT RELATED/OTHER: Pre-Existing conditions	1	7	N
2	TC	Y	Resolved (29AUG2020)	NOT RELATED/OTHER: Unknown	1	17	Y
3	N	N	Resolved (02OCT2020)	NOT RELATED/OTHER: unknown	2	32	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	06OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	02DEC2020	LOST TO FOLLOW-UP

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1938	81	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	64.5 kg	25.1 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Post Menopausal	Postmenopause	1982	Present
Hypothyroidism	Hypothyroidism	1999	Present
Diabetes Type II	Type 2 diabetes mellitus	10FEB1999	Present
Hypertension	Hypertension	2000	Present
Gastric Reflux	Gastrooesophageal reflux disease	10MAY2000	Present
Presbyopia	Presbyopia	2005	Present
Coronary artery disease	Coronary artery disease	2006	Present
Left Femoral popliteal bypass	Peripheral artery bypass	2006	Past
Coronary angioplasty	Coronary angioplasty	2007	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vicodin Allergy	Drug hypersensitivity	2007	Present
Peripheral Artery Disease	Peripheral arterial occlusive disease	01MAR2007	Present
Arterial Peripheral vascular disease	Peripheral arterial occlusive disease	01MAR2007	Present
Hypercholesterolemia	Hypercholesterolaemia	2008	Present
Carotid endarterectomy	Carotid endarterectomy	2009	Past
Iron Deficiency Anemia	Iron deficiency anaemia	JAN2011	Past
Cataract right Eye	Cataract	2014	Past
Cataract Left Eye	Cataract	2014	Past
Fracture right 5th finger	Hand fracture	09JUL2014	Present
Cataract surgery left eye	Cataract operation	2015	Past
recurrent left leg pain	Pain in extremity	MAR2016	Past
Cataract surgery right eye	Cataract operation	2017	Past
Myopia	Myopia	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	12:28
2	Placebo	02SEP2020 (22)	10:27

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GASTR	Pancreatic cyst	Pancreatic Cyst	04JAN2021 (146)		ONGOING			1
2	GASTR	Pancreatitis	Pancreatitis	30DEC2020 (141)		04JAN2021 (146)		6	3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Y	Yes	NOT RELATED/OTHER: Caused by Pancreatitis	2	125	Y
2	TC	Y	Resolved (04JAN2021)	NOT RELATED/OTHER: IDIOPATHIC	2	120	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Moderna COVID-19 Vaccine	COVID-19 VACCINE MRNA (MRNA 1273)	04FEB2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	30SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	22FEB2021	PROTOCOL DEVIATION

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	72	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	87.27 kg	25.3 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
gastric reflux	Gastrooesophageal reflux disease	1975	Present
Presbyopia	Presbyopia	1997	Present
Prostate Cancer	Prostate cancer	2004	Past
Radical prostatectomy	Radical prostatectomy	2004	Past
vasectomy	Vasectomy	2004	Past
Coronary stent placement	Coronary arterial stent insertion	2008	Past
Coronary artery disease	Coronary artery disease	2008	Present
Hypercholesterolemia	Hypercholesterolaemia	2008	Present
cardiac arrest	Cardiac arrest	2015	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Coronary stent placement	Coronary arterial stent insertion	2015	Past
Coronary Artery Occlusion	Coronary artery occlusion	2015	Past
Implantable Cardioverter Defibrillator Insertion	Implantable defibrillator insertion	2015	Past
cholecystectomy	Cholecystectomy	2017	Past
Cholelithiasis	Cholelithiasis	2017	Past
Bladder Cancer	Bladder cancer	2019	Past
Cystoscopy	Cystoscopy	2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14AUG2020 (1)	08:37
2	BNT162b2	04SEP2020 (22)	06:52

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Asthenia	Weakness	27OCT2020 (75)		29OCT2020 (77)		3	2
2	SURG	Cardioversion	Defibrillator Discharge	15OCT2020 (63)		15OCT2020 (63)		1	2

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Y	Resolved (29OCT2020)	NOT RELATED/OTHER: Medical History of Heart Issues	2	54	Y
2	N	N	Resolved (15OCT2020)	NOT RELATED/OTHER: Implanted Defibrillator	2	42	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	05OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	69	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168.91 cm	59.41 kg	20.8 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	1952	Present
Fractured Right Hip	Hip fracture	1985	Past
Right Hip Fracture Repair and Internal Fixation	Internal fixation of fracture	1985	Past
Hypertension	Hypertension	1988	Present
Fractured Left Hip	Hip fracture	1990	Past
Left Hip Fracture Repair and Internal Fixation	Internal fixation of fracture	1990	Past
Pneumonia	Pneumonia	1993	Past
Presbyopia	Presbyopia	1998	Present
Coronary Artery Disease	Coronary artery disease	2007	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	2007	Present
Hypercholesterolemia	Hypercholesterolaemia	2007	Present
Bilateral Hips Joint Pain	Arthralgia	2008	Present
Recurrent Back Pain	Back pain	2008	Present
Osteoarthritis Bilateral Hips	Osteoarthritis	2008	Present
Benign Prostate Hypertrophy	Benign prostatic hyperplasia	2012	Present
Chronic Obstructive Pulmonary Disease	Chronic obstructive pulmonary disease	2013	Present
Total Replacement Left Hip Surgery	Hip arthroplasty	2013	Past
Inguinal Hernia	Inguinal hernia	2013	Past
Herniorraphy Inguinal	Inguinal hernia repair	2013	Past
Chronic Kidney Disease Stage II	Chronic kidney disease	2016	Present
Cardiomegaly	Cardiomegaly	04OCT2016	Present
Gout	Gout	APR2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	08:32
2	Placebo	11SEP2020 (23)	09:53

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	BLOOD	Anaemia	Anemia	17DEC2020 (120)		19DEC2020 (122)		3

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TCN	Y	Resolved (19DEC2020)	NOT RELATED/OTHER: Iron Deficiency	2	98	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	38	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	64.41 kg	22.9 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Myopia	Myopia	1990	Past
Eczema	Eczema	1998	Present
Cosmetic Breast Reduction	Mammoplasty	2005	Past
Allergic Rhinitis	Rhinitis allergic	2010	Present
Hemorrhoids	Haemorrhoids	2011	Present
Hemorrhoids	Haemorrhoids	2011	Present
Herniated Lumbar Discs	Intervertebral disc protrusion	2012	Present
Iron Deficiency Anemia	Iron deficiency anaemia	2013	Present
Laminoectomy	Spinal laminectomy	AUG2013	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Breast Augmentation	Mammoplasty	2016	Past
Nasal Fracture	Facial bones fracture	2017	Past
Septoplasty	Nasal septal operation	2017	Past
Herpes Simplex Virus Type II	Herpes simplex	2018	Present
Chronic Cough	Cough	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	14:46
2	Placebo	23SEP2020 (23)	14:14

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Breast cancer	Ductal carcinoma right Breast	13NOV2020 (74)		ONGOING			3
2	INJ&P	Intentional overdose	Overdose Intentional	09MAR2021 (190)		10MAR2021 (191)		2	3
3	NEOPL	Invasive ductal breast carcinoma	Ductal Carcinoma Left Breast	13NOV2020 (74)		ONGOING			3
4	NEOPL	Metastases to lymph nodes	Right Axillary Metastases	13NOV2020 (74)		ONGOING			3
5	PSYCH	Suicide attempt	Attempted Suicide	09MAR2021 (190)		10MAR2021 (191)		2	3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	Y	Yes	NOT RELATED/OTHER: Idiopathic.	2	52	Y
2	N	Y	Resolved (10MAR2021)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	168	Y
3	TC	Y	Yes	NOT RELATED/OTHER: idiopathic	2	52	Y
4	TC	Y	Yes	NOT RELATED/OTHER: finding	2	52	Y
5	N	Y	Resolved (10MAR2021)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	168	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	22OCT2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	46	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168.91 cm	104.5 kg	36.5 kg/m2	23SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Myopia	Myopia	1987	Present
Allergic rhinitis	Rhinitis allergic	1990	Present
Recurrent back pain	Back pain	1991	Present
Nephrolithiasis	Nephrolithiasis	1991	Past
Obesity	Obesity	1994	Present
Presbyopia	Presbyopia	2000	Present
Intermittent leg cramps	Muscle spasms	2010	Present
Heartburn	Dyspepsia	2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Glaucoma	Glaucoma	2018	Present
Herpes zoster	Herpes zoster	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23SEP2020 (1)	12:54
2	Placebo	14OCT2020 (22)	12:33
3	BNT162b2	24FEB2021 (155)	10:34

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	COVID-19	COVID-19 Illness	28DEC2020 (97)		23JAN2021 (123)		27
2	GENRL	Fatigue	Mild Fatigue	23SEP2020 (1)	19:00	24SEP2020 (2)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Resolved (23JAN2021)	NOT RELATED/OTHER: COVID Illness	2	76	Y
2	1	N	N	Resolved (24SEP2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	23SEP2020	
Completed	VACCINATION	11NOV2020	
Completed	REPEAT SCREENING 1	24FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.75 cm	53.5 kg	21.2 kg/m2	24SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Myopia	Myopia	1988	Present
Osteoarthritis - knees	Osteoarthritis	1995	Present
Allergic rhinitis	Rhinitis allergic	1995	Present
Hemorrhoids	Haemorrhoids	1998	Present
Anxiety	Anxiety	2001	Present
Cyst - bilateral breasts	Breast cyst	2001	Past
Cystectomy - bilateral breasts	Breast cyst excision	2001	Past
Insomnia	Insomnia	2005	Present
Bilateral carpal tunnel syndrome	Carpal tunnel syndrome	2006	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Recurrent lumbar pain	Back pain	2010	Present
Recurrent abdominal pain	Abdominal pain	2012	Present
Chronic constipation	Constipation	2012	Past
Asthma	Asthma	2013	Present
Osteoporosis	Osteoporosis	2013	Present
Septal deviation - nasal	Nasal septum deviation	AUG2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24SEP2020 (1)	13:40
2	Placebo	15OCT2020 (22)	11:09

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Cardiac arrest	Cardiac Arrest	21NOV2020 (59)		21NOV2020 (59)		1	4	TCN	Y
2	CARD	Cardiac arrest	Cardiac Arrest	23NOV2020 (61)		23NOV2020 (61)		1	4	TCN	Y
3	VASC	Deep vein thrombosis	Left Superficial Femoral Vein Deep Vein Thrombosis	04NOV2020 (42)		04DEC2020 (72)		31	3	N	Y

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
4	GASTR	Gastrointestinal mucosa hyperaemia	Hyperemic Bowel	04NOV2020 (42)		05NOV2020 (43)		2	4	N	Y
5	RESP	Pneumothorax	Left Pneumothorax	04NOV2020 (42)		04DEC2020 (72)		31	4	N	Y
6	RESP	Pulmonary embolism	Left Pulmonary Emboli	04NOV2020 (42)		04DEC2020 (72)		31	3	N	Y
7	INJ&P	Rib fracture	Bilateral Rib Fractures	04NOV2020 (42)		ONGOING			3	N	Y
8	INJ&P	Road traffic accident	Injury Secondary to Pedestrian-Car Accident	04NOV2020 (42)		ONGOING			4	N	Y
9	INJ&P	Spinal column injury	Severe T2 Distraction Injury	04NOV2020 (42)		ONGOING			3	N	Y
10	NERV	Spinal cord compression	Spinal Cord Compression	04NOV2020 (42)		ONGOING			4	N	Y
11	INJ&P	Subdural haematoma	Small Parafalcine Subdural hematoma	04NOV2020 (42)		03DEC2020 (71)		30	3	N	Y
12	INJ&P	Traumatic haemothorax	Right Hemopneumothorax	04NOV2020 (42)		04DEC2020 (72)		31	4	N	Y
13	GASTR	Volvulus	Sigmoid Volvulus	04NOV2020 (42)		05NOV2020 (43)		2	4	N	Y

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (21NOV2020)	NOT RELATED/OTHER: Injury secondary to pedestrian-car accident	2	38	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	Resolved (23NOV2020)	NOT RELATED/OTHER: Injury secondary to pedestrian-vehicle accident	2	40	Y
3	Resolved (04DEC2020)	NOT RELATED/OTHER: Injury Secondary to Pedestrian-Car Accident	2	21	Y
4	Resolved (05NOV2020)	NOT RELATED/OTHER: Injury Secondary to Pedestrian-Car Accident	2	21	Y
5	Resolved (04DEC2020)	NOT RELATED/OTHER: Injury Secondary to Pedestrian-Car Accident	2	21	Y
6	Resolved (04DEC2020)	NOT RELATED/OTHER: injury Secondary to Pedestrian-Car Accident	2	21	Y
7	Yes	NOT RELATED/OTHER: Injury Secondary to Pedestrian-Car Accident	2	21	Y
8	Yes	NOT RELATED/OTHER: Pedestrian-Car Accident	2	21	Y
9	Yes	NOT RELATED/OTHER: Injury Secondary to Pedestrian-Car Accident	2	21	Y
10	Yes	NOT RELATED/OTHER: T2 distraction injury	2	21	Y
11	Resolved (03DEC2020)	NOT RELATED/OTHER: Injury Secondary to Pedestrian-Car Accident.	2	21	Y
12	Resolved (04DEC2020)	NOT RELATED/OTHER: Injury Secondary to Pedestrian-Car Accident	2	21	Y
13	Resolved (05NOV2020)	NOT RELATED/OTHER: Hyperemic Bowel	2	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24SEP2020	
Withdrawn	VACCINATION	12NOV2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	39	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166.37 cm	79.64 kg	28.7 kg/m2	05OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Myopia	Myopia	1995	Present
Recurrent back pain lumbar	Back pain	1998	Present
Polycystic Kidney Disease	Congenital cystic kidney disease	1999	Present
Migraine	Migraine	2000	Present
allergic rhinitis	Rhinitis allergic	2010	Present
Biliary Colic	Biliary colic	2012	Past
cholecystectomy	Cholecystectomy	2012	Past
bilateral tubal ligation	Female sterilisation	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05OCT2020 (1)	15:26
2	BNT162b2	17NOV2020 (44)	13:56

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Benign pancreatic neoplasm	Serious cystadenoma of Pancreas	24OCT2020 (20)		ONGOING			1
2	GASTR	Diverticulum	Diverticulosis	24OCT2020 (20)		ONGOING			1
3	INFEC	Urinary tract infection	Urinary Tract Infection	15OCT2020 (11)		24OCT2020 (20)		10	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Yes	NOT RELATED/OTHER: unknown	1	20	N
2	N	N	Yes	NOT RELATED/OTHER: incidental finding	1	20	N
3	TC	Y	Resolved (24OCT2020)	NOT RELATED/OTHER: Pancreatic Mass Found	1	11	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	05OCT2020	
Completed	VACCINATION	16DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	126.2 kg	45.3 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to penicillin	Drug hypersensitivity	2000	Present
Allergy to Amoxicillin	Drug hypersensitivity	2000	Present
Rosacea	Rosacea	2000	Present
Right Knee arthroscopy	Arthroscopy	2002	Past
Right Torn Meniscus	Meniscus injury	2002	Past
Postmenopausal	Postmenopause	2008	Present
Goiter	Goitre	2014	Past
Hyperthyroidism	Hyperthyroidism	2014	Past
Hypothyroidism	Hypothyroidism	2014	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bilateral Knee Replacement	Knee arthroplasty	2014	Past
Osteoarthritis in bilateral knees	Osteoarthritis	2014	Past
Osteoarthritis in bilateral hips	Osteoarthritis	2014	Past
Thyroidectomy	Thyroidectomy	2014	Past
Right Hip Replacement	Hip arthroplasty	2015	Past
Seasonal Allergic Rhinitis	Seasonal allergy	2015	Present
Hypertriglyceridemia	Hypertriglyceridaemia	2016	Present
L Shoulder Osteoarthritis	Osteoarthritis	JAN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	13:03
2	BNT162b2	09SEP2020 (24)	12:04

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Osteoarthritis	Worsening of osteoarthritis (left shoulder)	10FEB2021 (178)		ONGOING		

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC/TCN	Y	Yes	NOT RELATED/OTHER: L Shoulder osteoarthritis	2	155	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	12OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182 cm	92.3 kg	27.9 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergic Rhinitis	Seasonal allergy	1961	Present
L Achilles Tendon Tear	Tendon rupture	1980	Past
L Achilles Tendon Repair	Tenoplasty	1980	Past
L Knee Torn Ligament Repair	Ligament operation	1985	Past
Torn Ligament L Knee	Ligament rupture	1985	Past
Strawberry Allergy	Food allergy	1990	Present
L Knee Osteoarthritis	Osteoarthritis	1990	Past
L Knee Replacement	Knee arthroplasty	2016	Past
Prostate Cancer	Prostate cancer	2017	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Prostatectomy	Prostatectomy	2017	Past
Osteoarthritis (right knee)	Osteoarthritis	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	09:36
2	Placebo	15SEP2020 (23)	15:34
3	BNT162b2	22JAN2021 (152)	08:18
4	BNT162b2	10FEB2021 (171)	10:17

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INJ&P	Joint dislocation	Dislocated right patella	NOV2020 ()		12MAR2021 (201)			2	TC
2	INJ&P	Ligament sprain	L Knee Sprain	14OCT2020 (52)		21OCT2020 (59)		8	2	TC
3	MUSC	Osteoarthritis	Worsening of osteoarthritis (right knee)	12MAR2021 (201)		ONGOING			2	TC/TCN

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Resolved (12MAR2021)	NOT RELATED/OTHER: unknown	2		N
2	N	Resolved (21OCT2020)	NOT RELATED/OTHER: Not related to drug/non-drug treatment	2	30	N
3	Y	Yes	NOT RELATED/OTHER: unknown	4	31	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	13OCT2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	REPEAT SCREENING 1	22JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	75	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	87 kg	33.2 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Appendectomy	Appendicectomy	1968	Past
Appendicitis	Appendicitis	1968	Past
Cholecystectomy	Cholecystectomy	1968	Past
Gallstones	Cholelithiasis	1968	Past
Total Hysterectomy	Hysterectomy	1975	Past
Vaginal Bleeding	Vaginal haemorrhage	1975	Past
Osteoarthritis of Back	Spinal osteoarthritis	1980	Present
Herniated Disc Repair Lumbar Spine	Intervertebral disc operation	1988	Past
Herniated Disc Lumbar Spine	Intervertebral disc protrusion	1988	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic Sinusitis	Chronic sinusitis	1990	Present
Tetracycline Allergy	Drug hypersensitivity	1995	Present
Sulfa Allergy	Drug hypersensitivity	1995	Present
Penicillin Allergy	Drug hypersensitivity	2000	Present
Ruptured Disc Repair Lumbar Spine	Intervertebral disc operation	2000	Past
Ruptured Disc Lumbar Spine	Intervertebral disc protrusion	2000	Past
Achalasia	Oesophageal achalasia	2000	Past
Biaxin Allergy	Drug hypersensitivity	2005	Present
Hypertension	Hypertension	2010	Present
Vaginal Dryness	Vulvovaginal dryness	2010	Present
Esophagomyotomy	Oesophageal operation	2016	Past
Tylenol Allergy	Drug hypersensitivity	2018	Present
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	2018	Present
Osteopenia	Osteopenia	2018	Present
L Shoulder Injury	Limb injury	2019	Past
Bilateral Knee Osteoarthritis	Osteoarthritis	JAN2020	Present
Sinus Surgery	Sinus operation	JAN2020	Past
Thinning Skin	Skin atrophy	JAN2020	Present
L Shoulder Surgery	Shoulder operation	25JUN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	13:35
2	BNT162b2	15SEP2020 (23)	16:04

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	GASTR	Haematemesis	Vomiting blood	06MAR2021 (195)		ONGOING			3	N	Y
2	INJ&P	Ligament sprain	R Knee Sprain	03SEP2020 (11)		06SEP2020 (14)		4	1	TC	N

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Yes	NOT RELATED/OTHER: unknown	2	173	Y
2	Resolved (06SEP2020)	NOT RELATED/OTHER: AE is not related to any drug/non-drug treatment	1	11	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	13OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	83.2 kg	31.3 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to Penicillin	Drug hypersensitivity	1956	Present
Allergy to Morphine	Drug hypersensitivity	1959	Present
Tonsillectomy	Tonsillectomy	1959	Past
Tonsillitis	Tonsillitis	1959	Past
Post Menopausal	Postmenopause	1999	Present
Plummer Disease	Toxic nodular goitre	2003	Past
Hypertension	Hypertension	2004	Present
Hypothyroidism	Hypothyroidism	2004	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Total Thyroidectomy	Thyroidectomy	2004	Past
Allergy to Cipro	Drug hypersensitivity	2005	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	09:37
2	Placebo	01OCT2020 (22)	09:45
3	BNT162b2	22JAN2021 (135)	08:49
4	BNT162b2	10FEB2021 (154)	08:50

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Breast cancer	Breast Cancer (right breast)	11FEB2021 (155)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	N	Y	Yes	NOT RELATED/OTHER: unknown	4	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Seasonal Influenza Vaccine	INFLUENZA VACCINE	16OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	29OCT2020	
Completed	REPEAT SCREENING 1	22JAN2021	
Completed	OPEN LABEL TREATMENT	10MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154 cm	67.7 kg	28.5 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillectomy	Tonsillectomy	1959	Past
Tonsillitis	Tonsillitis	1959	Past
Seasonal Allergic Rhinitis	Seasonal allergy	1979	Present
Post Menopausal	Postmenopause	2000	Present
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10SEP2020 (1)	16:44
2	BNT162b2	01OCT2020 (22)	15:06

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	NERV	Cerebrovascular accident	Stroke (CVA)	02NOV2020 (54)		15DEC2020 (97)		44	3	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (15DEC2020)	NOT RELATED/OTHER: not related to drug or non-drug treatment	2	33	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	30OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	74.36 kg	29 kg/m2	17SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	02FEB2010	Past
Asthma	Asthma	25AUG2010	Present
Post traumatic stress disorder	Post-traumatic stress disorder	24JUN2011	Present
Depression	Depression	05JUL2012	Present
Tubular Adenoma of colon	Colon adenoma	13DEC2016	Past
Menopause	Menopause	2017	Present
Macrocytosis	Macrocytosis	23APR2018	Present
Symptomatic Cholethiasis	Cholelithiasis	27AUG2019	Present
Anemia	Anaemia	03AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17SEP2020 (1)	09:40
2	BNT162b2	08OCT2020 (22)	09:22

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Flank pain	Moderate left flank pain	02OCT2020 (16)	08:00	ONGOING		
2	GENRL	Injection site pain	Mild Injection Site Pain	17SEP2020 (1)	18:00	20SEP2020 (4)		4
3	GENRL	Injection site pain	Mild Injection Site Pain	08OCT2020 (22)	10:00	09OCT2020 (23)	07:00	2
4	GENRL	Injection site papule	Erythematous Papules around injection site	08OCT2020 (22)	12:00	09OCT2020 (23)	07:00	2
5	NEOPL	Plasma cell myeloma	IGA Kappa Multiple Myeloma	27NOV2020 (72)	14:06	ONGOING		
6	EAR	Vertigo positional	Benign Paroxysmal Positional Vertigo	16OCT2020 (30)	08:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/TCN	N	Yes	NOT RELATED/OTHER: Musculoskeletal	1	16	N
2	1	N	N	Resolved (20SEP2020)	Study Treatment	1	1	N

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
3	1	N	N	Resolved (09OCT2020)	Study Treatment	2	1	N
4	1	N	N	Resolved (09OCT2020)	Study Treatment	2	1	N
5	2	N	Y	Yes	NOT RELATED/OTHER: Idiopathic	2	51	Y
6	2	N	N	Yes	NOT RELATED/OTHER: Idiopathic	2	9	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
T-Dap	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	19OCT2020
Seasonal Flu Vaccine	INFLUENZA VACCINE	23OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17SEP2020	
Completed	VACCINATION	05NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	77	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.29 cm	66.45 kg	25.5 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DRUG ALLERGY TO CODEINE SULFATE	Drug hypersensitivity	1961	Present
NICOTINE DEPENDENCE	Nicotine dependence	1980	Past
DRUG ALLERGY TO ZESTRIL	Drug hypersensitivity	1996	Present
HYPERTENSION	Hypertension	1996	Present
POSTMENOPAUSAL	Postmenopause	1996	Present
DRUG ALLERGY TO LOPRESSOR	Drug hypersensitivity	1998	Present
HYPERLIPIDEMIA	Hyperlipidaemia	2000	Present
OSTEOPOROSIS	Osteoporosis	2008	Present
DRUG ALLERGY TO FOSAMAX	Drug hypersensitivity	2009	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
LEFT BUNDLE BRANCH BLOCK	Bundle branch block left	2010	Present
PALPITATIONS	Palpitations	2010	Present
SHORTNESS OF BREATH	Dyspnoea	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	15:28
2	BNT162b2	12SEP2020 (24)	10:48

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Acute myeloid leukaemia	Acute Myeloid Leukemia	08NOV2020 (81)		ONGOING	
2	VASC	Deep vein thrombosis	Deep Vein Thrombosis	11NOV2020 (84)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC/TCN	Y	Yes	NOT RELATED/OTHER: Unknown	2	58	Y
2		2	TC	N	Yes	NOT RELATED/OTHER: Acute Leukemia	2	61	N

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Decitabine (Dacogen)	DECITABINE	10NOV2020	ONGOING	INTRAVENOUS
Venetoclax (Venclexta)	VENETOCLAX	10NOV2020	ONGOING	ORAL

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	14OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.99 cm	76.91 kg	25.3 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Achilles tendon rupture, right	Tendon rupture	25JUN2018	Past
Achilles tendon rupture repair, right	Tenoplasty	07NOV2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	15:12
2	BNT162b2	11SEP2020 (23)	13:04

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INV	Body temperature increased	elevated body temperature	21AUG2020 (2)		22AUG2020 (3)		2	2
2	SOCCI	Miscarriage of partner	miscarriage for pregnant partner	22DEC2020 (125)		22DEC2020 (125)		1	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (22AUG2020)	Study Treatment	1	2	N
2	N	Y	Resolved (22DEC2020)	NOT RELATED/OTHER: partner pregnancy	2	103	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	12OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.47 cm	68.36 kg	25.2 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1985	Present
Asthma, Allergy Induced	Asthma	1992	Present
Amoxicillin Allergy	Drug hypersensitivity	1992	Present
Wisdom Teeth Extraction	Wisdom teeth removal	1994	Past
Ceftin Allergy	Drug hypersensitivity	1998	Present
Polycystic Ovarian Disease	Polycystic ovaries	2003	Present
Hyperlipidemia	Hyperlipidaemia	2015	Present
GERD	Gastrooesophageal reflux disease	2016	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	AUG2016	Past
Hypothyroidism	Hypothyroidism	30AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	10:01
2	Placebo	16SEP2020 (22)	10:55

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	REPRO	Breast mass	left breast lump	27AUG2020 (2)		29SEP2020 (35)		34
2	GASTR	Diarrhoea	diarrhea	01SEP2020 (7)		01SEP2020 (7)		1
3	GENRL	Injection site pain	left arm soreness at injection site.	27AUG2020 (2)		29AUG2020 (4)		3
4	NEOPL	Invasive ductal breast carcinoma	invasive ductal carcinoma stage 1B, left breast	30SEP2020 (36)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (29SEP2020)	NOT RELATED/OTHER: breast lump	1	2	N

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	2	N	N	Resolved (01SEP2020)	Study Treatment	1	7	N
3	2	N	N	Resolved (29AUG2020)	Study Treatment	1	2	N
4	2	TC	Y	Yes	NOT RELATED/OTHER: breast cancer	2	15	Y

Prohibited Concomitant Medications				
Investigator Text	WHO Drug Preferred Term	Start Date	End Date	Route
paclitaxel	PACLITAXEL	08FEB2021	08FEB2021	INTRAVENOUS

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	14OCT2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.04 cm	83 kg	31.9 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
environmental allergy	Hypersensitivity	1980	Present
asthma	Asthma	1984	Present
chronic back pain	Back pain	1989	Present
herpes simplex, genital	Genital herpes simplex	1990	Present
irritable bowel syndrome-constipation	Irritable bowel syndrome	1990	Present
drug abuse	Drug abuse	1999	Past
anxiety	Anxiety	2000	Present
depression	Depression	2000	Present
chronic vaginitis	Vaginal infection	2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
lumbar facet syndrome	Facet joint syndrome	2013	Present
degenerative disc disease	Intervertebral disc degeneration	2013	Present
herniated disc	Intervertebral disc protrusion	2013	Present
lumbar spondylosis	Spinal osteoarthritis	2014	Present
cervical spondylosis	Spinal osteoarthritis	2014	Present
bilateral sacro-iliac joint dysfunction	Spondyloarthropathy	2014	Present
dyspareunia	Dyspareunia	2015	Present
hot flashes	Hot flush	2015	Present
insomnia	Insomnia	2015	Present
osteoarthritis	Osteoarthritis	2015	Present
obesity	Obesity	2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	11:50
2	BNT162b2	17SEP2020 (23)	16:03

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Fatigue	Fatigue	27AUG2020 (2)		03SEP2020 (9)		8
2	INJ&P	Upper limb fracture	Closed fracture of right elbow	28OCT2020 (64)	19:35	29OCT2020 (65)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (03SEP2020)	Study Treatment	1	2	N
2	2	TC/TCN	Y	Resolved (29OCT2020)	NOT RELATED/OTHER: fall trauma	2	42	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	65	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.01 cm	71.82 kg	25.7 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
inguinal hernia	Inguinal hernia	1996	Past
inguinal hernia surgery	Inguinal hernia repair	1996	Past
inguinal hernia surgery	Inguinal hernia repair	1998	Past
cervical discectomy	Intervertebral disc operation	1999	Past
herniated discs	Intervertebral disc protrusion	1999	Past
inguinal hernia surgery	Inguinal hernia repair	2002	Past
osteoarthritis	Osteoarthritis	2005	Present
left hip arthroplasty	Hip arthroplasty	14JUN2007	Past
colonoscopy	Colonoscopy	06DEC2007	Past
hypertension	Hypertension	11NOV2011	Present
left hip bursitis	Bursitis	21JUN2017	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
actinic keratosis	Actinic keratosis	SEP2019	Present
hyperlipidemia	Hyperlipidaemia	APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	10:14
2	BNT162b2	21SEP2020 (22)	10:46

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	MUSC	Intervertebral disc degeneration	worsening cervical degenerative disc disease	05JAN2021 (128)		06JAN2021 (129)		2	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	Y	Resolved (06JAN2021)	NOT RELATED/OTHER: disc-cervical herniation	2	107	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	75 kg	26.5 kg/m2	27OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
codeine allergy	Drug hypersensitivity	1956	Present
chronic back pain	Back pain	1977	Present
vasectomy	Vasectomy	1990	Past
left bicep injury	Muscle injury	2005	Past
bicep tendon repair left	Tenoplasty	2005	Past
hypertension	Hypertension	2010	Present
herpes simplex labialis	Oral herpes	2013	Present
left hand laceration	Skin laceration	2013	Past
left hand tendon repair	Tenoplasty	2013	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
colonoscopy	Colonoscopy	08MAR2013	Past
colon polypectomy benign	Large intestinal polypectomy	08MAR2013	Past
chronic kidney disease stage 2	Chronic kidney disease	2014	Present
impaired fasting glucose	Impaired fasting glucose	2015	Present
overweight	Overweight	2015	Present
paresthesia bilateral feet	Paraesthesia	2015	Present
bilateral cataracts	Cataract	2016	Present
osteoarthritis	Osteoarthritis	2016	Present
benign prostatic hyperplasia	Benign prostatic hyperplasia	2017	Present
gastroesophageal reflux disease	Gastrooesophageal reflux disease	2017	Present
right renal cyst	Renal cyst	2017	Present
hyperlipidemia	Hyperlipidaemia	2018	Present
colonoscopy	Colonoscopy	28JUL2018	Past
colon polypectomy benign	Large intestinal polypectomy	28JUL2018	Past
bilateral carotid artery stenosis	Carotid artery stenosis	2019	Present
supraventricular tachycardia	Supraventricular tachycardia	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27OCT2020 (1)	12:56
2	Placebo	17NOV2020 (22)	13:47
3	BNT162b2	14JAN2021 (80)	09:35
4	BNT162b2	04FEB2021 (101)	10:51

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	RENAL	Acute kidney injury	acute kidney injury	16FEB2021 (113)	21:14	23FEB2021 (120)	12:20	8	2
2	CARD	Atrial fibrillation	atrial fibrillation	16FEB2021 (113)		ONGOING			2
3	CARD	Atrial fibrillation	atrial fibrillation with rapid ventricular response	16FEB2021 (113)	19:00	17FEB2021 (114)		2	2

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (23FEB2021)	NOT RELATED/OTHER: dehydration	4	13	N
2	N	N	Yes	NOT RELATED/OTHER: atrial fibrillation	4	13	N
3	TC	Y	Resolved (17FEB2021)	NOT RELATED/OTHER: atrial fibrillation	4	13	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27OCT2020	
Completed	VACCINATION	15DEC2020	
Completed	REPEAT SCREENING 1	14JAN2021	
Completed	OPEN LABEL TREATMENT	04MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	66 kg	24.2 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
depression	Depression	01JAN2012	Present
hyperlipidemia	Hyperlipidaemia	01JAN2015	Present
sleep apnea.	Sleep apnoea syndrome	01JAN2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09SEP2020 (1)	14:00
2	Placebo	02OCT2020 (24)	10:55
3	BNT162b2	21JAN2021 (135)	10:35
4	BNT162b2	25FEB2021 (170)	09:20

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Headache	headaches	22OCT2020 (44)	00:00	ONGOING	
2	NEOPL	Lung adenocarcinoma	adenocarcinoma, right lung	02DEC2020 (85)		ONGOING	
3	NEOPL	Metastases to lymph nodes	Metastasis to lymph Nodes	02DEC2020 (85)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	N	N	Yes	NOT RELATED/OTHER: car accident	2	21	N
2		2	TCN	Y	Yes	NOT RELATED/OTHER: NA	2	62	Y
3		2	TC	Y	Yes	NOT RELATED/OTHER: NA	2	62	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	05NOV2020	
Completed	REPEAT SCREENING 1	21JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	58 kg	21.9 kg/m2	18SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18SEP2020 (1)	13:40
2	Placebo	09OCT2020 (22)	09:05

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	12FEB2021 (148)	13:55
4	BNT162b2	04MAR2021 (168)	09:20

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Pharyngitis streptococcal	pharyngitis streptococcal	17JAN2021 (122)		30JAN2021 (135)		14	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (30JAN2021)	NOT RELATED/OTHER: Bacterial Infection	2	101	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18SEP2020	
Completed	VACCINATION	06NOV2020	
Completed	REPEAT SCREENING 1	12FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	44	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.6 cm	83.9 kg	31.7 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SEASONAL ALLERGIES	Seasonal allergy	1997	Present
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2010	Present
UTERINE SCARRING	Uterine disorder	2011	Past
ANXIETY	Anxiety	2016	Present
BIPOLAR DEPRESSION	Bipolar disorder	2016	Present
OBESITY	Obesity	2016	Present
HYSTERECTOMY	Hysterectomy	2017	Past
Exercise induced Asthma	Asthma exercise induced	2019	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	24AUG2020 (1)	09:44
2	BNT162b2	14SEP2020 (22)	14:09

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GASTR	Diarrhoea	DIARRHEA	25AUG2020 (2)		23SEP2020 (31)		30	1
2	RESP	Dyspnoea	INCREASED SHORTNESS OF BREATH	31JAN2021 (161)		ONGOING			3
3	EAR	Ear pain	EAR ACHE	18SEP2020 (26)		28SEP2020 (36)		11	1
4	GENRL	Influenza like illness	FLU LIKE SYMPTOMS	18SEP2020 (26)	12:00	20SEP2020 (28)		3	1
5	GENRL	Pyrexia	LOW GRADE FEVER	24AUG2020 (1)	13:00	25AUG2020 (2)	08:00	2	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (23SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	2	N
2	TC/TCN	Y	Yes	NOT RELATED/OTHER: UNKNOWN	2	140	Y
3	TC	N	Resolved (28SEP2020)	NOT RELATED/OTHER: SEASONAL ALLERGIES	2	5	N
4	N	N	Resolved (20SEP2020)	Study Treatment	2	5	N
5	N	N	Resolved (25AUG2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	12OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	74	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	99.79 kg	29 kg/m2	02OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HEPATITIS B	Hepatitis B	1968	Past
HYPERTENSION	Hypertension	1990	Present
Chest Pain (unspecified cardiac)	Chest pain	2009	Present
Myocardial Infarct	Myocardial infarction	2009	Past
BILATERAL CATARACTS	Cataract	2018	Present
Gout	Gout	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02OCT2020 (1)	11:55
2	Placebo	23OCT2020 (22)	09:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INV	Blood pressure increased	ELEVATED BLOOD PRESSURE	15DEC2020 (75)		18DEC2020 (78)		4	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (18DEC2020)	NOT RELATED/OTHER: PRE-EXISTING MEDICAL	2	54	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02OCT2020	
Completed	VACCINATION	20NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.99 cm	79.91 kg	26.3 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Nicotine Dependence	Nicotine dependence	DEC1975	Present
Post Menopausal	Postmenopause	1990	Present
Cholecystectomy	Cholecystectomy	1998	Past
Gallstones	Cholelithiasis	1998	Past
Hypertension	Hypertension	2012	Present
Surgery for Open Fracture of Hip	Fracture treatment	2013	Past
Hypothyroidism	Hypothyroidism	2014	Present
COPD	Chronic obstructive pulmonary disease	07NOV2014	Present
Osteoporosis	Osteoporosis	2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vitamin D Deficiency	Vitamin D deficiency	2018	Present
Dysenthesia of Multiple Sites	Dysaesthesia	DEC2019	Present
Hyperlipidemia	Hyperlipidaemia	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	14:25
2	Placebo	15SEP2020 (20)	13:37
3	BNT162b2	29JAN2021 (156)	10:45

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INV	Blood pressure increased	Elevated blood pressure	17FEB2021 (175)	20:00	17FEB2021 (175)		1	1
2	RESP	Chronic obstructive pulmonary disease	COPD exacerbation	07FEB2021 (165)	17:00	08FEB2021 (166)		2	2

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (17FEB2021)	NOT RELATED/OTHER: hypertension history	3	20	N
2	TC	Y	Resolved (08FEB2021)	NOT RELATED/OTHER: chronic condition	3	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	15OCT2020	
Completed	REPEAT SCREENING 1	29JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	69	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
195.58 cm	123.18 kg	32.1 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
old sport injury R knee	Sports injury	1963	Past
Allergic rhinitis	Rhinitis allergic	2000	Present
Surgery on R knee	Knee operation	2006	Past
Hypertension	Hypertension	14MAR2009	Present
Male erective disorder	Erectile dysfunction	2010	Present
Lumbar radiculopathy	Lumbar radiculopathy	22DEC2015	Present
Impingement syndrome of R shoulder	Rotator cuff syndrome	23FEB2017	Present
Bursitis of R shoulder	Bursitis	20JUN2017	Present
Bilateral carpal tunnel syndrome	Carpal tunnel syndrome	20DEC2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hyperlipidemia	Hyperlipidaemia	27DEC2018	Present
Obesity	Obesity	2019	Present
Cataract surgery L eye	Cataract operation	MAR2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	08SEP2020 (1)	09:41
2	BNT162b2	28SEP2020 (21)	09:07

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Fatigue	fatigue	09SEP2020 (2)	07:00	11SEP2020 (4)		3
2	GENRL	Injection site pain	Injection site tenderness	08SEP2020 (1)	12:00	11SEP2020 (4)		4
3	NERV	Ischaemic stroke	Acute Ischemic Stroke	04OCT2020 (27)	13:00	06OCT2020 (29)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (11SEP2020)	Study Treatment	1	2	N

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	1	N	N	Resolved (11SEP2020)	Study Treatment	1	1	N
3	2	N	Y	Resolved (06OCT2020)	NOT RELATED/OTHER: unknown	2	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	27OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1941	79	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.1 cm	83.9 kg	27.4 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ALLERGIC RHINITIS	Rhinitis allergic	1960	Present
DEEP VEIN THROMBOSIS	Deep vein thrombosis	1977	Present
Factor V Leiden carrier	Factor V Leiden carrier	1977	Present
PROSTATE CANCER	Prostate cancer	2003	Present
CATARACTS	Cataract	JAN2003	Present
SKIN CANCER	Skin cancer	JAN2006	Present
ELEVATED CHOLESTEROL	Blood cholesterol increased	2010	Present
RECURRENT BACK PAIN	Back pain	JAN2011	Present
IRRITABLE BOWEL SYNDROME- CONSTIPATION	Irritable bowel syndrome	2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
COLON TUBULOVILLOUS ADENOMA	Colon adenoma	JAN2019	Present
ESSENTIAL TREMOR	Essential tremor	2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	13:40
2	BNT162b2	10SEP2020 (21)	12:07

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Skin cancer	sebaceous carcinoma of skin	10DEC2020 (112)		31DEC2020 (133)		22

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TCN	Y	Resolved (31DEC2020)	NOT RELATED/OTHER: sun exposure	2	92	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	08OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	75	White	Not reported	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166.4 cm	64.6 kg	23.3 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hearing problems	Auditory disorder	1949	Present
tobacco use	Tobacco user	1958	Past
vasectomy	Vasectomy	1980	Past
rosacea	Rosacea	2000	Present
seasonal allergic rhinitis	Seasonal allergy	2000	Present
hypogonadism	Hypogonadism	2004	Present
osteoarthritis	Osteoarthritis	2004	Present
osteopenia	Osteopenia	2004	Present
vitamin d deficiency	Vitamin D deficiency	2004	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
recurrent back pain	Back pain	2010	Present
erectile dysfunction	Erectile dysfunction	2010	Present
overactive bladder	Hypertonic bladder	2010	Present
hypothyroidism	Hypothyroidism	2010	Present
insomnia	Insomnia	2010	Present
recurrent neck pain	Neck pain	2010	Present
Benign enlarged prostate	Benign prostatic hyperplasia	2015	Past
elevated cholesterol	Blood cholesterol increased	2016	Present
high blood pressure	Hypertension	2016	Present
benign pituitary adenoma	Pituitary tumour benign	2016	Present
glaucoma	Glaucoma	2017	Present
prostate surgery	Prostatic operation	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	14:25
2	BNT162b2	17SEP2020 (23)	13:47

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	INJ&P	Fall	FALL	15NOV2020 (82)	15:00	15NOV2020 (82)	15:00	1	3
2	INJ&P	Pelvic fracture	PELVIC FRACTURE	15NOV2020 (82)	15:00	08DEC2020 (105)		24	3

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (15NOV2020)	NOT RELATED/OTHER: CICYLE ACCIDENT	2	60	N
2	TC	Y	Resolved (08DEC2020)	NOT RELATED/OTHER: FALL	2	60	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
FLUZONE, INFLUENZA VACCINE, .5mL, 1 Injection, Intramuscular	INFLUENZA VACCINE	07OCT2020

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1936	84	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.1 cm	83.9 kg	33.6 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis	Rhinitis allergic	1970	Present
skin biopsy	Biopsy skin	1980	Present
hyperlipidemia	Hyperlipidaemia	1980	Present
high blood pressure	Hypertension	1990	Present
stent placement	Stent placement	1990	Past
anxiety	Anxiety	2010	Present
hypothyroidism	Hypothyroidism	2015	Present
vitamin d deficiency	Vitamin D deficiency	2016	Present
hearing problems	Auditory disorder	2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
cataract surgery	Cataract operation	2017	Past
colonoscopy	Colonoscopy	2017	Past
irritable bowel syndrome	Irritable bowel syndrome	2017	Present
abdominal hernia	Abdominal hernia	2018	Present
osteoarthritis	Osteoarthritis	2018	Present
type II diabetes	Type 2 diabetes mellitus	2018	Present
basal cell skin cancer	Basal cell carcinoma	2019	Past
congestive heart failure	Cardiac failure congestive	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	13:56
2	Placebo	23SEP2020 (22)	12:18
3	BNT162b2	06JAN2021 (127)	14:42
4	BNT162b2	28JAN2021 (149)	13:16

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Cardiac failure congestive	exacerbation of congestive heart failure	22JAN2021 (143)		26JAN2021 (147)		5	3

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
2	INFEC	Cellulitis	cellulitis- left ankle	23JAN2021 (144)		02MAR2021 (182)		39	2
3	INFEC	Conjunctivitis	conjunctivitis	09SEP2020 (8)		30OCT2020 (59)	13:00	52	2
4	NEOPL	Malignant melanoma	melanoma, left ankle	13NOV2020 (73)	00:00	23DEC2020 (113)		41	3
5	PSYCH	Panic attack	panic attack	05SEP2020 (4)	12:00	05SEP2020 (4)	12:05	1	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	Y	Resolved (26JAN2021)	NOT RELATED/OTHER: existing medical history	3	17	Y
2	TC	N	Resolved (02MAR2021)	NOT RELATED/OTHER: surgical site infection	3	18	N
3	TC	N	Resolved (30OCT2020)	NOT RELATED/OTHER: infection	1	8	N
4	TCN	Y	Resolved (23DEC2020)	NOT RELATED/OTHER: SUN EXPOSURE	2	52	Y
5	N	N	Resolved (05SEP2020)	NOT RELATED/OTHER: Patient has history of anxiety.	1	4	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	22OCT2020	
Completed	REPEAT SCREENING 1	06JAN2021	
Completed	OPEN LABEL TREATMENT	25FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	83 kg	31.3 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillitis	Tonsillitis	1982	Past
Uterine Fibroids	Uterine leiomyoma	JAN2000	Past
hypertension	Hypertension	2006	Present
Post-Menopausal	Postmenopause	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03AUG2020 (1)	12:36
2	Placebo	24AUG2020 (22)	17:52

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Lung adenocarcinoma	Adenocarcinoma of the lung	15JAN2021 (166)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Yes	NOT RELATED/OTHER: smoking - medical history	2	145	Y

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
bamlanivimab	BAMLANIVIMAB	25JAN2021	25JAN2021	INTRAVENOUS

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	21SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	81.45 kg	29.8 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillectomy	Tonsillectomy	2006	Past
Tonsillitis	Tonsillitis	2006	Past
Food Allergy to Peanuts	Food allergy	2012	Present
Drug Allergy to Sulfa-Reaction (Hives)	Urticaria	2014	Present
Seasonal Allergies	Seasonal allergy	2015	Present
Anxiety	Anxiety	JUL2016	Present
Panic Attacks	Panic attack	JUL2016	Present
Gastroesophageal Reflux	Gastrooesophageal reflux disease	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	04AUG2020 (1)	12:21
2	BNT162b2	25AUG2020 (22)	10:43

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	SKIN	Acne	Acne	NOV2020 ()		ONGOING			2
2	HEPAT	Cholecystitis	cholecystitis	07FEB2021 (188)		09FEB2021 (190)		3	3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Yes	NOT RELATED/OTHER: Wearing a mask	2		N
2	TC/TCN	Y	Resolved (09FEB2021)	NOT RELATED/OTHER: Gallbladder Infection	2	167	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Completed	VACCINATION	25SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	72.73 kg	25.8 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2010	Present
ROTATOR CUFF REPAIR RIGHT SIDE	Rotator cuff repair	2012	Past
TORN ROTATOR CUFF RIGHT SIDE	Rotator cuff syndrome	2012	Past
ROTATOR CUFF REPAIR LEFT SIDE	Rotator cuff repair	2015	Past
TORN ROTATOR CUFF LEFT SIDE	Rotator cuff syndrome	2015	Past
BENIGN PROSTATIC HYPERPLASIA	Benign prostatic hyperplasia	2017	Present
HYPOTHYROIDISM	Hypothyroidism	2017	Present
ARTHROSCOPIC REPAIR LEFT SIDE	Arthroscopic surgery	2019	Past
TORN MENISCUS LEFT SIDE	Meniscus injury	DEC2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	18:17
2	BNT162b2	02OCT2020 (38)	09:56

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Arthralgia	Acute Pain hip right side	03SEP2020 (9)		02OCT2020 (38)		30
2	MUSC	Arthralgia	Right Shoulder Pain	03SEP2020 (9)		20OCT2020 (56)		48
3	INJ&P	Brain contusion	Left frontal lobe contusion	03SEP2020 (9)		02OCT2020 (38)		30
4	INJ&P	Fall	FALL	03SEP2020 (9)		03SEP2020 (9)		1
5	MUSC	Mobility decreased	Decreased Mobility	03SEP2020 (9)		20OCT2020 (56)		48
6	MUSC	Muscle spasms	Muscle Spasm	03SEP2020 (9)		02OCT2020 (38)		30
7	INJ&P	Pelvic fracture	Closed Fracture of Rt Interior Pubic Ramus	03SEP2020 (9)		02OCT2020 (38)		30
8	INJ&P	Rib fracture	Closed Fracture of Four Ribs	03SEP2020 (9)		02OCT2020 (38)		30
9	INJ&P	Scapula fracture	Closed Displaced Fracture of body Right Scapula	03SEP2020 (9)		20OCT2020 (56)		48
10	NERV	Subarachnoid haemorrhage	SUBARACHNOID HEMORRAGE	03SEP2020 (9)		08SEP2020 (14)		6

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	TC	N	Resolved (02OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
2	1	TC	N	Resolved (20OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
3	1	N	N	Resolved (02OCT2020)	NOT RELATED/OTHER: fall from bicycle	1	9	N
4	1	TC	N	Resolved (03SEP2020)	NOT RELATED/OTHER: fall from bicycle	1	9	N
5	1	N	N	Resolved (20OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
6	2	N	N	Resolved (02OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
7	2	N	N	Resolved (02OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
8	2	N	N	Resolved (02OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
9	2	N	N	Resolved (20OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
10	3	TC	Y	Resolved (08SEP2020)	NOT RELATED/OTHER: FALL	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Tetanus shot	TETANUS VACCINE	03SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	30OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	59	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.3 cm	71.8 kg	23.4 kg/m2	08SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	08SEP2020 (1)	13:15
2	BNT162b2	28SEP2020 (21)	15:13

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	METAB	Hypokalaemia	Hypokalemia	23OCT2020 (46)		24OCT2020 (47)		2
2	METAB	Hypomagnesaemia	Hypomagnesemia	23OCT2020 (46)		24OCT2020 (47)		2
3	INJ&P	Muscle injury	Muscle Sprain (Right Leg)	23SEP2020 (16)		ONGOING		
4	INJ&P	Overdose	Heroin Overdose	23OCT2020 (46)		24OCT2020 (47)		2

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC	N	Resolved (24OCT2020)	NOT RELATED/OTHER: heroin overdose	2	26	N
2	2	TC	N	Resolved (24OCT2020)	NOT RELATED/OTHER: heroin overdose	2	26	N
3	1	TC	N	Yes	NOT RELATED/OTHER: unk	1	16	N
4	4	TC	Y	Resolved (24OCT2020)	NOT RELATED/OTHER: heroin overdose	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	26OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	77.9 kg	24.6 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Peyronie's disease	Peyronie's disease	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	09:45
2	Placebo	01OCT2020 (21)	10:34

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	16FEB2021 (159)	10:20
4	BNT162b2	09MAR2021 (180)	10:23

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Cerebrovascular accident	stroke	01MAR2021 (172)		02MAR2021 (173)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Resolved (02MAR2021)	NOT RELATED/OTHER: unk	3	14	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	29OCT2020	
Completed	REPEAT SCREENING 1	16FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	51	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.5 cm	70.5 kg	28.4 kg/m2	28SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hiv	HIV test positive	2001	Present
Total Hysterectomy	Hysterectomy	2008	Past
Left breast cancer	Breast cancer	2009	Past
Left Breast Cancer	Breast cancer	2009	Past
Lumpectomy	Breast conserving surgery	2009	Past
Left Breast Cancer	Breast cancer	2013	Past
Chemotherapy Treatment	Chemotherapy	2013	Past
BREAST RADIATION THERAPY	Radiotherapy to breast	2013	Past
Paroxetine drug intolerance	Drug intolerance	2016	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sertraline drug intolerance	Drug intolerance	2016	Present
Major Depressive Disorder	Major depression	26MAY2016	Present
Generalized Anxiety Disorder	Generalised anxiety disorder	07OCT2016	Present
Left Breast Cancer	Breast cancer	2017	Past
Chemotherapy Treatment	Chemotherapy	2017	Past
Vitamin D Deficiency	Vitamin D deficiency	24AUG2018	Present
Asthma	Asthma	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28SEP2020 (1)	15:06
2	Placebo	19OCT2020 (22)	12:04

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Breast cancer	breast cancer initial diagnosis	28DEC2020 (92)		ONGOING			2
2	GASTR	Mouth ulceration	oral Ulcer	24OCT2020 (27)		26OCT2020 (29)		3	1
3	GASTR	Stomatitis	Stomatitis	24OCT2020 (27)		26OCT2020 (29)		3	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	Y	Yes	NOT RELATED/OTHER: new onset breast cancer	2	71	Y
2	N	N	Resolved (26OCT2020)	NOT RELATED/OTHER: unk	2	6	N
3	N	N	Resolved (26OCT2020)	NOT RELATED/OTHER: unk	2	6	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28SEP2020	
Completed	VACCINATION	16NOV2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.7 cm	68.9 kg	23.1 kg/m2	18OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Nitrofurantoin Allergy	Drug hypersensitivity	1980	Present
Bactrim Allergy	Drug hypersensitivity	1980	Present
Asthma	Asthma	1985	Present
Naratriptan Allergy	Drug hypersensitivity	1987	Present
Tizanidine Allergy	Drug hypersensitivity	1987	Present
Migraine Headaches	Migraine	1987	Present
Anxiety	Anxiety	1990	Present
Cervical Radiculopathy	Cervical radiculopathy	1990	Present
Arthritis (General)	Polyarthritis	1990	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Rosacea	Rosacea	1990	Present
Latex Allergy	Rubber sensitivity	1990	Present
NSAIDS Allergy	Drug hypersensitivity	1995	Present
GERD	Gastrooesophageal reflux disease	2000	Present
Left Shoulder Pain	Arthralgia	JUN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18OCT2020 (1)	11:17
2	Placebo	06NOV2020 (20)	10:24
3	BNT162b2	05FEB2021 (111)	13:05
4	BNT162b2	26FEB2021 (132)	11:01

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Balance disorder	Unsteadiness on feet	07FEB2021 (113)		ONGOING			1
2	GASTR	Dry mouth	dry mouth	08FEB2021 (114)		ONGOING			1
3	GENRL	Fatigue	Severe Fatigue	07FEB2021 (113)		07FEB2021 (113)		1	4
4	GENRL	Fatigue	fatigue	08FEB2021 (114)		ONGOING			2
5	GENRL	Injection site erythema	injection site Erythema	26FEB2021 (132)		27FEB2021 (133)		2	1

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
6	GENRL	Injection site pain	injection site pain	18OCT2020 (1)		19OCT2020 (2)		2	1
7	GENRL	Injection site pain	injection site pain	06NOV2020 (20)		07NOV2020 (21)		2	1
8	INJ&P	Skin laceration	laceration right hand	06FEB2021 (112)		ONGOING			1

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Yes	NOT RELATED/OTHER: opiod overdose effects	3	3	N
2	N	N	Yes	NOT RELATED/OTHER: unk	3	4	N
3	TC	Y	Resolved (07FEB2021)	NOT RELATED/OTHER: opioids overdose	3	3	Y
4	N	N	Yes	NOT RELATED/OTHER: unk	3	4	N
5	N	N	Resolved (27FEB2021)	Study Treatment	4	1	N
6	N	N	Resolved (19OCT2020)	Study Treatment	1	1	N
7	N	N	Resolved (07NOV2020)	Study Treatment	2	1	N
8	TCN	N	Yes	NOT RELATED/OTHER: accident	3	2	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18OCT2020	
Completed	VACCINATION	07DEC2020	
Completed	REPEAT SCREENING 1	05FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	88.18 kg	26.3 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to Sulfa	Drug hypersensitivity	1960	Present
Juvenile Petite Mal Seizures	Petit mal epilepsy	1961	Past
Stomach Aneurysm	Aortic aneurysm	1991	Past
Hypothyroidism	Hypothyroidism	2010	Present
Double Hernia Repair	Hernia repair	2011	Past
BPH	Benign prostatic hyperplasia	2018	Present
Corneal Transplant	Corneal transplant	2018	Past
Kidney Stone Removal	Renal stone removal	2018	Past
GERD	Gastrooesophageal reflux disease	01JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13AUG2020 (1)	12:20
2	Placebo	01SEP2020 (20)	09:58
3	BNT162b2	25JAN2021 (166)	13:45
4	BNT162b2	17FEB2021 (189)	14:05

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Hiatus hernia	Hiatal Hernia	13DEC2020 (123)	08:00	18DEC2020 (128)	10:00	6

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	Y	Resolved (18DEC2020)	NOT RELATED/OTHER: unknown	2	104	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	01OCT2020	
Completed	REPEAT SCREENING 1	25JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	32	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	127.27 kg	52.9 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Kidney Stones	Nephrolithiasis	2009	Present
Vitamin D Deficiency	Vitamin D deficiency	2009	Present
ADHD	Attention deficit hyperactivity disorder	2011	Present
GERD	Gastrooesophageal reflux disease	2015	Present
Pre-Diabetes	Glucose tolerance impaired	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	09:30
2	Placebo	22SEP2020 (20)	12:35

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	COVID-19	CoVid19	14JAN2021 (134)	08:00	25JAN2021 (145)	14:00	12

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (25JAN2021)	NOT RELATED/OTHER: unknown	2	115	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	108.09 kg	35.1 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
obesity	Obesity	1992	Present
gastric bypass	Gastric bypass	JUN2001	Past
migraines	Migraine	2003	Present
hysterectomy	Hysterectomy	DEC2003	Past
depression	Depression	2008	Present
allergy to sulfa	Drug hypersensitivity	2013	Present
hypothyriodism	Hypothyroidism	2015	Present
dysfunctional gallbladder	Gallbladder disorder	2018	Present
cholecystectomy	Cholecystectomy	FEB2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	12:29
2	BNT162b2	08SEP2020 (20)	19:58

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Syncope	Syncope episodes	19JAN2021 (153)		21FEB2021 (186)		34

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	Y	Resolved (21FEB2021)	NOT RELATED/OTHER: Stress	2	134	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	26OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	76	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	100 kg	32.5 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bilateral broken Knees	Lower limb fracture	1953	Past
Bilateral Hip Replacement	Hip arthroplasty	1990	Past
Hypothyroidism	Hypothyroidism	1999	Present
Angioplasty	Angioplasty	2000	Past
Joint Pain	Arthralgia	2000	Present
High Cholestrol	Blood cholesterol increased	2000	Present
Congestive Heart Failure	Cardiac failure congestive	2000	Present
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	2000	Present
Hypertension	Hypertension	2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	2000	Present
Tinnitis	Tinnitus	2000	Present
Left Eye Vision Loss	Blindness unilateral	APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02SEP2020 (1)	15:25
2	BNT162b2	23SEP2020 (22)	14:40

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NERV	Cerebrovascular accident	multi focal Cerebral Vascular Accidents	18OCT2020 (47)		ONGOING			3	N	Y
2	INJ&P	Cervical vertebral fracture	Cervical spine fracture	18OCT2020 (47)		ONGOING			2	TCN	N
3	GASTR	Diarrhoea	diarrhea	24SEP2020 (23)	19:00	24SEP2020 (23)	23:00	1	1	N	N
4	GASTR	Dysphagia	Dysphagia	28OCT2020 (57)		ONGOING			2	TCN	N
5	INJ&P	Fall	Accidental Fall	18OCT2020 (47)		18OCT2020 (47)		1	1	N	N

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
6	GASTR	Nausea	nausea	24SEP2020 (23)	19:00	24SEP2020 (23)	23:00	1	1	N	N
7	GASTR	Vomiting	vomiting	24SEP2020 (23)	19:00	24SEP2020 (23)	23:00	1	1	N	N

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Yes	NOT RELATED/OTHER: medical history of hypertension and congestive heart failure	2	26	Y
2	Yes	NOT RELATED/OTHER: accidental fall	2	26	N
3	Resolved (24SEP2020)	Study Treatment	2	2	N
4	Yes	NOT RELATED/OTHER: stroke	2	36	N
5	Resolved (18OCT2020)	NOT RELATED/OTHER: accident	2	26	N
6	Resolved (24SEP2020)	Study Treatment	2	2	N
7	Resolved (24SEP2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Withdrawn	VACCINATION	22OCT2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	57	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	94.55 kg	33.6 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Gastric Bypass	Gastric bypass	1993	Past
Hysterectomy	Hysterectomy	1995	Past
Gastric Bypass Reversal	Gastric bypass reversal	2000	Past
Restless Leg Syndrome	Restless legs syndrome	2000	Present
Right Knee Injury	Joint injury	2011	Past
Right Knee Replacement	Knee arthroplasty	2011	Past
Right Knee ACL Repair	Ligament operation	2011	Past
COPD	Chronic obstructive pulmonary disease	2012	Present
Anxiety	Anxiety	2015	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Left Hip Replacement	Hip arthroplasty	2019	Past
Left Hip Broken	Hip fracture	2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	16:33
2	Placebo	19OCT2020 (39)	13:49

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Chronic obstructive pulmonary disease	Dyspena with exacerbation of COPD	04FEB2021 (147)		07FEB2021 (150)		4	3
2	INJ&P	Fall	Fall	06NOV2020 (57)		06NOV2020 (57)		1	2
3	INJ&P	Upper limb fracture	Fractured Left Elbow	06NOV2020 (57)	14:00	15DEC2020 (96)		40	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (07FEB2021)	NOT RELATED/OTHER: exacerbation of known COPD	2	109	Y

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	N	N	Resolved (06NOV2020)	NOT RELATED/OTHER: accident	2	19	N
3	N	N	Resolved (15DEC2020)	NOT RELATED/OTHER: Fall	2	19	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccine	INFLUENZA VACCINE	02OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	16NOV2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	111.36 kg	32.3 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
bilateral broken ankles	Ankle fracture	2010	Past
bilateral fused ankles	Arthrodesis	2010	Past
cholecystectomy	Cholecystectomy	2010	Past
gallstones	Cholelithiasis	2010	Past
rotator cuff repair (right)	Rotator cuff repair	2010	Past
torn rotator cuff (right)	Rotator cuff syndrome	2010	Past
diabetes type II	Type 2 diabetes mellitus	2010	Present
atrial fibrillation	Atrial fibrillation	2012	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ace inhibitor allergy	Drug hypersensitivity	2015	Present
left knee replacement	Knee arthroplasty	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21SEP2020 (1)	14:10
3	BNT162b2	10FEB2021 (143)	15:29
4	BNT162b2	01MAR2021 (162)	14:03

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	CARD	Acute coronary syndrome	acute coronary syndrome	25SEP2020 (5)	10:43	27SEP2020 (7)		3	2	TC/TCN
2	CARD	Bundle branch block left	left bundle branch block	25SEP2020 (5)	10:43	27SEP2020 (7)		3	2	TC/TCN

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (27SEP2020)	NOT RELATED/OTHER: history of diabetes type 2 and atrial fibrillation	1	5	Y
2	N	Resolved (27SEP2020)	NOT RELATED/OTHER: history of diabetes type 2 and atrial fibrllation	1	5	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Withdrawn	VACCINATION	12OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
Completed	REPEAT SCREENING 1	10FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
193.04 cm	136.36 kg	36.5 kg/m2	24SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
correction of left arm fracture	Fracture treatment	1978	Past
left arm fracture	Upper limb fracture	1978	Past
tonsillectomy	Tonsillectomy	1980	Past
tonsillitis	Tonsillitis	1980	Past
left knee osteoarthritis	Osteoarthritis	2010	Present
osteoarthrosis right foot	Osteoarthritis	2014	Present
lumbar disc extrusion	Intervertebral disc protrusion	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24SEP2020 (1)	14:17
2	BNT162b2	13OCT2020 (20)	14:21

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GASTR	Abdominal hernia	Abdominal hernia	07DEC2020 (75)		14DEC2020 (82)		8	3	TCN	Y
2	HEPAT	Cholelithiasis	Cholelithiasis	07DEC2020 (75)		12JAN2021 (111)		37	2	TCN	N
3	GASTR	Gastrointestinal haemorrhage	possible GI Bleed	22FEB2021 (152)		22FEB2021 (152)		1	1	TC	N
4	GASTR	Intestinal strangulation	Small bowel strangulation	07DEC2020 (75)		14DEC2020 (82)		8	3	TCN	Y
5	INFEC	Post procedural infection	Intra abdominal infection post cholecystectomy	22FEB2021 (152)		ONGOING			3	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (14DEC2020)	NOT RELATED/OTHER: abdominal hernia	2	56	Y

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	Resolved (12JAN2021)	NOT RELATED/OTHER: Gallstones formed	2	56	N
3	Resolved (22FEB2021)	NOT RELATED/OTHER: NSAID use for pain	2	133	N
4	Resolved (14DEC2020)	NOT RELATED/OTHER: hernia entrapment	2	56	Y
5	Yes	NOT RELATED/OTHER: post op complication of infection with 3 types of e coli	2	133	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24SEP2020	
Completed	VACCINATION	10NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	81.82 kg	30 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
obesity	Obesity	2000	Present
bipolar disorder	Bipolar disorder	2001	Present
hypothyroidism	Hypothyroidism	2010	Present
difficulty with sleeping	Insomnia	2013	Present
akathisia	Akathisia	2015	Present
degenerative disc disease	Intervertebral disc degeneration	2015	Present
muscle spasms	Muscle spasms	2015	Present
Tardive Diskinesia	Tardive dyskinesia	2015	Present
sleep apnea	Sleep apnoea syndrome	2016	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
post menopausal	Postmenopause	2018	Present
gastritis	Gastritis	MAY2020	Present
Hiatal hernia	Hiatus hernia	MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	15:15
2	BNT162b2	15SEP2020 (22)	12:00

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Fatigue	Fatigue	16SEP2020 (23)	09:00	17SEP2020 (24)	18:00	2	2
2	GASTR	Gastritis	Worsening of gastritis	14FEB2021 (174)	08:00	17FEB2021 (177)		4	3
3	GASTR	Impaired gastric emptying	Worsening of gastroparesis	14FEB2021 (174)	08:00	17FEB2021 (177)		4	3
4	GENRL	Injection site pain	PAIN AT INJECTION SITE	26AUG2020 (2)		30AUG2020 (6)		5	1
5	MUSC	Intervertebral disc degeneration	Worsening of degenerative disc disease	11JAN2021 (140)		ONGOING			1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (17SEP2020)	Study Treatment	2	2	N
2	TC	Y	Resolved (17FEB2021)	NOT RELATED/OTHER: Progression of disease	2	153	Y
3	TC	Y	Resolved (17FEB2021)	NOT RELATED/OTHER: Progression of disease	2	153	Y
4	N	N	Resolved (30AUG2020)	Study Treatment	1	2	N
5	TC	N	Yes	NOT RELATED/OTHER: Natural progression of the disease	2	119	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Influenza vaccine	INFLUENZA VACCINE	27OCT2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25AUG2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152.4 cm	88.64 kg	38.1 kg/m2	25SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25SEP2020 (1)	12:05
2	Placebo	14OCT2020 (20)	11:30

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	07JAN2021 (105)	10:15
4	BNT162b2	26JAN2021 (124)	09:51

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Infection	infection	05FEB2021 (134)	12:49	ONGOING		
2	METAB	Lactic acidosis	lactic acidosis	05FEB2021 (134)	10:00	05FEB2021 (134)	12:49	1
3	NERV	Seizure	Seizure	05FEB2021 (134)		05FEB2021 (134)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Yes	NOT RELATED/OTHER: unknown	4	11	N
2	2	TC	N	Resolved (05FEB2021)	NOT RELATED/OTHER: Infection	4	11	N
3	1	TC	Y	Resolved (05FEB2021)	NOT RELATED/OTHER: unknown	4	11	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25SEP2020	
Completed	VACCINATION	16NOV2020	
Completed	REPEAT SCREENING 1	07JAN2021	
Completed	OPEN LABEL TREATMENT	23FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	64	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
144.78 cm	82.73 kg	39.5 kg/m2	17SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cesarean section	Caesarean section	22MAR1976	Past
abdominal surgical scar	Scar	22MAR1976	Present
Cesarean section	Caesarean section	26OCT1979	Past
post-menopause	Postmenopause	1990	Present
obesity	Obesity	1995	Present
mild intermittent headacheq	Headache	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17SEP2020 (1)	12:59
2	BNT162b2	08OCT2020 (22)	08:33

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Lumbar vertebral fracture	closed fracture, transverse process of lumbar vertebra	03DEC2020 (78)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Yes	NOT RELATED/OTHER: pedestrian vs motor vehicle accident	2	57	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17SEP2020	
Completed	VACCINATION	05NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	88.64 kg	29.7 kg/m2	18SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	MAY2005	Past
appendicitis	Appendicitis	MAY2005	Past
abdominal scar	Scar	MAY2005	Present
bilateral lower legs edema 1+	Oedema peripheral	2015	Present
bilateral fungus toenails	Onychomycosis	2015	Present
nerve pain, cervical spine	Neuralgia	11SEP2020	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	18SEP2020 (1)	11:50
2	Placebo	09OCT2020 (22)	11:22

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	CARD	Aortic valve incompetence	acute aortic insufficiency	28OCT2020 (41)		15DEC2020 (89)		49	4	TC/TCN	Y
2	CARD	Atrial fibrillation	intermittent atrial fibrillation	06NOV2020 (50)		ONGOING			2	TC	N
3	MUSC	Myalgia	pain L hamstring muscles	28OCT2020 (41)		ONGOING			2	TC	N
4	INFEC	Subacute endocarditis	subacute bacterial endocarditis	28OCT2020 (41)		15DEC2020 (89)		49	4	TC/TCN	Y
5	NERV	Subarachnoid haemorrhage	subarachnoid hemorrhage	05NOV2020 (49)		05NOV2020 (49)		1	3	TC/TCN	Y

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (15DEC2020)	NOT RELATED/OTHER: subacute bacterial endocarditis	2	20	Y
2	Yes	NOT RELATED/OTHER: bacterial endocarditis	2	29	N
3	Yes	NOT RELATED/OTHER: heavy lifting	2	20	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
4	Resolved (15DEC2020)	NOT RELATED/OTHER: gram positive cocci, source unknown	2	20	Y
5	Resolved (05NOV2020)	NOT RELATED/OTHER: possibly secondary to underlying bacterial endocarditis (mycotic aneurysm)	2	28	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18SEP2020	
Withdrawn	VACCINATION	08FEB2021	ADVERSE EVENT
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	104.3 kg	36.1 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergies	Seasonal allergy	01APR1982	Present
Hypertension	Hypertension	01OCT2000	Present
Anomalous coronary artery	Congenital coronary artery malformation	2010	Present
Coronary artery bypass graft	Coronary artery bypass	2010	Past
Angina	Angina pectoris	24MAR2010	Past
Coronary vasospasm	Arteriospasm coronary	24MAR2010	Past
Hypertriglyceridemia	Hypertriglyceridaemia	01APR2010	Present
Redo of coronary bypass graft with re-implantation RCA and unroofing of LAD bridge	Coronary artery bypass	2016	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sinus tachycardia	Sinus tachycardia	01APR2019	Present
Type 2 diabetes	Type 2 diabetes mellitus	01FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	12:14
2	Placebo	23SEP2020 (21)	10:18

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Arteriospasm coronary	Coronary vasospasm	25SEP2020 (23)		26SEP2020 (24)		2	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (26SEP2020)	NOT RELATED/OTHER: underlying cardiac disease	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine	INFLUENZA VACCINE	09OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	22OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	18DEC2020	WITHDRAWAL BY SUBJECT

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.4 cm	109 kg	33.5 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergies	Seasonal allergy	1970	Present
Hypertension	Hypertension	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	15:09

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	25SEP2020 (23)	13:41
3	BNT162b2	23FEB2021 (174)	12:12

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
5	INFEC	Latent tuberculosis	Latent Tuberculosis Infection	17FEB2021 (168)		ONGOING			2
6	NEOPL	Malignant melanoma	Melanoma	16NOV2020 (75)		ONGOING			2
7	SKIN	Skin lesion	skin lesion of scalp	25SEP2020 (23)	10:00	16NOV2020 (75)		53	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
5	TC	N	Yes	NOT RELATED/OTHER: Unknown exposure	2	146	N
6	TC/TCN	Y	Yes	NOT RELATED/OTHER: Sun exposure	2	53	Y
7	TCN	N	Resolved (16NOV2020)	NOT RELATED/OTHER: sun exposure	2	1	N

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Keytruda	PEMBROLIZUMAB	JAN2021	ONGOING	INTRAVENOUS

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu vaccine.	INFLUENZA VACCINE	14OCT2020
Shingles virus vaccine	VARICELLA ZOSTER VACCINE	25JAN2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	26OCT2020	
Completed	REPEAT SCREENING 1	23FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.5 cm	92.2 kg	34.1 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPOTHYROIDISM	Hypothyroidism	18MAR1993	Present
TYPE II DIABETES	Type 2 diabetes mellitus	18MAR1995	Present
OBESITY	Obesity	2000	Present
OSTEOARTHRITIS	Osteoarthritis	18MAR2003	Present
CHRONIC PAIN	Pain	18MAR2003	Present
POST MENOPAUSAL	Postmenopause	2008	Present
RIGHT HEMITHYROIDECTOMY	Thyroidectomy	2015	Past
CORONARY ARTERY BYPASS GRAFT	Coronary artery bypass	19AUG2018	Past
CORONARY ARTERY DISEASE	Coronary artery disease	19AUG2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	19AUG2018	Present
HYPERTENSION	Hypertension	19AUG2018	Present
MYOCARDIAL INFARCTION	Myocardial infarction	19AUG2018	Past
BILATERAL LEG EDEMA	Oedema peripheral	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	12:25
2	Placebo	09SEP2020 (22)	15:08

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INFEC	Pneumonia	PNEUMONIA	20SEP2020 (33)		04OCT2020 (47)	08:00	15	2	TC

Adverse Events					
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (04OCT2020)	NOT RELATED/OTHER: COMMUNITY ACQUIRED PNEUMONIA	2	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	44	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168.5 cm	100.4 kg	35.4 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OBESITY	Obesity	2000	Present
TYPE II DIABETES MELLITUS	Type 2 diabetes mellitus	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	13:58
2	BNT162b2	09SEP2020 (20)	14:38

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	HEPAT	Cholecystitis acute	ACUTE CHOLECYSTITIS	05FEB2021 (169)	10:10	08FEB2021 (172)	14:32	4	3
2	INFEC	Postoperative abscess	POST CHOLECYSTECTOMY ABSCESS	12FEB2021 (176)	21:00	ONGOING			3
3	HEPAT	Steatohepatitis	STEATOHEPATITIS	07FEB2021 (171)	13:51	ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	Y	Resolved (08FEB2021)	NOT RELATED/OTHER: OBESE,DIABETES,BILE DUCT	2	150	Y
2	TC	Y	Yes	NOT RELATED/OTHER: CHOLECYSTECTOMY	2	157	Y
3	TCN	N	Yes	NOT RELATED/OTHER: DIET, OBESITY, METABOLIC	2	152	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	44	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.3 cm	128.4 kg	41.8 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ASTHMA	Asthma	1980	Present
PENICILLIN ALLERGY	Drug hypersensitivity	1985	Present
MIGRAINE HEADACHES	Migraine	1994	Present
CESAREAN SECTION	Caesarean section	20MAY1994	Past
CESAREAN SECTION	Caesarean section	24MAY1996	Past
BILATERAL TUBAL LIGATION	Female sterilisation	1999	Past
CESAREAN SECTION	Caesarean section	29NOV1999	Past
OBESITY	Obesity	2000	Present
UTERINE FIBROIDS	Uterine leiomyoma	2000	Present

Medical History

Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
BENIGN CARDIAC MASS	Benign cardiac neoplasm	NOV2008	Past
THORACTOMY WITH RESECTION OF BENIGN CARDIAC MASS	Cardiac operation	NOV2008	Past
OSTEOARTHRITIS BILATERAL KNEES	Osteoarthritis	2010	Present
GOITER	Goitre	2011	Past
HYPOTHYROIDISM	Hypothyroidism	2011	Present
THYROIDECTOMY	Thyroidectomy	2011	Past
MAJOR DEPRESSION	Major depression	2014	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	01SEP2020 (1)	11:47
2	Placebo	01OCT2020 (31)	13:41
3	BNT162b2	04FEB2021 (157)	14:46
4	BNT162b2	25FEB2021 (178)	13:45

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	NEOPL	Uterine leiomyoma	WORSENING OF UTERINE FIBROIDS	14SEP2020 (14)	08:00	19SEP2020 (19)	12:00	6	2	TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (19SEP2020)	NOT RELATED/OTHER: MEDICAL HISTORY OF UTERINE FIBROIDS	1	14	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	29OCT2020	
Completed	REPEAT SCREENING 1	04FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
155 cm	88.6 kg	36.9 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	1970	Present
Cholecystectomy	Cholecystectomy	1985	Past
Cholelithiasis	Cholelithiasis	1985	Past
Seasonal Allergies	Seasonal allergy	1990	Present
Cesarean Section	Caesarean section	27JUL1999	Past
Obesity	Obesity	2000	Present
Hypertension	Hypertension	2002	Present
Cesarean Section	Caesarean section	23SEP2002	Past
Depression	Depression	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type II Diabetes Mellitus	Type 2 diabetes mellitus	2010	Present
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	2011	Present
Chronic Obstructive Pulmonary Disease	Chronic obstructive pulmonary disease	2014	Present
Post Menopausal	Postmenopause	2016	Present
Dyslipidemia	Dyslipidaemia	2017	Present
Coronary Artery Stent Placement	Coronary arterial stent insertion	28MAY2017	Past
Myocardial Infarction	Myocardial infarction	28MAY2017	Past
Bilateral Hands Carpal Tunnel Syndrome	Carpal tunnel syndrome	2019	Present
Left Wrist Carpal Tunnel Surgery	Carpal tunnel decompression	OCT2019	Past
Right Wrist Carpal Tunnel Surgery	Carpal tunnel decompression	MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	11:17
2	Placebo	04NOV2020 (20)	14:00
3	BNT162b2	26JAN2021 (103)	10:26
4	BNT162b2	15FEB2021 (123)	10:39

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INFEC	Peritonsillar abscess	LEFT PERITONSILLAR ABSCESS	22OCT2020 (7)		23NOV2020 (39)		33	3	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (23NOV2020)	NOT RELATED/OTHER: unknown, medical records did not identify causation	1	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
Completed	VACCINATION	02DEC2020	
Completed	REPEAT SCREENING 1	26JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	54	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	115.05 kg	33.4 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
iodine allergy	Iodine allergy	2000	Present
L. Calf DVT	Deep vein thrombosis	2016	Present
chronic back pain	Back pain	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	14:56
2	Placebo	02OCT2020 (22)	16:52
3	BNT162b2	18JAN2021 (130)	07:23
4	BNT162b2	10FEB2021 (153)	07:20

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	RESP	Pleuritic pain	pleuritic chest pain	15FEB2021 (158)		22FEB2021 (165)		8	2	TC	N
2	RESP	Pulmonary embolism	Pulmonary Embolism with bilateral lower lobe Pulmonary embolisms	15FEB2021 (158)		16FEB2021 (159)		2	3	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (22FEB2021)	NOT RELATED/OTHER: incidental finding related to AE/SAE 1	4	6	N
2	Resolved (16FEB2021)	NOT RELATED/OTHER: history of DVT/ possibly related to Covid illness in December	4	6	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	30OCT2020	
Completed	REPEAT SCREENING 1	18JAN2021	
Completed	OPEN LABEL TREATMENT	10MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	74.8 kg	27.8 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Crohn's Disease	Crohn's disease	1969	Present
mixed hyperlipidemia	Type V hyperlipidaemia	18FEB2020	Present
rectovaginal fistula	Female genital tract fistula	09MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	16:37
2	BNT162b2	21SEP2020 (22)	17:04

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	NERV	Headache	Headache	22SEP2020 (23)	10:30	22SEP2020 (23)	12:00	1	1	N
2	INFEC	Meningitis bacterial	Suspected bacterial meningitis	06FEB2021 (160)	08:54	20FEB2021 (174)		15	3	TC
3	MUSC	Myalgia	Muscle aches	21SEP2020 (22)	23:00	22SEP2020 (23)	12:00	2	1	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Resolved (22SEP2020)	Study Treatment	2	2	N
2	Y	Resolved (20FEB2021)	NOT RELATED/OTHER: suspected secondary to pyelonephritis	2	139	Y
3	N	Resolved (22SEP2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.5 cm	57.47 kg	21.2 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
recurrent cold sores	Oral herpes	1960	Present
menopause syndrome	Menopausal symptoms	28JAN2018	Past
osteopenia	Osteopenia	01AUG2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	12:09
2	Placebo	23SEP2020 (22)	17:14
3	BNT162b2	29JAN2021 (150)	15:57
4	BNT162b2	19FEB2021 (171)	15:40

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Fall	Fall	20JAN2021 (141)	12:22	20JAN2021 (141)		1	2
2	INJ&P	Hip fracture	Left Hip Fracture	20JAN2021 (141)	12:22	ONGOING			4
3	VASC	Orthostatic hypotension	orthostatic hypotension	22JAN2021 (143)	10:00	22JAN2021 (143)	10:00	1	1
4	NERV	Syncope	Syncopal Episode	22JAN2021 (143)		22JAN2021 (143)		1	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	N	Resolved (20JAN2021)	NOT RELATED/OTHER: icy conditions caused fall	2	120	N
2	TCN	Y	Yes	NOT RELATED/OTHER: incidental, caused by fall on ice	2	120	Y
3	N	N	Resolved (22JAN2021)	NOT RELATED/OTHER: cause unknown	2	122	N
4	N	N	Resolved (22JAN2021)	NOT RELATED/OTHER: cause unknown	2	122	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	22OCT2020	
Completed	REPEAT SCREENING 1	29JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	64	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.9 cm	116.1 kg	48.4 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OBESITY	Obesity	1980	Present
POSTMENOPAUSAL	Postmenopause	2007	Present
HYSTERECTOMY	Hysterectomy	AUG2007	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16SEP2020 (1)	11:10
2	Placebo	05OCT2020 (20)	13:30
3	BNT162b2	30JAN2021 (137)	14:36
4	BNT162b2	20FEB2021 (158)	14:37

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PSYCH	Confusional state	MENTAL CONFUSION	27FEB2021 (165)		27FEB2021 (165)		1
2	VASC	Hypertension	HYPERTENSION	27FEB2021 (165)		28FEB2021 (166)		2
3	VASC	Hypertension	HYPERTENSION	28FEB2021 (166)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (27FEB2021)	NOT RELATED/OTHER: UNKNOWN	4	8	N
2	3	TC	Y	Resolved (28FEB2021)	NOT RELATED/OTHER: UNKNOWN	4	8	Y
3	2	TC	N	Yes	NOT RELATED/OTHER: UNKNOWN	4	9	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
FLU ZONE HIGH DOSE PROPHYLAXIS INFLUENZA VACCINE	INFLUENZA VACCINE INACT SPLIT 3V	27OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16SEP2020	
Completed	VACCINATION	02NOV2020	
Completed	REPEAT SCREENING 1	30JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	81.82 kg	30.9 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteoarthritis	Osteoarthritis	2005	Present
Carotid Artery Disease	Carotid artery disease	2013	Present
Hypercholesterolemia	Hypercholesterolaemia	2013	Present
Hypertension	Hypertension	2013	Present
Heartburn	Dyspepsia	2015	Present
Hodgkin's Lymphoma	Hodgkin's disease	JUN2016	Past
Non-Hodgkins's Lymphoma	Non-Hodgkin's lymphoma	JUN2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	17:35
2	BNT162b2	23SEP2020 (38)	16:38

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Transient ischaemic attack	Transient Ischaemic Attack	04SEP2020 (19)		09SEP2020 (24)		6	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: carotid artery disease	1	19	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	22OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	77	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	104.55 kg	33 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	1993	Present
Hypercholesterolemia	Hypercholesterolaemia	1995	Present
Hypertension	Hypertension	1995	Present
Quadruple Coronary Artery Bypass Surgery	Coronary artery bypass	2006	Past
Right Knee Pain	Arthralgia	2015	Present
Right Knee Torn Meniscus	Meniscus injury	2015	Past
Insomnia	Insomnia	2018	Present
Benign Prostatic Hyperplasia	Benign prostatic hyperplasia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	15:33
2	Placebo	16SEP2020 (20)	14:07
3	BNT162b2	19FEB2021 (176)	14:25

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Myocardial infarction	myocardial infarction	06MAR2021 (191)		09MAR2021 (194)		4	3	TC/TCN	Y
2	EAR	Vertigo	vertigo	31AUG2020 (4)		31AUG2020 (4)		1	1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (09MAR2021)	NOT RELATED/OTHER: medical history of HTN, hypercholesterolemia, CAD, CABG in 2006.	3	16	Y
2	Resolved (31AUG2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	4	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	21OCT2020	
Completed	REPEAT SCREENING 1	19FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.5 cm	57.8 kg	23.3 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PENICILLIN ALLERGY	Drug hypersensitivity	1985	Present
INSOMNIA	Insomnia	2016	Present
POSTMENOPAUSAL	Postmenopause	2016	Present
DEPRESSION	Depression	2018	Present
ROSACEA	Rosacea	2019	Present
HEMATOMA LEFT THIGH	Haematoma	06APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27AUG2020 (1)	11:25
2	BNT162b2	17SEP2020 (22)	09:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Diarrhoea	DIARRHEA	28AUG2020 (2)		29AUG2020 (3)		2	1
2	GENRL	Fatigue	FATIGUE	28AUG2020 (2)		30AUG2020 (4)		3	2
3	GENRL	Fatigue	FATIGUE	30AUG2020 (4)		31AUG2020 (5)		2	1
4	GENRL	Injection site pain	PAIN AT INJECTION SITE-LEFT ARM	28AUG2020 (2)		29AUG2020 (3)		2	1
5	GENRL	Injection site swelling	SWELLING AT INJECTION SITE- LEFT ARM	28AUG2020 (2)		29AUG2020 (3)		2	1
6	MUSC	Myalgia	MUSCLE PAIN	30AUG2020 (4)		31AUG2020 (5)		2	1
7	INJ&P	Tibia fracture	LEFT TIBIAL PLATEAU FRACTURE	28JAN2021 (155)		ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (29AUG2020)	Study Treatment	1	2	N
2	N	N	Resolved (30AUG2020)	Study Treatment	1	2	N
3	N	N	Resolved (31AUG2020)	Study Treatment	1	4	N

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	N	N	Resolved (29AUG2020)	Study Treatment	1	2	N
5	N	N	Resolved (29AUG2020)	Study Treatment	1	2	N
6	N	N	Resolved (31AUG2020)	Study Treatment	1	4	N
7	TC/TCN	Y	Yes	NOT RELATED/OTHER: TRAUMA TO LEG	2	134	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	64	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	83.18 kg	26.3 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PENICILLIN ALLERGY	Drug hypersensitivity	1965	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2007	Present
HYPERTENSION	Hypertension	2007	Present
VASECTOMY	Vasectomy	2015	Past
INSOMNIA	Insomnia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	08:44
2	BNT162b2	25SEP2020 (22)	15:57

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Acute myocardial infarction	ST ELEVATION MYOCARDIAL INFARCTION (STEMI)	28JAN2021 (147)		30JAN2021 (149)		3	4	TC	Y
2	GASTR	Aphthous ulcer	RECURRENT ORAL APTHAE	12SEP2020 (9)		ONGOING			1	TC	N
3	INFEC	Cellulitis	CELLULITIS RIGHT 5TH FINGER	08OCT2020 (35)		19OCT2020 (46)		12	1	TC	N
4	GENRL	Chest pain	ACUTE CHEST PAIN	01FEB2021 (151)	11:00	02FEB2021 (152)		2	1	TC	N
5	CARD	Coronary artery disease	CORONARY ARTERY DISEASE	28JAN2021 (147)		ONGOING			2	TC	N
6	GASTR	Stomatitis	ORAL MUCOSITIS	12SEP2020 (9)		ONGOING			1	TC	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (30JAN2021)	NOT RELATED/OTHER: CORONARY ARTERY DISEASE	2	126	Y
2	Yes	NOT RELATED/OTHER: TOPICAL IRRITANT	1	9	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	Resolved (19OCT2020)	NOT RELATED/OTHER: BLUNT TRAUMA	2	14	N
4	Resolved (02FEB2021)	NOT RELATED/OTHER: CORONARY ARTERY DISEASE	2	130	N
5	Yes	NOT RELATED/OTHER: SECONDARY TO PROLONGED HISTORY OF HYPERTENSION	2	126	N
6	Yes	NOT RELATED/OTHER: TOPICAL IRRITANT	1	9	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	23OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179 cm	76.5 kg	23.9 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ACNE	Acne	1965	Present
BENIGN PROSTATIC HYPERPLASIA	Benign prostatic hyperplasia	2000	Present
OSTEOARTHRITIS	Osteoarthritis	2005	Present
CHRONIC BRONCHITIS	Bronchitis chronic	2010	Present
HYPERLIPIDEMIA	Hyperlipidaemia	2010	Present
HYPERTENSION	Hypertension	2015	Present
DIABETIC NEUROPATHY	Diabetic neuropathy	2016	Present
TYPE II DIABETES	Type 2 diabetes mellitus	2016	Present
VITAMIN D DEFICIENCY	Vitamin D deficiency	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11SEP2020 (1)	08:58
2	BNT162b2	02OCT2020 (22)	08:02

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RENAL	Nephrolithiasis	BILATERAL KIDNEY STONES	29NOV2020 (80)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TCN	Y	Yes	NOT RELATED/OTHER: NEW MEDICAL EVENT	2	59	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	30OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	71	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161 cm	72.8 kg	28.1 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	1964	Present
Hyperpigmintation ON SKIN	Skin hyperpigmentation	1980	Present
Menopause	Menopause	1995	Present
Insomnia	Insomnia	2007	Present
Hypertension	Hypertension	2015	Present
Allergic Rhinitis - Seasonal	Seasonal allergy	2015	Present
Osteoarthritis - Bilateral Knees	Osteoarthritis	2018	Present
Internal Hemorrhoids - Stage 1	Haemorrhoids	18JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03AUG2020 (1)	16:05
2	BNT162b2	25AUG2020 (23)	15:05

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Osteoarthritis	Worsening of Osteoarthritis Bilateral Knee	05OCT2020 (64)		07DEC2020 (127)		64

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/TCN	Y	Resolved (07DEC2020)	NOT RELATED/OTHER: OA of Knee	2	42	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	96 kg	36.2 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type II Diabetes	Type 2 diabetes mellitus	1989	Present
Depression	Depression	2005	Present
Post-Menopausal	Postmenopause	2005	Present
Blind (R - Eye)	Blindness unilateral	2014	Present
GERD	Gastrooesophageal reflux disease	2015	Present
Hypertension	Hypertension	2015	Present
Hypercholesterolemia	Hypercholesterolaemia	2019	Present
Hot Flahses	Hot flush	JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07AUG2020 (1)	10:48
2	BNT162b2	28AUG2020 (22)	09:27

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Uterine cancer	Uterine Cancer	25JAN2021 (172)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/TCN	Y	Yes	NOT RELATED/OTHER: Unopposed ERT	2	151	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	29SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	81.82 kg	24.4 kg/m2	26AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	10:24
2	Placebo	16SEP2020 (22)	09:30
3	BNT162b2	25FEB2021 (184)	09:00

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	INV	Blood cholesterol increased	Elevated Cholesterol	06MAR2021 (193)		ONGOING			2
2	NERV	Cerebrovascular accident	Cerebrovascular event	06MAR2021 (193)		ONGOING			1
3	VASC	Hypertension	Hypertension	06MAR2021 (193)		ONGOING			2

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Yes	NOT RELATED/OTHER: Lifestyle Choices.	3	10	N
2	TC	Y	Yes	NOT RELATED/OTHER: Lifestyle Chooses. I.e. Alcohol and Tobacco use.	3	10	Y
3	TC	N	Yes	NOT RELATED/OTHER: Lifestyle Choices	3	10	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	15OCT2020	
Completed	REPEAT SCREENING 1	25FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	38	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	86.36 kg	26.5 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety (Mild)	Anxiety	2015	Present
Alopecia	Alopecia	2018	Present
Attention Deficit Hyper Disorder (ADHD)- Mild	Attention deficit hyperactivity disorder	2018	Present
Benign Prostatic Hyperplasia (BPH)	Benign prostatic hyperplasia	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27AUG2020 (1)	17:03
2	BNT162b2	16SEP2020 (21)	13:48

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Seizure	Seizure	03MAR2021 (189)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		4	TC	Y	Yes	NOT RELATED/OTHER: Unknown	2	169	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187 cm	100.9 kg	28.9 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to Codeine	Drug hypersensitivity	1960	Present
Tonsillectomy	Tonsillectomy	1960	Past
Appendectomy	Appendicectomy	1964	Past
Hernia Repair	Hernia repair	1970	Past
Hernia Repair	Hernia repair	1978	Past
Testicular Cancer	Testis cancer	1982	Past
Low Testosterone	Blood testosterone decreased	1983	Present
Hypercholesterolemia	Hypercholesterolaemia	2000	Present
Hypertension	Hypertension	2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 2 Diabetes	Type 2 diabetes mellitus	2005	Present
Deep Vein Thrombosis	Deep vein thrombosis	2010	Present
Depression	Depression	2010	Present
Pressure in Eyes	Ocular discomfort	2018	Present
Erectile Dysfunction	Erectile dysfunction	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	11:33
2	Placebo	29SEP2020 (28)	13:13
3	BNT162b2	21DEC2020 (111)	12:38
4	BNT162b2	11JAN2021 (132)	11:46

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	EYE	Retinal artery occlusion	Central Retinal Artery Occlusion	29SEP2020 (28)	15:30	ONGOING			1	N	Y

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Yes	NOT RELATED/OTHER: Pre-existing medical conditions,hypercoagulable state due to hypertension, TIID	2	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	29OCT2020	
Completed	REPEAT SCREENING 1	21DEC2020	
Completed	OPEN LABEL TREATMENT	12FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	85.91 kg	29.6 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Post Menopausal	Postmenopause	2000	Present
Seasonal Allergies	Seasonal allergy	2000	Present
Osteoarthritis, right knee	Osteoarthritis	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	15:36
2	BNT162b2	25SEP2020 (22)	14:38

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Aphasia	Expressive Aphasia	22OCT2020 (49)		26OCT2020 (53)		5	2
2	NERV	Cerebrovascular accident	CVA	22OCT2020 (49)		26OCT2020 (53)		5	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (26OCT2020)	NOT RELATED/OTHER: Pending medical records	2	28	N
2	N	Y	Resolved (26OCT2020)	NOT RELATED/OTHER: PENDING MEDICAL RECORDS	2	28	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	29OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	76.3 kg	26.7 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	1995	Present
Vaginal dry Skin	Dry skin	2010	Present
Hypothyroid	Hypothyroidism	2010	Present
Vaginal Dryness	Vulvovaginal dryness	2010	Present
Glaucoma - right eye	Glaucoma	2014	Present
Recurrent Panic Attack	Panic attack	2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10AUG2020 (1)	16:08
2	Placebo	31AUG2020 (22)	15:36
3	BNT162b2	26JAN2021 (170)	10:10
4	BNT162b2	16FEB2021 (191)	09:57

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	MUSC	Back pain	Lower Back Pain	14AUG2020 (5)	08:00	17AUG2020 (8)		4	1
2	GENRL	Chills	Chills	13AUG2020 (4)		14AUG2020 (5)		2	1
3	GASTR	Diarrhoea	Intermittent Diarrhea	12AUG2020 (3)		19AUG2020 (10)		8	1
4	GENRL	Drug withdrawal syndrome	Withdraw from valium	08MAR2021 (211)		ONGOING			3
5	NERV	Headache	Headache	08SEP2020 (30)		28SEP2020 (50)		21	1
6	GENRL	Injection site erythema	Redness at injection site	10AUG2020 (1)	16:08	10AUG2020 (1)	17:08	1	1
7	GENRL	Injection site swelling	Swelling at injection site	10AUG2020 (1)	16:08	10AUG2020 (1)	17:08	1	1
8	GASTR	Nausea	Nausea	10AUG2020 (1)	16:37	10AUG2020 (1)	17:08	1	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (17AUG2020)	NOT RELATED/OTHER: Unknown	1	5	N
2	N	N	Resolved (14AUG2020)	NOT RELATED/OTHER: Unknown	1	4	N

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	N	N	Resolved (19AUG2020)	NOT RELATED/OTHER: Unknown	1	3	N
4	TC/TCN	Y	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT	4	21	Y
5	N	N	Resolved (28SEP2020)	Study Treatment	2	9	N
6	N	N	Resolved (10AUG2020)	Study Treatment	1	1	N
7	N	N	Resolved (10AUG2020)	Study Treatment	1	1	N
8	N	N	Resolved (10AUG2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10AUG2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	28SEP2020	
Completed	REPEAT SCREENING 1	26JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1942	77	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156.5 cm	66.5 kg	27.2 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Fibromyalgia	Fibromyalgia	1990	Present
Hypertension	Hypertension	1995	Present
Torn Meniscus	Meniscus injury	2005	Past
Bilateral Inguinal Hernia	Inguinal hernia	JUL2006	Present
Knee Replacement, Left Leg	Knee arthroplasty	JAN2011	Past
Upset Stomach	Abdominal discomfort	2012	Present
Insomnia	Insomnia	2012	Present
Dermatographia	Mechanical urticaria	2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Dry Eyes, Bilateral	Dry eye	2019	Present
Osteoarthritis	Osteoarthritis	2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	13:42
2	Placebo	01SEP2020 (22)	12:20
3	BNT162b2	14JAN2021 (157)	13:26
4	BNT162b2	04FEB2021 (178)	12:10

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	SKIN	Alopecia	Unusual hair loss	26FEB2021 (200)		ONGOING			2	N	N
2	CARD	Atrial fibrillation	Atrial Fibrillation	11NOV2020 (93)		ONGOING			2	N	N
3	GASTR	Colitis ischaemic	Ischemic colitis	31OCT2020 (82)		ONGOING			3	TC/TCN	Y
4	GASTR	Constipation	Constipation	31OCT2020 (82)		ONGOING			3	TC/TCN	Y

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
5	GASTR	Large intestine perforation	Perforated Colon	31OCT2020 (82)		ONGOING			3	TC/TCN	Y
6	MUSC	Osteoarthritis	Osteoarthritis of the knee	26OCT2020 (77)		26OCT2020 (77)		1	3	TC/TCN	Y
7	INFEC	Parotitis	Acute parotitis	08NOV2020 (90)		ONGOING			2	TC/TCN	N
8	RENAL	Polyuria	Diuresis	09NOV2020 (91)		ONGOING			2	TC/TCN	N

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Yes	NOT RELATED/OTHER: Dr. suspects this is telogen effluvian caused by SAE	4	23	N
2	Yes	NOT RELATED/OTHER: unknown	2	72	N
3	Yes	NOT RELATED/OTHER: Constipation	2	61	Y
4	Yes	NOT RELATED/OTHER: Unknown	2	61	Y
5	Yes	NOT RELATED/OTHER: Constipation	2	61	Y
6	Resolved (26OCT2020)	NOT RELATED/OTHER: Osteoarthritis of the knee which led to knee replacement	2	56	Y
7	Yes	NOT RELATED/OTHER: unknown	2	69	N
8	Yes	NOT RELATED/OTHER: unknown	2	70	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	30SEP2020	
Completed	REPEAT SCREENING 1	14JAN2021	
Completed	OPEN LABEL TREATMENT	04MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168.5 cm	66.2 kg	23.3 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Recurrent Depression	Depression	1995	Present
Hypothyroid	Hypothyroidism	2000	Present
Osteoporosis	Osteoporosis	2000	Present
Post menopausal	Postmenopause	2002	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14AUG2020 (1)	11:43
2	BNT162b2	04SEP2020 (22)	11:21

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NEOPL	Breast cancer in situ	Stage 0 Breast Cancer Right Breast	30OCT2020 (78)		03DEC2020 (112)		35	3	TCN	Y
2	GENRL	Fatigue	Fatigue	07JAN2021 (147)		ONGOING			1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (03DEC2020)	NOT RELATED/OTHER: Unknown	2	57	Y
2	Yes	NOT RELATED/OTHER: Due to radiation therapy, has improved since finishing Radiation	2	126	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	76	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	135.4 kg	48.5 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Histerectomy	Hysterectomy	1974	Past
Growth on Thyroid	Thyroid neoplasm	1974	Past
Fibroids	Uterine leiomyoma	1974	Past
Partial Thyroidectomy	Thyroidectomy	1975	Past
Hypothyroid	Hypothyroidism	1984	Present
Obesity	Obesity	1990	Present
Arrhythmia- A-Fib	Atrial fibrillation	1996	Present
Acid Reflux	Gastrooesophageal reflux disease	1997	Present
Hiatal Hernia	Hiatus hernia	1997	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Left Knee Replacement Surgery	Knee arthroplasty	1998	Past
Seasonal Allergies	Seasonal allergy	2000	Present
Hypertension	Hypertension	2008	Present
Right Knee Replacement Surgery	Knee arthroplasty	2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	09:46
2	BNT162b2	01OCT2020 (28)	08:28

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	METAB	Fluid retention	Worsening of WATER RETENTION in lower extremities	16SEP2020 (13)		18SEP2020 (15)		3
2	VASC	Hypertension	Worsening of HYPERTENSION	16SEP2020 (13)		18SEP2020 (15)		3

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC	Y	Resolved (18SEP2020)	NOT RELATED/OTHER: UNKNOWN	1	13	Y
2	3	TC	Y	Resolved (18SEP2020)	NOT RELATED/OTHER: UNKNOWN	1	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	02NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	117.91 kg	41.9 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	1962	Present
Seasonal Allergies	Seasonal allergy	1972	Present
Hypothyroidism	Hypothyroidism	1984	Present
Hypertension	Hypertension	1987	Present
Adrenal Hyperplasia	Hyperplasia adrenal	1997	Present
Bilateral Carpal Tunnel Surgery	Carpal tunnel decompression	2002	Past
Carpal Tunnel Syndrome- Bilateral	Carpal tunnel syndrome	2002	Present
Dyslipidemia	Dyslipidaemia	2002	Present
Gallstones	Cholelithiasis	FEB2002	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cholecystectomy	Cholecystectomy	2003	Past
Total Knee Replacement Right Knee	Knee arthroplasty	2003	Past
Osteoarthritis-Bilateral Knees	Osteoarthritis	2003	Present
Osteoarthritis of Right Thumb	Osteoarthritis	2003	Present
Fracture-Bilateral Wrists	Wrist fracture	2007	Past
Squamous Cell Skin Cancer removed from Nose	Skin neoplasm excision	2010	Past
Skin Cancer-Squamous Cell on Nose	Squamous cell carcinoma of skin	2010	Past
Anemia	Anaemia	2011	Past
Colon Polyps- Benign	Large intestine polyp	2011	Past
Colonoscopy/Removal of Benign Colon Polyps	Large intestinal polypectomy	01DEC2011	Past
Diabetes Mellitus Type 2	Type 2 diabetes mellitus	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12AUG2020 (1)	11:49
2	BNT162b2	02SEP2020 (22)	11:06

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	GASTR	Abdominal pain lower	lower abdominal pain	11OCT2020 (61)		16OCT2020 (66)		6	3	TC/TCN

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
2	BLOOD	Anaemia	Worsening of Anemia	11OCT2020 (61)		29OCT2020 (79)		19	3	N
3	NEOPL	Borderline serous tumour of ovary	Serous borderline tumor of left ovary	11OCT2020 (61)		29OCT2020 (79)		19	3	TC/TCN
4	INFEC	Urinary tract infection	Urinary Tract Infection	05OCT2020 (55)		16OCT2020 (66)		12	1	TC

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Resolved (16OCT2020)	NOT RELATED/OTHER: Neoplasm of uncertain behavior of left ovary	2	40	N
2	N	Resolved (29OCT2020)	NOT RELATED/OTHER: Tumor of left ovary	2	40	N
3	Y	Resolved (29OCT2020)	NOT RELATED/OTHER: Cancerous	2	40	Y
4	N	Resolved (16OCT2020)	NOT RELATED/OTHER: Idiopathic	2	34	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	30SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1945	75	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	98.73 kg	33 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Fracture-left fingers/thumb	Hand fracture	1965	Present
Fracture-Left foot	Foot fracture	1970	Present
Hypertension	Hypertension	2002	Present
Angina-Stable	Angina pectoris	2006	Present
Coronary Artery bypass graft	Coronary artery bypass	2006	Past
Coronary Artery Disease	Coronary artery disease	2006	Present
Dyslipidemia	Dyslipidaemia	2006	Present
Obesity	Obesity	2009	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12AUG2020 (1)	13:57
2	BNT162b2	01SEP2020 (21)	13:11

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Prostate cancer	Prostate Cancer	10SEP2020 (30)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TCN	Y	Yes	NOT RELATED/OTHER: Unknown	2	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	29SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	63	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	81.82 kg	34 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tonsillitis	Tonsillitis	01JAN1964	Past
tonsillectomy	Tonsillectomy	1965	Past
myopia	Myopia	1970	Present
C-section	Caesarean section	1988	Past
C-section	Caesarean section	1989	Past
Fall	Fall	1995	Past
fractured right wrist	Wrist fracture	1995	Past
benign lump right breast	Benign breast neoplasm	1998	Past
Lumpectomy of Right breast	Breast conserving surgery	1998	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
occasional headache	Headache	2000	Present
seasonal allergic rhinitis	Seasonal allergy	2000	Present
obesity	Obesity	01JAN2001	Present
menopause moodiness	Menopausal symptoms	2008	Past
postmenopausal	Postmenopause	01JAN2008	Past
GERD	Gastrooesophageal reflux disease	01JAN2009	Present
tinnitus	Tinnitus	01JAN2014	Present
anemia	Anaemia	2018	Past
Osteoarthritis of bilateral index fingers	Osteoarthritis	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	10:41
2	BNT162b2	09SEP2020 (24)	09:58

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	CARD	Atrial fibrillation	Atrial Fibrillation with Rapid Ventricular Response	17NOV2020 (93)	06:00	01DEC2020 (107)		15	2	TC	Y
2	RESP	Sleep apnoea syndrome	Unspecified Sleep Apnea	05JAN2021 (142)		ONGOING			2	N	N

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (01DEC2020)	NOT RELATED/OTHER: Idiopathic, no cause noted in medical records	2	70	Y
2	Yes	NOT RELATED/OTHER: Obesity	2	119	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
Flu Vaccination	INFLUENZA VACCINE	11NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.47 cm	92.95 kg	34.3 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy-Sulfa	Drug hypersensitivity	1989	Present
Blood Transfusion	Transfusion	1989	Past
Allergy-Shellfish-Hives	Urticaria	1989	Present
Hysterectomy	Hysterectomy	1999	Past
Anxiety	Anxiety	2000	Present
Obesity	Obesity	2003	Present
Chronic Bronchitis-Stable	Bronchitis chronic	2005	Present
Hypertension	Hypertension	2008	Present
Insomnia	Insomnia	2008	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	2009	Present
Allergy-Dilaudid-itching	Pruritus allergic	2010	Present
Pneumonia	Pneumonia	2011	Past
Abdominal Hernia	Abdominal hernia	2012	Past
Abdominal Hernia Repair	Abdominal hernia repair	2012	Past
Chronic Back Pain	Back pain	2014	Present
Osteoarthritis of Left Knee	Osteoarthritis	2014	Present
Pneumonia	Pneumonia	2014	Past
Sleep Apnea	Sleep apnoea syndrome	2014	Present
Osteoarthritis of Low Back	Spinal osteoarthritis	2014	Present
Dyslipidemia	Dyslipidaemia	2016	Present
Presbyopia	Presbyopia	2016	Present
Diabetes Mellitus Type 2	Type 2 diabetes mellitus	2016	Present
Abdominal Hernia Repair	Abdominal hernia repair	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	11:32
2	BNT162b2	09SEP2020 (24)	10:49

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	METAB	Diabetic ketoacidosis	Diabetic Ketoacidosis	17SEP2020 (32)		18SEP2020 (33)		2	3	N

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (18SEP2020)	NOT RELATED/OTHER: self-induced due to watermelon diet	2	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1935	85	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
142.24 cm	53.18 kg	26.2 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillitis	Tonsillitis	1940	Past
Tonsillectomy	Tonsillectomy	JUL1940	Past
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	1944	Present
Ovarian Cystectomy	Ovarian cystectomy	1960	Past
Cholecystectomy	Cholecystectomy	1966	Past
Gallstones	Cholelithiasis	1966	Past
Dyslipidemia	Dyslipidaemia	1998	Present
Osteoarthritis-Toes-All	Osteoarthritis	2000	Present
Osteoarthritis-Right Hand	Osteoarthritis	2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteoarthritis-Bilateral Knees	Osteoarthritis	2000	Present
Presbyopia	Presbyopia	2000	Present
Allergy-Codeine	Drug hypersensitivity	2002	Present
Colon Polyps-Benign	Large intestine polyp	2002	Present
Arthroscopic Surgery-Right Knee Cartilage Removal	Meniscus removal	2002	Past
Osteoporosis	Osteoporosis	2004	Present
Knee Replacement-Left Knee	Knee arthroplasty	2009	Past
Glaucoma-Bilateral	Glaucoma	2013	Past
Irritable Bowel Syndrome	Irritable bowel syndrome	2014	Present
Cataract Repair Surgery	Cataract operation	2017	Past
HYPOTHYROIDISM	Hypothyroidism	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	12:18
2	Placebo	09SEP2020 (24)	11:46
3	BNT162b2	29JAN2021 (166)	12:14
4	BNT162b2	22FEB2021 (190)	13:02

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	Fall	Fall on stairs at home	12JAN2021 (149)		12JAN2021 (149)		1	3	TC/TCN	Y
2	INJ&P	Hip fracture	Hip Fracture, right	12JAN2021 (149)		22JAN2021 (159)		11	3	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (12JAN2021)	NOT RELATED/OTHER: fall at home-no underlying suspected medical cause	2	126	Y
2	Resolved (22JAN2021)	NOT RELATED/OTHER: fall at home	2	126	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
Completed	REPEAT SCREENING 1	29JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	90.91 kg	27.1 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Spastic Cerebral Palsy	Cerebral palsy	(b) (6) 1964	Present
Hypertension	Hypertension	2015	Present
Transient Ischemic Attack	Transient ischaemic attack	01DEC2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	14:55
2	BNT162b2	14SEP2020 (22)	14:39

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Myocardial infarction	Myocardial Infarction	15NOV2020 (84)		18NOV2020 (87)		4	4	TC/TCN	Y
2	PSYCH	Suicide attempt	Suicide attempt	15JAN2021 (145)		18JAN2021 (148)		4	3	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (18NOV2020)	NOT RELATED/OTHER: Hypertension	2	63	Y
2	Resolved (18JAN2021)	NOT RELATED/OTHER: Anxiety and depression following cardiac event	2	124	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	13OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
190.5 cm	90.45 kg	24.9 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
osteoarthritis generalized	Osteoarthritis	2000	Present
Allergy metaxalone - hives	Urticaria	2001	Present
ALLERGY TO LOBSTER	Food allergy	2008	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	16:03
2	BNT162b2	15SEP2020 (22)	12:13

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Angina pectoris	Angina	10JAN2021 (139)		ONGOING			2
2	HEPAT	Jaundice	jaundice	24FEB2021 (184)		ONGOING			2
3	INFEC	Urinary tract infection	Urinary Tract Infection	22FEB2021 (182)		01MAR2021 (189)		8	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Yes	NOT RELATED/OTHER: Idiopathic	2	118	Y
2	TC	N	Yes	NOT RELATED/OTHER: Antibiotic Keflex	2	163	N
3	TC	N	Resolved (01MAR2021)	NOT RELATED/OTHER: Infection	2	161	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1939	81	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.45 cm	65.64 kg	22.3 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1957	Present
Osteopenia-stable since 2016	Osteopenia	1985	Present
Hysterectomy	Hysterectomy	1989	Past
Migraine	Migraine	1990	Present
Chronic Urinary Tract Infections	Urinary tract infection	2000	Present
Hypothyroidism	Hypothyroidism	AUG2009	Present
Osteoarthritis of bilateral hands	Osteoarthritis	2013	Present
Rosacea	Rosacea	2013	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2014	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Skin Cancer-Right Leg	Skin cancer	2014	Past
Skin Cancer- Left Arm	Skin cancer	2014	Past
Raynaud's Disease- No associated autoimmune conditions	Raynaud's phenomenon	2016	Present
Sleep Apnea	Sleep apnoea syndrome	APR2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	12:34
2	BNT162b2	16SEP2020 (22)	10:13

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Empyema	loculated empyema	11OCT2020 (47)		18NOV2020 (85)		39
2	INFEC	Pneumonia	Right lower lobe pneumonia	11OCT2020 (47)		18NOV2020 (85)		39

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (18NOV2020)	NOT RELATED/OTHER: idiopathic	2	26	Y
2	3	TC	Y	Resolved (18NOV2020)	NOT RELATED/OTHER: idiopathic	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	14OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	48	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	110.82 kg	35 kg/m2	31AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	12:15
2	Placebo	22SEP2020 (23)	12:18

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	CARD	Coronary artery disease	Coronary Artery disease	04NOV2020 (66)		ONGOING		
2	VASC	Essential hypertension	New onset Essential Hypertension	31AUG2020 (1)	12:11	ONGOING		
3	METAB	Hyperlipidaemia	New onset Unspecified Hyperlipidemia	29OCT2020 (60)		ONGOING		
4	CARD	Myocardial infarction	Myocardial Infarction	21OCT2020 (52)		28OCT2020 (59)		8
5	METAB	Type 2 diabetes mellitus	Type II Diabetes Mellitus	27OCT2020 (58)		ONGOING		

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC/TCN	N	Yes	NOT RELATED/OTHER: Idiopathic	2	44	N
2	2	TC	N	Yes	NOT RELATED/OTHER: Idiopathic	1	1	N
3	2	TC	N	Yes	NOT RELATED/OTHER: Idiopathic	2	38	N
4	4	TC/TCN	Y	Resolved (28OCT2020)	NOT RELATED/OTHER: Cardiac Event	2	30	Y
5	3	TC	Y	Yes	NOT RELATED/OTHER: Insulin Resistance	2	36	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu Vaccination	INFLUENZA VACCINE	28OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	74	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	125.73 kg	36.5 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2000	Present
Dyslipidemia	Dyslipidaemia	JAN2001	Present
Nonspecific Seasonal Allergies	Seasonal allergy	2013	Present
Benign Prostatic Hyperplasia	Benign prostatic hyperplasia	APR2013	Present
Obesity	Obesity	17MAR2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	10:48
2	Placebo	23SEP2020 (21)	09:43
3	BNT162b2	29JAN2021 (149)	13:08
4	BNT162b2	18FEB2021 (169)	11:26

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Prostate cancer	Malignant Neoplasm of Prostate	04NOV2020 (63)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TCN	Y	Yes	NOT RELATED/OTHER: Idiopathic	2	43	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
flu vaccine	INFLUENZA VACCINE	13OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	22OCT2020	
Completed	REPEAT SCREENING 1	29JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168.91 cm	88.64 kg	31 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hysterectomy	Hysterectomy	1992	Past
Dyslipidemia	Dyslipidaemia	2004	Present
Chronic Urinary Tract Infections	Urinary tract infection	2006	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2007	Present
Osteoarthritis of the Left foot	Osteoarthritis	2009	Present
Diabetes Mellitus Type 2	Type 2 diabetes mellitus	OCT2011	Present
Obesity	Obesity	18MAR2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	16:01
2	Placebo	24SEP2020 (22)	11:58
3	BNT162b2	29JAN2021 (149)	13:06
4	BNT162b2	18FEB2021 (169)	11:12

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Breast cancer stage II	Stage II Breast Cancer (Left)	23FEB2021 (174)		ONGOING			3
2	MUSC	Osteoarthritis	worsening-Left Big Toe Osteoarthritis	14OCT2020 (42)		14OCT2020 (42)		1	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT	4	6	Y
2	TCN	N	Resolved (14OCT2020)	NOT RELATED/OTHER: Left big toe bone fusion	2	21	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	29OCT2020	
Completed	REPEAT SCREENING 1	29JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174.5 cm	87.3 kg	28.7 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
diabetes mellitus type II	Type 2 diabetes mellitus	2004	Past
hyperopia	Hypermetropia	2005	Present
presbyopia	Presbyopia	2005	Present
gastric bypass surgery	Gastric bypass	2009	Past
benign prostate hyperplasia	Benign prostatic hyperplasia	2012	Past
prostatic surgery	Prostatic operation	2012	Past
spinal fusion	Spinal fusion surgery	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07AUG2020 (1)	12:28
2	BNT162b2	28AUG2020 (22)	11:08

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Cholelithiasis	cholelithiasis	13AUG2020 (7)		15AUG2020 (9)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	Y	Resolved (15AUG2020)	NOT RELATED/OTHER: concurrent illness	1	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.2 cm	108.4 kg	34.5 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
anxiety	Anxiety	02APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07AUG2020 (1)	14:58

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	28AUG2020 (22)	09:03
3	BNT162b2	01MAR2021 (207)	08:30

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Myocardial infarction	myocardial infarction	28OCT2020 (83)		04NOV2020 (90)		8

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	N	Y	Resolved (04NOV2020)	NOT RELATED/OTHER: unknown etiology	2	62	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	25SEP2020	
Completed	REPEAT SCREENING 1	01MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
181.5 cm	120 kg	36.4 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
left ankle fracture	Ankle fracture	1988	Past
left ankle open reduction internal fixation	Open reduction of fracture	1988	Past
arthritis, bilateral knee	Arthritis	2000	Past
arthritis	Arthritis	2000	Present
idiopathic peripheral neuropathy	Neuropathy peripheral	2000	Present
allergy to amitriptyline	Drug hypersensitivity	2005	Past
left knee replacement	Knee arthroplasty	2013	Past
COPD	Chronic obstructive pulmonary disease	2015	Present
right knee replacement	Knee arthroplasty	2015	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	2016	Past
appendicitis	Appendicitis	2016	Past
cataracts, bilateral	Cataract	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	14:51
2	Placebo	01SEP2020 (22)	13:35
3	BNT162b2	12JAN2021 (155)	12:50
4	BNT162b2	02FEB2021 (176)	12:43

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	METAB	Type 2 diabetes mellitus	New onset type 2 diabetes	05NOV2020 (87)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	TC	Y	Yes	NOT RELATED/OTHER: etiology unknown	2	66	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	30SEP2020	
Completed	REPEAT SCREENING 1	12JAN2021	
Completed	OPEN LABEL TREATMENT	02MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1941	78	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
147.32 cm	76.64 kg	35.2 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	1961	Present
Depression-Mild	Depression	1965	Present
Bladder Prolapse	Bladder prolapse	1981	Past
Bladder Lift	Urinary bladder suspension	1981	Past
Post Menopausal	Postmenopause	1990	Present
penicillin allergy	Drug hypersensitivity	1995	Present
sulfa allergy	Drug hypersensitivity	1995	Present
cataracts	Cataract	2000	Past
Osteoarthritis-Knees Bilateral	Osteoarthritis	2000	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Knee Replacement-Left	Knee arthroplasty	2001	Past
Laparoscopic adjustable gastric banding surgery	Gastric banding	2003	Past
Anxiety	Anxiety	2005	Present
Knee Replacement-Right	Knee arthroplasty	2005	Present
glaucoma	Glaucoma	2008	Present
LEFT ARM BASOSQUAMOUS CARCINOMA REMOVAL	Cancer surgery	2015	Past
iron deficient anemia	Iron deficiency anaemia	2015	Present
Back Pain-Lumbar	Back pain	2016	Present
Left Shoulder Soreness	Arthralgia	02AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	05AUG2020 (1)	13:49
2	Placebo	03SEP2020 (30)	16:27

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	GASTR	Acute abdomen	Acute Abdomen	04MAR2021 (212)	00:00	ONGOING			2	TC/TCN
2	INJ&P	Contusion	Brusing-Bilateral Legs	30SEP2020 (57)	00:00	ONGOING			1	N
3	INJ&P	Fall	Fall	01SEP2020 (28)	00:00	01SEP2020 (28)	00:00	1	2	N

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
4	INJ&P	Fall	Fall	30SEP2020 (57)	00:00	30SEP2020 (57)	00:00	1	1	N
5	MUSC	Musculoskeletal stiffness	Neck Stiffness	29AUG2020 (25)	00:00	01SEP2020 (28)	00:00	4	1	N
6	MUSC	Rotator cuff syndrome	Rotator Cuff Seperation-Right	01SEP2020 (28)	00:00	ONGOING			2	N
7	INJ&P	Skin abrasion	Scrapping -Bilateral Legs	30SEP2020 (57)	00:00	ONGOING			1	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Yes	NOT RELATED/OTHER: Procedural Complication	2	183	Y
2	N	Yes	NOT RELATED/OTHER: Injury	2	28	N
3	N	Resolved (01SEP2020)	NOT RELATED/OTHER: Injury	1	28	N
4	N	Resolved (30SEP2020)	NOT RELATED/OTHER: Injury	2	28	N
5	N	Resolved (01SEP2020)	NOT RELATED/OTHER: ergonomic injury from sleeping wrong	1	25	N
6	N	Yes	NOT RELATED/OTHER: Orthopedic	1	28	N
7	N	Yes	NOT RELATED/OTHER: Injury	2	28	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	59.45 kg	24.7 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sulfa Allergy	Drug hypersensitivity	1992	Present
Allergic Rhinitis-Seasonal	Seasonal allergy	1993	Present
Dysmenorrhea	Dysmenorrhoea	2003	Present
Headaches	Headache	2005	Past
Anxiety	Anxiety	2009	Present
Pomegranate Allergy	Food allergy	2012	Present
Migraines	Migraine	2015	Present
Right Upper Quadrant Pain	Abdominal pain upper	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	26AUG2020 (1)	13:06
2	BNT162b2	16SEP2020 (22)	16:12

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GASTR	Abdominal pain upper	Worsening of Right Upper Quadrant Pain	14SEP2020 (20)	00:00	ONGOING			1
2	PREG	Abortion spontaneous	Miscarriage	04DEC2020 (101)	00:00	05DEC2020 (102)	00:00	2	2
3	GASTR	Vomiting	Vomiting	18SEP2020 (24)	00:00	20SEP2020 (26)	00:00	3	2

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Yes	NOT RELATED/OTHER: Cystic Duct Spasm	1	20	N
2	N	Y	Resolved (05DEC2020)	NOT RELATED/OTHER: Loss of Pregnancy	2	80	Y
3	N	N	Resolved (20SEP2020)	NOT RELATED/OTHER: Stomach Ache	2	3	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Pfizer BNT162b2	BNT162B2	21DEC2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	26FEB2021	PROTOCOL DEVIATION

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	87.59 kg	27.6 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic Rhinitis-Seasonal	Seasonal allergy	1965	Present
Hypothyroidism	Hypothyroidism	1972	Present
Penicillin Allergy	Drug hypersensitivity	1987	Present
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2009	Present
Testicular Hypogonadism	Hypogonadism male	2009	Present
Anxiety	Anxiety	2010	Present
Hypercholesterolemia	Hypercholesterolaemia	2010	Present
Insomnia	Insomnia	2010	Present
Erectile Dysfunction	Erectile dysfunction	2011	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Testicular Hypofunction	Testicular failure	2013	Present
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	2015	Present
Elevated Prostate-Specific Antigen	Prostatic specific antigen increased	2017	Present
Nodular Prostate	Prostatic mass	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27AUG2020 (1)	15:36
UNPLANNED	BNT162b2	12MAR2021 (198)	16:06

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Injection site pain	Injection Site Soreness-Left Arm	12MAR2021 (198)	00:00	13MAR2021 (199)	00:00	2
2	NEOPL	Prostate cancer	Prostate Cancer	02NOV2020 (68)	00:00	ONGOING		
3	SURG	Tooth extraction	Tooth Extraction	20NOV2020 (86)	00:00	20NOV2020 (86)	00:00	1
4	INFEC	Tooth infection	Tooth Infection	12OCT2020 (47)	00:00	03NOV2020 (69)	00:00	23

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (13MAR2021)	Study Treatment	UNPLANNED	1	N
2	3	TC/TCN	Y	Yes	NOT RELATED/OTHER: Cancer	1	68	Y
3	1	TC	N	Resolved (20NOV2020)	NOT RELATED/OTHER: Dental Caries	1	86	N
4	2	N	N	Resolved (03NOV2020)	NOT RELATED/OTHER: Dental Caries	1	47	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Tetanus Vaccine	TETANUS VACCINE	10SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Withdrawn	VACCINATION	02NOV2020	ADVERSE EVENT

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184.15 cm	124.18 kg	36.5 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	1986	Present
Sleep Apnea	Sleep apnoea syndrome	2014	Present
Allergic Rhinitis-Seasonal	Seasonal allergy	2016	Present
Hypertension	Hypertension	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04SEP2020 (1)	12:40
2	Placebo	23SEP2020 (20)	14:51
3	BNT162b2	22JAN2021 (141)	09:16
4	BNT162b2	12FEB2021 (162)	09:05

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Atrial fibrillation	New Onset Atrial Fibrillation with rapid ventricular response	26OCT2020 (53)	00:00	ONGOING		
2	GENRL	Chest pain	Chest Pain	26OCT2020 (53)	00:00	28OCT2020 (55)	00:00	3
3	CARD	Mitral valve incompetence	Trivial Mitral Regurgitation	26OCT2020 (53)	00:00	ONGOING		
4	CARD	Palpitations	Heart Palpitations	26OCT2020 (53)	00:20	28OCT2020 (55)	00:00	3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Yes	NOT RELATED/OTHER: Arrhythmia	2	34	Y
2	2	TC	N	Resolved (28OCT2020)	NOT RELATED/OTHER: Arrhythmia	2	34	N
3	1	TC	N	Yes	NOT RELATED/OTHER: Heart Disease	2	34	N
4	2	TC	N	Resolved (28OCT2020)	NOT RELATED/OTHER: Arrhythmia	2	34	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	22OCT2020	
Completed	REPEAT SCREENING 1	22JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	56	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.7 cm	73.35 kg	27.4 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Headaches	Headache	1983	Present
Decreased visual acuity	Visual acuity reduced	2003	Present
spine tumor	Bone neoplasm	2004	Past
Tumor removal surgery, from spine	Spinal operation	2004	Past
Amoxicillin Allergy	Drug hypersensitivity	2005	Present
Post-Menopausal	Postmenopause	2005	Present
Seasonal Allergies	Seasonal allergy	2005	Present
Hemangioma on Liver	Haemangioma of liver	2009	Past
hemangioma removal surgery	Haemangioma removal	2009	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Morphine Allergy	Drug hypersensitivity	2010	Present
benign mass from bottom of right foot removal surgery	Foot operation	2010	Past
benign mass from bottom of right foot	Limb mass	2010	Past
Tumor removal surgery, from mouth	Oral cavity neoplasm surgery	2010	Past
tumor in mouth	Oral neoplasm	2010	Past
Vertigo	Vertigo	2010	Present
Situational Depression	Adjustment disorder with depressed mood	01MAY2020	Present
Prolapsed Bladder	Bladder prolapse	01MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	16:53
2	BNT162b2	09SEP2020 (24)	13:47

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GASTR	Diarrhoea	Diarrhea	21AUG2020 (5)		21AUG2020 (5)		1	1	N	N
2	GENRL	Fatigue	Fatigue	20AUG2020 (4)		20AUG2020 (4)		1	1	N	N

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
3	REPRO	Ovarian cyst	Left ovarian cyst, benign tumor	24AUG2020 (8)		19SEP2020 (34)		27	2	TC/TCN	Y
4	REPRO	Uterine prolapse	Prolapsed uterus	24AUG2020 (8)		19SEP2020 (34)		27	2	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (21AUG2020)	Study Treatment	1	5	N
2	Resolved (20AUG2020)	Study Treatment	1	4	N
3	Resolved (19SEP2020)	NOT RELATED/OTHER: medical condition	1	8	Y
4	Resolved (19SEP2020)	NOT RELATED/OTHER: per PI Unknown, this is second time this has happened.Documentation is in medhx	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	30	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178.6 cm	94 kg	29.5 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin allergy	Drug hypersensitivity	1995	Present
hernia	Hernia	1998	Past
hernia repair	Hernia repair	1998	Past
inflammation	Inflammation	1998	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28AUG2020 (1)	13:47
2	BNT162b2	25SEP2020 (29)	09:24

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Cellulitis	Cellulitis in Left leg	08SEP2020 (12)		16SEP2020 (20)		9	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (16SEP2020)	NOT RELATED/OTHER: BACTERIAL INFECTION	1	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	26OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	46	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169.5 cm	96.2 kg	33.5 kg/m2	14OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
BETADINE ALLERGY	Drug hypersensitivity	1986	Present
AMOXIXILLIN ALLERGY	Drug hypersensitivity	1986	Present
BILATERAL DECREASED VISUAL ACUITY	Visual acuity reduced	1987	Present
HEADACHES	Headache	1991	Present
GENERAL MUSCLE PAINS	Myalgia	1991	Present
SEASONAL ALLERGIES	Seasonal allergy	2000	Present
LEFT BICEP TENDON TEAR	Tendon rupture	MAR2006	Past
LEFT BICEP TENDON REPAIR	Tenoplasty	MAR2006	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ABDOMINAL HERNIA	Abdominal hernia	SEP2019	Past
ABDOMINAL HERNIA REPAIR	Abdominal hernia repair	SEP2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14OCT2020 (1)	12:42
2	Placebo	02NOV2020 (20)	10:16

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	CARD	Acute coronary syndrome	Acute Coronary Syndrome	26OCT2020 (13)		26OCT2020 (13)		1	3	TC/TCN	N
2	CARD	Acute myocardial infarction	ST-segment elevated MYOCARDIAL INFARCTION	26OCT2020 (13)	07:30	26OCT2020 (13)	15:55	1	2	TC	Y
3	INV	Blood creatinine increased	Elevated Creatinine	26OCT2020 (13)		27OCT2020 (14)		2	1	N	N
4	METAB	Hyperglycaemia	Hyperglycemia	26OCT2020 (13)		27OCT2020 (14)		2	1	N	N
5	VASC	Hypertensive urgency	Hypertensive Urgency	26OCT2020 (13)		29OCT2020 (16)		4	2	TC	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (26OCT2020)	NOT RELATED/OTHER: ST-Segment Elevated Myocardial Infarction	1	13	N
2	Resolved (26OCT2020)	NOT RELATED/OTHER: previously undiagnosed coronary artery disease	1	13	Y
3	Resolved (27OCT2020)	NOT RELATED/OTHER: ST-segment elevated myocardial infarction	1	13	N
4	Resolved (27OCT2020)	NOT RELATED/OTHER: ST-segment elevated myocardial infarction	1	13	N
5	Resolved (29OCT2020)	NOT RELATED/OTHER: ST-segment elevated myocardial infarction	1	13	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PFIZER BIONTECH COVID 19 VACCINE	TOZINAMERAN	07JAN2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14OCT2020	
Completed	VACCINATION	30NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	07JAN2021	WITHDRAWAL BY SUBJECT

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2004	16	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.5 cm	79.6 kg	29.1 kg/m2	06NOV2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tonsillitis	Tonsillitis	2004	Past
tonsillectomy	Tonsillectomy	2006	Past
seasonal allergies	Seasonal allergy	2009	Present
kidney infection	Kidney infection	AUG2010	Present
urinary tract infection	Urinary tract infection	SEP2010	Present
post-traumatic stress disorder	Post-traumatic stress disorder	2015	Present
anxiety	Anxiety	2018	Present
depression	Depression	2018	Present
insomnia	Insomnia	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	06NOV2020 (1)	10:57
2	BNT162b2	30NOV2020 (25)	09:56

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	PSYCH	Bipolar I disorder	Bipolar I	31JAN2021 (87)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC/TCN	Y	Yes	NOT RELATED/OTHER: Depression	2	63	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06NOV2020	
Completed	VACCINATION	30DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	40	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	104.55 kg	36 kg/m2	01AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	2000	Present
Migraines	Migraine	2000	Present
Tubal Ligation	Female sterilisation	2005	Past
Hypertension	Hypertension	2015	Present
Seasonal Allergies	Seasonal allergy	2015	Present
Left Ventricle Hypertrophy	Left ventricular hypertrophy	MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01AUG2020 (1)	11:56
2	BNT162b2	22AUG2020 (22)	11:21

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	REPRO	Endometrial thickening	Endometrial thickening	09FEB2021 (193)		11FEB2021 (195)		3	3	TCN
2	REPRO	Endometriosis	Endometriosis	09FEB2021 (193)		11FEB2021 (195)		3	3	TCN

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (11FEB2021)	NOT RELATED/OTHER: Endometrial thickening/Endometriosis	2	172	Y
2	Y	Resolved (11FEB2021)	NOT RELATED/OTHER: Endometrial thickening	2	172	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01AUG2020	
Completed	VACCINATION	21SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
189.23 cm	86.5 kg	24.1 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasectomy	Vasectomy	1990	Past
L4-L5 Lumbar Fusion	Spinal fusion surgery	2000	Past
Hypertension	Hypertension	2007	Present
Gout	Gout	2009	Present
Aortic Valve Repair	Aortic valve repair	2010	Past
Hypercholesterolemia	Hypercholesterolaemia	2010	Present
Arthritis	Arthritis	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18AUG2020 (1)	12:25
2	BNT162b2	10SEP2020 (24)	09:13

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	RENAL	Acute kidney injury	Acute Kidney Injury	26DEC2020 (131)		29DEC2020 (134)		4	3	N
2	CARD	Acute myocardial infarction	ACUTE NON ST ELEVATION MYOCARDIAL INFARCTION (MI) - NSTEMI	26DEC2020 (131)		29DEC2020 (134)		4	4	TC/TCN
3	CARD	Cardiac failure congestive	ACUTE DIASTOLIC CONGESTIVE HEART FAILURE (CHF)	26DEC2020 (131)		29DEC2020 (134)		4	3	TC/TCN
4	RESP	Haemoptysis	MILD HEMOPTYSIS	26DEC2020 (131)		30DEC2020 (135)		5	2	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (29DEC2020)	NOT RELATED/OTHER: Acute congestive heart failure	2	108	Y
2	Y	Resolved (29DEC2020)	NOT RELATED/OTHER: Medical history	2	108	Y

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	Y	Resolved (29DEC2020)	NOT RELATED/OTHER: NSTEMI	2	108	Y
4	N	Resolved (30DEC2020)	NOT RELATED/OTHER: CONGESTIVE HEART FAILURE	2	108	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	85.91 kg	29.6 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypothyroidism	Hypothyroidism	1990	Present
vasectomy	Vasectomy	1996	Past
hypertension	Hypertension	2015	Present
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	16:23
2	Placebo	23SEP2020 (24)	16:41
3	BNT162b2	12FEB2021 (166)	12:13
4	BNT162b2	03MAR2021 (185)	11:24

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Fall	Fall in hole	17OCT2020 (48)		17OCT2020 (48)		1	1
2	INJ&P	Lower limb fracture	Left leg fracture of tibia/fibula	17OCT2020 (48)		18OCT2020 (49)		2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (17OCT2020)	NOT RELATED/OTHER: Fall in hole	2	25	N
2	TC/TCN	Y	Resolved (18OCT2020)	NOT RELATED/OTHER: STEPPING IN HOLE	2	25	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	21OCT2020	
Completed	REPEAT SCREENING 1	12FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1940	80	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	80.8 kg	31.6 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ALLERGY TO CODEINE	Drug hypersensitivity	1970	Present
FOOD ALLERGY TO ALCOHOL	Food allergy	1980	Present
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	1980	Present
MIGRAINE HEADACHES	Migraine	1980	Present
NAUSEA	Nausea	1980	Present
OBESITY	Obesity	1980	Present
HEARING PROBLEMS (BILATERAL EARS)	Auditory disorder	1990	Present
FOOD ALLERGY TO SHRIMP	Food allergy	1990	Present
GOUT	Gout	1990	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERLIPIDEMIA	Hyperlipidaemia	1992	Present
HYPERTENSION	Hypertension	1992	Present
CONGESTIVE HEART FAILURE (CLASS 2)	Cardiac failure congestive	1995	Present
CHRONIC OBSTRUCTIVE PULMONARY DISEASE	Chronic obstructive pulmonary disease	1995	Present
CORONARY ARTERY DISEASE	Coronary artery disease	1995	Present
SHORTNESS OF BREATH	Dyspnoea	1995	Present
MITRAL VALVE DISORDER	Mitral valve disease	1998	Present
ANEMIA	Anaemia	2000	Present
CHRONIC KIDNEY DISEASE (STAGE 3)	Chronic kidney disease	2000	Present
DEPRESSION	Depression	2000	Present
OSTEOARTHRITIS (BILATERAL LEGS)	Osteoarthritis	2000	Present
OSTEOARTHRITIS (BILATERAL HANDS)	Osteoarthritis	2000	Present
OSTEOARTHRITIS (BILATERAL FEET)	Osteoarthritis	2000	Present
OSTEOPOROSIS	Osteoporosis	2000	Present
POST MENOPAUSAL	Postmenopause	2000	Present
SEASONAL ALLERGIC RHINITIS	Seasonal allergy	2000	Present
SLEEP APNEA	Sleep apnoea syndrome	2005	Present
RECURRENT CONSTIPATION	Constipation	2010	Present
DIABETIC NEUROPATHY	Diabetic neuropathy	2010	Present
TYPE 2 DIABETES	Type 2 diabetes mellitus	2010	Present
TREMOR (BILATERAL ARMS)	Tremor	2016	Present
MEMORY LOSS	Amnesia	2018	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	07AUG2020 (1)	17:04
2	BNT162b2	26AUG2020 (20)	14:23

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GASTR	Abdominal pain	Functional Abdominal Pain	28OCT2020 (83)		05NOV2020 (91)		9	2
2	GASTR	Diverticulum	Diverticulosis	28OCT2020 (83)		ONGOING			2
3	HEPAT	Gallbladder disorder	Distended Gallbladder	28OCT2020 (83)		ONGOING			1
4	GASTR	Hiatus hernia	Small Hiatal Hernia	28OCT2020 (83)		ONGOING			1
5	NERV	Toxic encephalopathy	Acute Toxic Metabolic Encephalopathy	28OCT2020 (83)		05NOV2020 (91)		9	3
6	INFEC	Urinary tract infection	Urinary Tract Infection	28OCT2020 (83)		05NOV2020 (91)		9	2

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (05NOV2020)	NOT RELATED/OTHER: Diverticulosis	2	64	N
2	N	N	Yes	NOT RELATED/OTHER: Poor Diet	2	64	N
3	N	N	Yes	NOT RELATED/OTHER: Idiopathic	2	64	N
4	N	N	Yes	NOT RELATED/OTHER: Idiopathic	2	64	N
5	TC	Y	Resolved (05NOV2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	64	Y
6	N	N	Resolved (05NOV2020)	NOT RELATED/OTHER: Probable Bacterial Infection	2	64	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	23SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	59	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152.4 cm	78.8 kg	33.9 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERTENSION	Hypertension	1985	Present
CHRONIC BACK PAIN	Back pain	1995	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	1995	Present
TRAUMATIC BRAIN INJURY	Craniocerebral injury	2000	Present
GLAUCOMA	Glaucoma	2005	Present
POST-MENOPAUSAL	Postmenopause	2005	Present
ALLERGY TO NUCYNTA	Drug hypersensitivity	2010	Present
CORONARY ARTERY DISEASE	Coronary artery disease	2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	15:37
2	Placebo	01SEP2020 (22)	14:05
3	BNT162b2	09FEB2021 (183)	13:12
4	BNT162b2	02MAR2021 (204)	11:45

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Acute coronary syndrome	ACUTE CORONARY SYNDROME	08SEP2020 (29)		10SEP2020 (31)		3	3
2	CARD	Angina unstable	UNSTABLE ANGINA	08SEP2020 (29)		10SEP2020 (31)		3	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (10SEP2020)	NOT RELATED/OTHER: CORONARY ARTERY DISEASE	2	8	Y
2	N	N	Resolved (10SEP2020)	NOT RELATED/OTHER: CORONARY ARTERY DISEASE	2	8	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINE	INFLUENZA VACCINE	22SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	29SEP2020	
Completed	REPEAT SCREENING 1	09FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	70	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.07 cm	72.56 kg	28.3 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
headaches	Headache	1969	Present
osteoarthritis	Osteoarthritis	2000	Present
osteoporosis	Osteoporosis	2000	Present
post menopausal	Postmenopause	2000	Present
pre-diabetes	Glucose tolerance impaired	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	17:05
2	BNT162b2	21SEP2020 (22)	11:17

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Gallbladder cancer stage II	Gallbladder Cancer - Stage 2	20NOV2020 (82)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		4	TC/TCN	Y	Yes	NOT RELATED/OTHER: Idiopathic	2	61	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	71	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.2 cm	87.6 kg	30.2 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anemia	Anaemia	2000	Present
Hypertension	Hypertension	2000	Present
Diverticulitis	Diverticulitis	2012	Present
Allergy to nonsteroidal anti-inflammatory drugs	Drug hypersensitivity	2012	Present
Vitamin D3 deficiency	Vitamin D deficiency	2015	Present
Anxiety	Anxiety	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01SEP2020 (1)	13:36
2	BNT162b2	22SEP2020 (22)	12:12

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	BLOOD	Blood loss anaemia	Acute Blood Loss Anemia	04NOV2020 (65)		05NOV2020 (66)		2	3
2	GASTR	Gastric antral vascular ectasia	Gastric Antral Vascular Ectasia	06NOV2020 (67)		07NOV2020 (68)		2	3
3	CONG	Gastrointestinal arteriovenous malformation	Arteriovenous Malformation of the Colon	06NOV2020 (67)		07NOV2020 (68)		2	3
4	GASTR	Gastrointestinal haemorrhage	Gastrointestinal Bleed	04NOV2020 (65)		06NOV2020 (67)		3	3
5	GASTR	Haematochezia	Hematochezia	04NOV2020 (65)		07NOV2020 (68)		4	2
6	INV	Haemoglobin decreased	Decreased Hemoglobin	04NOV2020 (65)		04JAN2021 (126)		62	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	N	Resolved (05NOV2020)	NOT RELATED/OTHER: Gastrointestinal Bleed	2	44	N
2	TCN	N	Resolved (07NOV2020)	NOT RELATED/OTHER: Idiopathic	2	46	N
3	TCN	N	Resolved (07NOV2020)	NOT RELATED/OTHER: Idiopathic	2	46	N

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	TC/TCN	Y	Resolved (06NOV2020)	NOT RELATED/OTHER: AVM of the colon	2	44	Y
5	N	N	Resolved (07NOV2020)	NOT RELATED/OTHER: AVM of the colon	2	44	N
6	N	N	Resolved (04JAN2021)	NOT RELATED/OTHER: Gastrointestinal Bleed	2	44	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	76.4 kg	27.4 kg/m2	18SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
headaches	Headache	2009	Present
allergic rhinitis	Rhinitis allergic	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18SEP2020 (1)	10:08
2	BNT162b2	09OCT2020 (22)	13:41

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Meningioma	right frontal meningioma	23SEP2020 (6)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	N	Y	Yes	NOT RELATED/OTHER: unknown	1	6	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18SEP2020	
Completed	VACCINATION	06NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	66 kg	27.4 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cholecystectomy	Cholecystectomy	1973	Past
Gallstones	Cholelithiasis	1973	Past
tetracycline drug allergy	Drug hypersensitivity	1985	Present
Type II diabetes	Type 2 diabetes mellitus	2002	Present
Right foot ulcer	Skin ulcer	2003	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	05AUG2020 (1)	15:30
2	Placebo	27AUG2020 (23)	15:43
3	BNT162b2	22FEB2021 (202)	15:45

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Diabetic foot infection	Infection right pinky toe (secondary to diabetes)	17JAN2021 (166)	18:00	18FEB2021 (198)		33	3
2	VASC	Hypertension	Hypertension	14FEB2021 (194)	18:00	ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (18FEB2021)	NOT RELATED/OTHER: Secondary to diabetes	2	144	Y
2	TC	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	172	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	24SEP2020	
Completed	REPEAT SCREENING 1	22FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	Multiple	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.96 cm	98.55 kg	27.8 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tonsillectomy	Tonsillectomy	1953	Past
tonsillitis	Tonsillitis	1953	Past
left knee arthroscopy	Arthroscopy	1991	Past
osteoarthritis	Osteoarthritis	1991	Present
vasectomy	Vasectomy	1991	Past
gastroparesis	Impaired gastric emptying	1995	Present
dizziness	Dizziness	2000	Present
right knee arthroscopy	Arthroscopy	2001	Past
left knee arthroscopy	Arthroscopy	2001	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
elevated cholesterol	Blood cholesterol increased	2010	Present
right knee arthroscopy	Arthroscopy	2015	Past
hypertension	Hypertension	2015	Present
stroke	Cerebrovascular accident	2017	Past
watchman installed	Atrial appendage closure	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	10:39
2	Placebo	09SEP2020 (22)	12:35
3	BNT162b2	19JAN2021 (154)	14:18
4	BNT162b2	08FEB2021 (174)	08:45

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Atrial fibrillation	Chronic atrial fibrillation with RVR'	04OCT2020 (47)		05OCT2020 (48)		2	3	TC/TCN	Y

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (05OCT2020)	NOT RELATED/OTHER: subject is 71 years old and susceptible to heart issues	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
flu vaccine	INFLUENZA VACCINE	01OCT2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	07OCT2020	
Completed	REPEAT SCREENING 1	19JAN2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	08MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	68.27 kg	23.5 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
abdominal surgery	Abdominal operation		Past
arthritis	Arthritis		Present
asthma	Asthma		Present
Atrial Fibrillation	Atrial fibrillation		Present
Lymph node biopsy	Biopsy lymph gland		Past
stroke	Cerebrovascular accident		Past
undescended testicle right	Cryptorchism		Past
penicillin drug allergy	Drug hypersensitivity		Present
erythromycin drug allergy	Drug hypersensitivity		Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
codeine drug allergy	Drug hypersensitivity		Present
amoxicillin drug allergy	Drug hypersensitivity		Present
beans food allergy	Food allergy		Present
hernia repair	Hernia repair		Past
hypertension	Hypertension		Present
funnel chest	Pectus excavatum		Present
PTSD	Post-traumatic stress disorder		Present
Seizure disorder	Seizure		Present
testicle exploration right	Testes exploration		Past
borderline personality disorder	Borderline personality disorder	2014	Present
COPD	Chronic obstructive pulmonary disease	17DEC2014	Present
schizophrenia	Schizophrenia	03NOV2017	Present
Polysubstance Abuse	Substance abuse	17AUG2018	Present
skin rash	Rash	27JUL2020	Present
left hand fracture	Hand fracture	12AUG2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	14:22

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	RESP	Chronic obstructive pulmonary disease	worsening of COPD	26AUG2020 (2)		27AUG2020 (3)		2	2
2	INJ&P	Fall	Fall	09SEP2020 (16)	03:00	09SEP2020 (16)	03:00	1	2
3	INJ&P	Hip fracture	Left Hip Closed Fracture	09SEP2020 (16)	03:00	25SEP2020 (32)		17	3
4	GASTR	Nausea	nausea	27SEP2020 (34)		28SEP2020 (35)		2	2
5	PSYCH	Psychotic disorder	Psychosis	27SEP2020 (34)		ONGOING			3
6	PSYCH	Substance abuse	worsening of polysubstance abuse	27SEP2020 (34)		28SEP2020 (35)		2	2

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (27AUG2020)	NOT RELATED/OTHER: Med HX of COPD	1	2	N
2	N	N	Resolved (09SEP2020)	NOT RELATED/OTHER: fall from dumpster	1	16	N
3	TC	Y	Resolved (25SEP2020)	NOT RELATED/OTHER: Fall	1	16	Y
4	N	N	Resolved (28SEP2020)	NOT RELATED/OTHER: subject detoxing from substance use	1	34	N
5	TC/TCN	Y	Yes	NOT RELATED/OTHER: Hx of mental disorders	1	34	Y
6	N	N	Resolved (28SEP2020)	NOT RELATED/OTHER: medical history of polysubstance abuse	1	34	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Withdrawn	VACCINATION	23NOV2020	LOST TO FOLLOW-UP
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	23NOV2020	LOST TO FOLLOW-UP

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	63	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	80.2 kg	26.2 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hernia, R inguinal	Inguinal hernia	1956	Past
Pilonidal Cystectomy	Pilonidal sinus repair	1977	Past
GERD	Gastrooesophageal reflux disease	1980	Past
Allergy to Iodine	Iodine allergy	1989	Present
Brachial Cleft Cyst	Cyst	1990	Past
Allergic Rhinitis	Rhinitis allergic	1994	Present
Allergy to Morphine	Drug hypersensitivity	2005	Present
Prediabetes	Glucose tolerance impaired	2005	Present
Vertebrae Fusion C4 and C5	Spinal fusion surgery	2005	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Peripheral Vascular Disease Left Leg	Peripheral vascular disorder	2006	Present
Elevated Cholesterol	Blood cholesterol increased	2010	Present
Premature Ventricular Contractions	Ventricular extrasystoles	2010	Present
Allergy to Penicillin	Drug hypersensitivity	2017	Present
Basal Cell Carcinoma Removal	Skin neoplasm excision	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13AUG2020 (1)	16:45
2	Placebo	04SEP2020 (23)	09:50
3	BNT162b2	26FEB2021 (198)	14:29

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Clavicle fracture	left clavicle, fractured	07NOV2020 (87)		03DEC2020 (113)		27
2	INJ&P	Concussion	concussion	07NOV2020 (87)		14NOV2020 (94)		8
3	INJ&P	Contusion	left scalp contusion	07NOV2020 (87)		14NOV2020 (94)		8
4	NERV	Intraventricular haemorrhage	intraventricular hemorrhage, left occipital horn	07NOV2020 (87)		14NOV2020 (94)		8

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
5	INJ&P	Rib fracture	broken ribs	07NOV2020 (87)		03DEC2020 (113)		27
6	INJ&P	Road traffic accident	bike accident	07NOV2020 (87)		07NOV2020 (87)		1

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC	N	Resolved (03DEC2020)	NOT RELATED/OTHER: bike accident	2	65	N
2	2	TC/TCN	Y	Resolved (14NOV2020)	NOT RELATED/OTHER: bike accident	2	65	Y
3	2	N	N	Resolved (14NOV2020)	NOT RELATED/OTHER: bike accident	2	65	N
4	2	TC	Y	Resolved (14NOV2020)	NOT RELATED/OTHER: bike accident	2	65	Y
5	2	TC	N	Resolved (03DEC2020)	NOT RELATED/OTHER: bike accident	2	65	N
6	3	TC	Y	Resolved (07NOV2020)	NOT RELATED/OTHER: unknown	2	65	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	30SEP2020	
Completed	REPEAT SCREENING 1	26FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.5 cm	78.5 kg	28 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Ear Tube Implantation	Ear tube insertion	1981	Past
Penicillin Allergy	Drug hypersensitivity	1985	Present
Acne	Acne	1994	Present
Allergic Rhinitis	Rhinitis allergic	2002	Present
Depression	Depression	2007	Present
Stress Urinary Incontinence	Stress urinary incontinence	2009	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14SEP2020 (1)	11:36
2	Placebo	06OCT2020 (23)	11:47

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	REPRO	Adnexal torsion	Right ovarian torsion	07DEC2020 (85)		12DEC2020 (90)		6

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TCN	Y	Resolved (12DEC2020)	NOT RELATED/OTHER: unk	2	63	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu vaccine	INFLUENZA VACCINE	28OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	03NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.8 cm	58.1 kg	21.4 kg/m2	07OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Erythromycin Allergy	Drug hypersensitivity	1990	Present
tension headaches	Tension headache	1990	Past
Eczema	Eczema	1995	Past
Allergic Rhinitis	Rhinitis allergic	2005	Present
Post-Menopausal	Postmenopause	2008	Present
Elevated Cholesterol	Blood cholesterol increased	2010	Present
Hypothyroidism	Hypothyroidism	2012	Present
Metatarsal Repair (R)	Bone operation	JUN2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07OCT2020 (1)	12:50
2	BNT162b2	26OCT2020 (20)	12:42

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Duodenal obstruction	duodenal obstruction	13JAN2021 (99)		16JAN2021 (102)		4

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/TCN	Y	Resolved (16JAN2021)	NOT RELATED/OTHER: unk	2	80	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07OCT2020	
Completed	VACCINATION	20NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.2 cm	95.6 kg	31.9 kg/m2	23OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	1967	Present
Depression	Depression	1985	Present
Hypertension	Hypertension	1990	Present
vasectomy	Vasectomy	2001	Past
Levaquin allergy	Drug hypersensitivity	2005	Present
Ciprofloxacin allergy	Drug hypersensitivity	2005	Present
Nephrolithiasis	Nephrolithiasis	2005	Present
Low Vitamin D	Vitamin D decreased	2012	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Low Testosterone	Blood testosterone decreased	2015	Present
Low serum iron	Blood iron decreased	JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	23OCT2020 (1)	10:34
2	BNT162b2	13NOV2020 (22)	13:50

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Myalgia	Myalgia	24OCT2020 (2)		25OCT2020 (3)		2
2	MUSC	Myalgia	Myalgia	14NOV2020 (23)		16NOV2020 (25)		3
3	INFEC	Pyelonephritis	pyelonephritis	11FEB2021 (112)		12FEB2021 (113)		2
4	GENRL	Pyrexia	Fever	24OCT2020 (2)		25OCT2020 (3)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Resolved (25OCT2020)	Study Treatment	1	2	N

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	1	TC	N	Resolved (16NOV2020)	Study Treatment	2	2	N
3	2	TC	Y	Resolved (12FEB2021)	NOT RELATED/OTHER: nephrolithiasis	2	91	Y
4	1	TC	N	Resolved (25OCT2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23OCT2020	
Completed	VACCINATION	18DEC2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
181 cm	84.6 kg	25.8 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	1976	Present
chest pain	Chest pain	2008	Past
cyst in esophagus	Oesophageal cyst	2008	Past
removal of esophageal cyst	Oesophageal lesion excision	2008	Past
DVT	Deep vein thrombosis	2017	Past
restless leg syndrome	Restless legs syndrome	2017	Present
depression	Depression	OCT2019	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	28AUG2020 (1)	11:43
2	Placebo	17SEP2020 (21)	10:02
3	BNT162b2	01MAR2021 (186)	08:23

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GASTR	Diarrhoea	Diarrhea	17SEP2020 (21)		03OCT2020 (37)		17	1
2	RESP	Hypoxia	hypoxia	26SEP2020 (30)		27SEP2020 (31)		2	3
3	RESP	Nasal congestion	nasal congestion	10OCT2020 (44)		17OCT2020 (51)	10:00	8	1
4	RESP	Pneumonia aspiration	Aspiration Pneumonia	26SEP2020 (30)		06OCT2020 (40)		11	3
5	INJ&P	Toxicity to various agents	poisoning by cocaine	26SEP2020 (30)		27SEP2020 (31)		2	4

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (03OCT2020)	Study Treatment	2	1	N
2	TC/TCN	Y	Resolved (27SEP2020)	NOT RELATED/OTHER: opioid overdose	2	10	Y
3	N	N	Resolved (17OCT2020)	NOT RELATED/OTHER: environmental irritant	2	24	N
4	TC	Y	Resolved (06OCT2020)	NOT RELATED/OTHER: poisoning by cocaine	2	10	Y
5	TC/TCN	Y	Resolved (27SEP2020)	NOT RELATED/OTHER: substance abuse	2	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	19OCT2020	
Completed	REPEAT SCREENING 1	01MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.5 cm	87.4 kg	29 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
brain injury	Brain injury	2006	Present
migraines	Migraine	2006	Present
post traumatic stress disorder	Post-traumatic stress disorder	2006	Present
vertigo	Vertigo	2006	Present
anxiety	Anxiety	2013	Present
chronic right shoulder pain	Arthralgia	2013	Past
chronic kidney disease	Chronic kidney disease	2013	Present
depression	Depression	2013	Present
esophageal reflux	Gastrooesophageal reflux disease	2013	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
generalized osteoarthritis	Osteoarthritis	2013	Present
sleep apnea	Sleep apnoea syndrome	2013	Present
hypertriglyceridemia	Hypertriglyceridaemia	2019	Present
right shoulder replacement	Shoulder arthroplasty	NOV2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01SEP2020 (1)	11:56
2	BNT162b2	21SEP2020 (21)	09:50

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Injection site erythema	injection site redness	22SEP2020 (22)	21:00	24SEP2020 (24)		3
2	GENRL	Injection site pain	injection site pain	22SEP2020 (22)	21:00	24SEP2020 (24)		3
3	GENRL	Injection site pain	injection site soreness	02SEP2020 (2)		09SEP2020 (9)		8
4	CARD	Myocardial infarction	Myocardial Infarction	06NOV2020 (67)	19:00	06NOV2020 (67)	23:30	1

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (24SEP2020)	Study Treatment	2	2	N
2	1	N	N	Resolved (24SEP2020)	Study Treatment	2	2	N
3	1	N	N	Resolved (09SEP2020)	Study Treatment	1	2	N
4	4	TC/TCN	Y	Resolved (06NOV2020)	NOT RELATED/OTHER: Unknown	2	47	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	03NOV2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1941	79	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.01 cm	66 kg	23.6 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypothyroidism	Hypothyroidism	1990	Present
angina	Angina pectoris	1994	Past
percutaneous transluminal coronary angioplasty	Coronary angioplasty	1994	Past
fibroid tumors	Fibroma	1997	Past
total hysterectomy	Hysterectomy	1997	Past
allergic to penicillin	Drug hypersensitivity	2000	Present
bilateral knee replacements	Knee arthroplasty	2004	Past
osteoarthritis bilateral knees	Osteoarthritis	2004	Present
presbyopia	Presbyopia	2005	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Coronary artery bypass graft	Coronary artery bypass	01MAR2008	Past
dyslipidemia	Dyslipidaemia	01MAR2008	Present
right rotator cuff repair	Rotator cuff repair	2009	Past
right rotator cuff tear	Rotator cuff syndrome	2009	Past
left cataract	Cataract	2010	Past
GERD	Gastrooesophageal reflux disease	01AUG2010	Present
hypertension	Hypertension	01AUG2010	Present
right cataract	Cataract	2014	Past
heart arrhythmias- due to pause between beats	Arrhythmia	2016	Past
pacemaker implantation	Cardiac pacemaker insertion	2016	Present
left cataract surgery	Cataract operation	MAR2016	Past
Intermittent stomach pain	Abdominal pain upper	01JAN2017	Present
hypercalcemia	Hypercalcaemia	2018	Past
insomnia	Insomnia	2018	Present
parathyroidectomy	Parathyroidectomy	2018	Past
chronic urinary tract infection	Urinary tract infection	2018	Past
myopia	Myopia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	12:59
2	BNT162b2	09SEP2020 (22)	11:21

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GASTR	Abdominal pain upper	Worsening Intermittent Stomach Pain	02FEB2021 (168)		ONGOING			2
2	INFEC	Vulvovaginitis	Vulvovaginitis	03SEP2020 (16)		12OCT2020 (55)		40	1

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	Y	Yes	NOT RELATED/OTHER: Not related to study treatment	2	147	Y
2	TC	N	Resolved (12OCT2020)	NOT RELATED/OTHER: Unknown	1	16	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
influenza vaccine	INFLUENZA VACCINE	30SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.96 cm	85.82 kg	29 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
environmental allergies	Hypersensitivity	1952	Present
seasonal allergies	Seasonal allergy	1952	Present
umbilical hernia	Umbilical hernia	1955	Past
Myopia	Myopia	JUN1962	Present
tonsillitis	Tonsillitis	JUN1962	Past
appendicitis	Appendicitis	JUN1968	Past
dyslipidemia	Dyslipidaemia	JUN1988	Present
hypertension	Hypertension	JUN1988	Present
inguinal hernia	Inguinal hernia	2011	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
basal cell carcinoma right shoulder	Basal cell carcinoma	2012	Past
actinic keratosis	Actinic keratosis	JUN2013	Present
plantar fasciitis in the right foot	Plantar fasciitis	JUN2017	Past
basal cell carcinoma on nose	Basal cell carcinoma	AUG2018	Past
gastro esophageal reflux disease	Gastrooesophageal reflux disease	JUN2019	Present
basal cell carcinoma on nose	Basal cell carcinoma	JUN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	15:54
2	BNT162b2	06OCT2020 (49)	14:30

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Atrial fibrillation	Arrhythmia atrial fibrillation	26AUG2020 (8)		27AUG2020 (9)		2	2	TC	Y
2	INV	Troponin increased	Elevated troponin	26AUG2020 (8)		26AUG2020 (8)		1	1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (27AUG2020)	NOT RELATED/OTHER: medical records being reviewed not able to answer at this time.	1	8	Y
2	Resolved (26AUG2020)	NOT RELATED/OTHER: Unknown	1	8	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	02NOV2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179.07 cm	141.55 kg	44 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
gastro esophageal reflux disease	Gastrooesophageal reflux disease	1995	Present
dyslipidemia	Dyslipidaemia	1998	Present
sleep apnea	Sleep apnoea syndrome	1998	Present
coronary artery disease	Coronary artery disease	2005	Present
myocardial infarction	Myocardial infarction	2005	Past
hypertension	Hypertension	2007	Present
obesity	Obesity	2007	Present
stable angina	Angina pectoris	2009	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
percutaneous transluminal coronary angioplasty	Coronary angioplasty	2009	Past
type 2 diabetes	Type 2 diabetes mellitus	2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	13:46
2	Placebo	14SEP2020 (22)	11:32
3	BNT162b2	10FEB2021 (171)	10:41
4	BNT162b2	02MAR2021 (191)	10:38

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Atrial fibrillation	Atrial Fibrillation	23NOV2020 (92)		25NOV2020 (94)		3	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (25NOV2020)	NOT RELATED/OTHER: Cardiac medical history	2	71	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	12OCT2020	
Completed	REPEAT SCREENING 1	10FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	70	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	91.41 kg	27.3 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
dyslipidemia	Dyslipidaemia	1993	Present
osteoarthritis of the neck	Spinal osteoarthritis	2008	Present
osteoarthritis of the spine	Spinal osteoarthritis	2008	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	08:27
2	Placebo	22SEP2020 (22)	07:39
3	BNT162b2	25JAN2021 (147)	07:49
4	BNT162b2	15FEB2021 (168)	07:41

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INV	Blood pressure increased	Elevated Blood Pressure	16JAN2021 (138)		16JAN2021 (138)		1
2	METAB	Hypokalaemia	Hypokalemia	16JAN2021 (138)		16JAN2021 (138)		1
3	GASTR	Nausea	Nausea	16JAN2021 (138)		16JAN2021 (138)		1
4	NERV	Transient ischaemic attack	Transient Ischemic Attack (TIA)	16JAN2021 (138)		16JAN2021 (138)		1
5	INFEC	Urinary tract infection	Urinary Tract Infection	06OCT2020 (36)		10OCT2020 (40)		5
6	EAR	Vertigo	Vertigo	16JAN2021 (138)		18JAN2021 (140)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (16JAN2021)	NOT RELATED/OTHER: Unknown	2	117	N
2	1	N	N	Resolved (16JAN2021)	NOT RELATED/OTHER: Unknown	2	117	N
3	2	TC	N	Resolved (16JAN2021)	NOT RELATED/OTHER: Unknown	2	117	N
4	3	TC	Y	Resolved (16JAN2021)	NOT RELATED/OTHER: Unknown	2	117	Y

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	1	TC	N	Resolved (10OCT2020)	NOT RELATED/OTHER: UNK	2	15	N
6	3	TC	Y	Resolved (18JAN2021)	NOT RELATED/OTHER: Unknown	2	117	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	20OCT2020	
Completed	REPEAT SCREENING 1	25JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.83 cm	91 kg	33.8 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
postmenopausal	Postmenopause	2003	Present
Gastric Bypass	Gastric bypass	2007	Present
dyslipidemia	Dyslipidaemia	2010	Present
hypertension	Hypertension	2010	Present
type 2 diabetes	Type 2 diabetes mellitus	2010	Present
Lap Band procedure	Gastric banding	2012	Present
gastro esophageal reflux disease	Gastrooesophageal reflux disease	2015	Present
anxiety	Anxiety	2018	Present
Hernia repair	Hernia repair	26JUN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	10:03
2	Placebo	19OCT2020 (49)	09:12
3	BNT162b2	25JAN2021 (147)	11:46
4	BNT162b2	15FEB2021 (168)	10:14

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain upper	Epigastric Pain	07OCT2020 (37)	21:30	08OCT2020 (38)	17:30	2	3
2	GASTR	Chronic gastritis	Chronic Focally Active Gastritis	07OCT2020 (37)		ONGOING			2
3	EYE	Eye swelling	Swelling of eyes	17SEP2020 (17)		18SEP2020 (18)		2	2
4	GASTR	Lip swelling	Swelling of lip	17SEP2020 (17)		18SEP2020 (18)		2	2
5	SKIN	Urticaria	Hives (Urticaria)	17SEP2020 (17)		18SEP2020 (18)		2	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (08OCT2020)	NOT RELATED/OTHER: Gastric Pouch distention	1	37	Y
2	N	N	Yes	NOT RELATED/OTHER: Unknown	1	37	N
3	TC	N	Resolved (18SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	17	N

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	TC	N	Resolved (18SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	17	N
5	TC	N	Resolved (18SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	17	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	16NOV2020	
Completed	REPEAT SCREENING 1	25JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	72	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	134.64 kg	40.2 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
type 2 diabetes	Type 2 diabetes mellitus	2003	Present
asthma Controlled	Asthma	2004	Present
seasonal allergies	Seasonal allergy	2005	Present
obesity	Obesity	2010	Present
dyslipidemia	Dyslipidaemia	MAY2010	Present
hypertension	Hypertension	SEP2010	Present
transient ischemic attack	Transient ischaemic attack	06DEC2013	Past
insomnia	Insomnia	2017	Present
coronary artery bypass graft	Coronary artery bypass	10JAN2020	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
coronary artery disease	Coronary artery disease	10JAN2020	Present
atrial fibrillation	Atrial fibrillation	06JUL2020	Present
insertion of intra-cardiac defibrillator	Implantable defibrillator insertion	06JUL2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15SEP2020 (1)	11:06
2	BNT162b2	06OCT2020 (22)	10:49

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	CARD	Cardiac failure congestive	Congestive heart failure	01OCT2020 (17)	01:00	03OCT2020 (19)		3	2	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (03OCT2020)	NOT RELATED/OTHER: Progression of cardiovascular disease	1	17	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15SEP2020	
Completed	VACCINATION	03NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	68.82 kg	20 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
BILATERAL TUBAL LIGATION	Female sterilisation	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	14:30
2	BNT162b2	16SEP2020 (22)	10:07

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Subcutaneous abscess	Cutaneous abscess of left upper extremity	20FEB2021 (179)		08MAR2021 (195)		17

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	Y	Resolved (08MAR2021)	NOT RELATED/OTHER: BACTERIAL	2	158	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	14OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	121 kg	40.5 kg/m2	22SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
MENORRHAGIA	Menorrhagia	1968	Past
UTERINE CYSTS	Uterine cyst	1975	Past
BILATERAL TUBAL LIGATION	Female sterilisation	1977	Past
PENICILLIN ALLERGY	Drug hypersensitivity	1980	Present
HERNIATED DISCS	Intervertebral disc protrusion	1994	Past
CERVICAL FUSION	Spinal fusion surgery	1996	Past
HYSTERECTOMY	Hysterectomy	2001	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22SEP2020 (1)	14:31
2	Placebo	14OCT2020 (23)	14:00
3	BNT162b2	23FEB2021 (155)	14:27

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Upper respiratory tract infection	UPPER RESPIRATORY INFECTION	26DEC2020 (96)		28DEC2020 (98)		3
2	INFEC	Urinary tract infection	URINARY TRACT INFECTION	26DEC2020 (96)		28DEC2020 (98)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	Y	Resolved (28DEC2020)	NOT RELATED/OTHER: VIRAL	2	74	Y
2	1	TC	Y	Resolved (28DEC2020)	NOT RELATED/OTHER: GYNOCOLOGY	2	74	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINE	INFLUENZA VACCINE	04OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22SEP2020	
Completed	VACCINATION	11NOV2020	
Completed	REPEAT SCREENING 1	23FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1993	26	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.8 cm	90.9 kg	27.2 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	1995	Present
Eczema	Eczema	1995	Present
Seasonal allergies	Seasonal allergy	1995	Present
Inguinal hernia	Inguinal hernia	1998	Past
Inguinal hernia repair	Inguinal hernia repair	1998	Past
Diabetes Type II	Type 2 diabetes mellitus	2011	Present
wisdom teeth removal	Wisdom teeth removal	2013	Past
Anxiety	Anxiety	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25SEP2020 (1)	11:21
2	Placebo	10NOV2020 (47)	11:21
3	BNT162b2	27JAN2021 (125)	15:58
4	BNT162b2	18FEB2021 (147)	09:48

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Colon injury	colon injury	16OCT2020 (22)		23OCT2020 (29)		8	3
2	INJ&P	Road traffic accident	motor vehicle accident	16OCT2020 (22)		16OCT2020 (22)		1	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (23OCT2020)	NOT RELATED/OTHER: Motor vehicle accident	1	22	Y
2	N	N	Resolved (16OCT2020)	NOT RELATED/OTHER: driving accident	1	22	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25SEP2020	
Completed	VACCINATION	08DEC2020	
Completed	REPEAT SCREENING 1	27JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	38	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	81.6 kg	27.3 kg/m2	31JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Heavy menses	Menorrhagia	1994	Past
subdural hematoma	Subdural haematoma	03APR2006	Past
Moderate Anxiety	Anxiety	2014	Present
deviated septum	Nasal septum deviation	2015	Past
seasonal allergies	Seasonal allergy	2015	Present
hysterectomy	Hysterectomy	15MAY2018	Past
sinus surgery	Sinus operation	APR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31JUL2020 (1)	10:11
2	Placebo	21AUG2020 (22)	11:42
3	BNT162b2	03FEB2021 (188)	14:01
4	BNT162b2	02MAR2021 (215)	14:19

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	REPRO	Adnexal torsion	torsion of right ovary	23DEC2020 (146)		18JAN2021 (172)		27

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (18JAN2021)	NOT RELATED/OTHER: ovarian cyst	2	125	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31JUL2020	
Completed	VACCINATION	22SEP2020	
Completed	REPEAT SCREENING 1	03FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	49.3 kg	17.9 kg/m2	06AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
endometriosis	Endometriosis	1990	Past
post menopausal symptoms	Menopausal symptoms	2013	Present
donor site palate chronic pain	Donor site complication	31DEC2019	Present
gum graft placement periodontal surgery	Gingival graft	31DEC2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	06AUG2020 (1)	14:38
2	Placebo	27AUG2020 (22)	14:17
3	BNT162b2	16DEC2020 (133)	16:58
4	BNT162b2	05JAN2021 (153)	13:49

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Lobular breast carcinoma in situ	Left Lobular Breast Cancer, Stage I, Grade I	12DEC2020 (129)		ONGOING			2
2	GENRL	Injection site pain	Injection Site Pain	16DEC2020 (133)	17:23	18DEC2020 (135)	18:00	3	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	Y	Yes	NOT RELATED/OTHER: genetics/aging/combipatch	2	108	Y
2	N	N	Resolved (18DEC2020)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06AUG2020	
Completed	VACCINATION	25SEP2020	
Completed	REPEAT SCREENING 1	16DEC2020	
Completed	OPEN LABEL TREATMENT	02FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	65	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.5 cm	99.3 kg	33 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
congenital jaw misalignment	Congenital jaw malformation	(b) (6) 1954	Past
tonsillectomy	Tonsillectomy	1965	Past
tonsillitis	Tonsillitis	1965	Past
hepatitis B	Hepatitis B	1981	Past
migraines	Migraine	1985	Present
jaw surgery- fix misalignment	Jaw operation	2000	Past
mitral valve prolapse	Mitral valve prolapse	2005	Present
postmenopausal symptoms	Menopausal symptoms	2009	Present
seasonal allergies	Seasonal allergy	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
cartilage deterioration (both knees)	Cartilage injury	2011	Past
partial knee replacement (left)	Knee arthroplasty	2011	Past
partial knee replacement (right)	Knee arthroplasty	2013	Past
ankel surgery (right ankle)	Ankle operation	2017	Past
torn right ankle tendon	Tendon rupture	2017	Past
cataracts (bilateral)	Cataract	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07AUG2020 (1)	15:10
2	BNT162b2	28AUG2020 (22)	09:53

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Pulmonary embolism	Pulmonary Embolism	30OCT2020 (85)		07NOV2020 (93)		9	3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	Y	Resolved (07NOV2020)	NOT RELATED/OTHER: HRT and prolonged immobilization	2	64	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	28SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1938	82	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	103.8 kg	32 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hepatitis A	Hepatitis A	1965	Past
Coronary stents Insertion (3)	Coronary arterial stent insertion	1995	Present
Post Traumatic Stress Disorder	Post-traumatic stress disorder	1995	Present
Diabetes mellitus Type 2	Type 2 diabetes mellitus	1995	Present
Hypercholesterolemia	Hypercholesterolaemia	1998	Present
Hypertension	Hypertension	2000	Present
hyperthyroidism	Hyperthyroidism	2009	Past
Hypothyroidism	Hypothyroidism	2009	Present
Thyroidectomy	Thyroidectomy	2009	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Eastern Equine Encephalitis	Encephalitis eastern equine	2010	Present
Coronary artery disease	Coronary artery disease	2013	Present
Sleep apnea	Sleep apnoea syndrome	2016	Present
Irritable Bowel Syndrome	Irritable bowel syndrome	2018	Present
Pacemaker Implant	Cardiac pacemaker insertion	23DEC2019	Past
Mild cellulitis (right arm)	Cellulitis	MAR2020	Present
insomnia	Insomnia	15JUL2020	Present
Pacemaker Explant	Cardiac pacemaker removal	24JUL2020	Past
Muscle strain (left arm)	Muscle strain	31JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07AUG2020 (1)	17:55
2	Placebo	27AUG2020 (21)	15:11

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NERV	Dizziness	Dizziness, secondary to Clonidine reaction	31AUG2020 (25)	16:00	02SEP2020 (27)		3	2	N	Y

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
2	METAB	Hypoglycaemia	Hypoglycemia	12AUG2020 (6)	12:00	12AUG2020 (6)	13:00	1	1	TCN	N
3	CARD	Tachyarrhythmia	Suspected tachy-arrythmia	08SEP2020 (33)		22SEP2020 (47)		15	3	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (02SEP2020)	NOT RELATED/OTHER: unknown	2	5	Y
2	Resolved (12AUG2020)	NOT RELATED/OTHER: Hypoglycemia, on insulin, is type II diabetic	1	6	N
3	Resolved (22SEP2020)	NOT RELATED/OTHER: underlying cardiac condition likely requiring pacemaker	2	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	28SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	28SEP2020	WITHDRAWAL BY SUBJECT

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	68	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	88.1 kg	35.7 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Urinary incontinence	Urinary incontinence	2005	Past
Bladder suspension	Urinary bladder suspension	2011	Past
Alopecia	Alopecia	2014	Present
Sleep apnea	Sleep apnoea syndrome	NOV2014	Present
Type II diabetes	Type 2 diabetes mellitus	NOV2014	Present
Depression	Depression	JUN2016	Present
Hyperlipidemia	Hyperlipidaemia	JUN2016	Present
Hypertension	Hypertension	SEP2016	Present
Hypothyroidism	Hypothyroidism	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	15:01
2	Placebo	14SEP2020 (22)	11:04
3	BNT162b2	28DEC2020 (127)	14:01
4	BNT162b2	18JAN2021 (148)	16:08

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	EYE	Diplopia	Diplopia	08JAN2021 (138)	16:00	20JAN2021 (150)		13	1
2	MUSC	Osteoarthritis	right knee osteoarthritis	01SEP2020 (9)		ONGOING			1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (20JAN2021)	NOT RELATED/OTHER: idiopathic diplopia	3	12	Y
2	TCN	N	Yes	NOT RELATED/OTHER: mechanical stress	1	9	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	12OCT2020	
Completed	REPEAT SCREENING 1	28DEC2020	
Completed	OPEN LABEL TREATMENT	05MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.5 cm	68.9 kg	23.4 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Diabetes Mellitus Type 2	Type 2 diabetes mellitus	1995	Present
Hypertension	Hypertension	2009	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	17:39
2	BNT162b2	15SEP2020 (22)	12:15

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	CARD	Cardiac arrest	Cardiac Arrest	16OCT2020 (53)		16NOV2020 (84)		32	4	TC/TCN
2	INJ&P	Cervical vertebral fracture	C6 Fracture	16OCT2020 (53)		ONGOING			3	TC/TCN
3	INJ&P	Craniocerebral injury	Traumatic Brain Injury	16OCT2020 (53)		ONGOING			4	TC/TCN
4	INJ&P	Facial bones fracture	multiple facial and orbital fractures	16OCT2020 (53)		ONGOING			3	TC/TCN
5	RESP	Pneumothorax	Collapsed Lung	16OCT2020 (53)		2020 ()			3	TC/TCN
6	INJ&P	Road traffic accident	Bicycle Accident	16OCT2020 (53)		11DEC2020 (109)		57	4	TCN
7	INJ&P	Subdural haematoma	Subdural hematoma	16OCT2020 (53)		2020 ()			3	TC/TCN

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (16NOV2020)	NOT RELATED/OTHER: Bicycle Accident SAE # 2020455697	2	32	Y
2	N	Yes	NOT RELATED/OTHER: Bicycle Accident, SAE#2020455697	2	32	N
3	Y	Yes	NOT RELATED/OTHER: Bicycle Accident SAE # 2020455697	2	32	Y
4	N	Yes	NOT RELATED/OTHER: Bicycle Accident, SAE#2020455697	2	32	N
5	N	Resolved (2020)	NOT RELATED/OTHER: Bicycle Accident, SAE#2020455697	2	32	N

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
6	Y	Resolved (11DEC2020)	NOT RELATED/OTHER: environmental factor	2	32	Y
7	N	Resolved (2020)	NOT RELATED/OTHER: Bicycle Accident SAE#2020455697	2	32	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	13OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	87.5 kg	31.4 kg/m2	29AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	2006	Present
vasectomy	Vasectomy	2014	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29AUG2020 (1)	15:16
UNPLANNED	BNT162b2	04FEB2021 (160)	11:01

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Acute myocardial infarction	STEMI: ST elevation Myocardial Infarction	05SEP2020 (8)		09SEP2020 (12)		5	4
2	CARD	Coronary artery disease	Coronary Artery Disease	05SEP2020 (8)		ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: undiagnosed Obstructive CAD	1	8	Y
2	TC	N	Yes	NOT RELATED/OTHER: CAD	1	8	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine 1 dose IM once for influenza prevention	INFLUENZA VACCINE	28OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	
	VACCINATION		
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.5 cm	84.6 kg	28.1 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Atrial Septal Defect	Atrial septal defect	(b) (6) 1953	Present
Vasectomy	Vasectomy	1986	Past
Osteoarthritis (left knee)	Osteoarthritis	2000	Past
Knee replacement (left)	Knee arthroplasty	2001	Past
Osteoarthritis (right knee)	Osteoarthritis	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	12:08
2	BNT162b2	22SEP2020 (23)	14:26

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Dizziness	Dizziness	05NOV2020 (67)		06NOV2020 (68)		2	1
2	MUSC	Myalgia	post vaccination myalgia	31AUG2020 (1)	18:00	31AUG2020 (1)	23:00	1	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (06NOV2020)	NOT RELATED/OTHER: Atrial Septal Defect	2	45	Y
2	N	N	Resolved (31AUG2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine 1 dose IM once for influenza prophylaxis	INFLUENZA VACCINE	13OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176 cm	84.6 kg	27.3 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	JAN1990	Present
Depression	Depression	01JAN1993	Present
Vitiligo	Vitiligo	01JAN1994	Present
Anxiety	Anxiety	01JAN1996	Present
Iron deficient anemia	Iron deficiency anaemia	01JAN2010	Present
Irritable bowel syndrome	Irritable bowel syndrome	01JAN2012	Present
Degenerative disc disease	Intervertebral disc degeneration	01JAN2013	Present
spinal stenosis	Spinal stenosis	01JAN2013	Present
laperoscopic cyst removal	Cyst removal	JAN2016	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ovarian cysts	Ovarian cyst	01JAN2016	Past
pyelonephritis (both kidneys)	Pyelonephritis	APR2017	Past
Epstein-Barr based on high IgG titers without acute infection	Epstein-Barr virus test positive	01JAN2019	Present
Fibromyalgia	Fibromyalgia	01JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	16:57
2	Placebo	19OCT2020 (49)	16:09

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	SKIN	Drug eruption	Fixed drug erruption on feet bilaterally	26OCT2020 (56)		ONGOING			2	N
2	MUSC	Intervertebral disc degeneration	exacerbation of Degenerative Disc Disease	14JAN2021 (136)		15JAN2021 (137)		2	3	TC/TCN

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Yes	Study Treatment	2	8	N
2	Y	Resolved (15JAN2021)	NOT RELATED/OTHER: DEGENERATIVE DISC DISEASE	2	88	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	17NOV2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.5 cm	77.5 kg	25.7 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillectomy	Tonsillectomy	1954	Past
Tonsillitis	Tonsillitis	1954	Past
Inguinal Hernia Repair	Inguinal hernia repair	1986	Past
Hypertension	Hypertension	2009	Present
Benign prostatic Hyperplasia	Benign prostatic hyperplasia	2010	Present
Hypercholesterolemia	Hypercholesterolaemia	2010	Present
Angina	Angina pectoris	SEP2010	Present
Coronary Stent placement	Coronary arterial stent insertion	SEP2010	Present
Coronary Artery disease	Coronary artery disease	SEP2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Myocardial infarction	Myocardial infarction	SEP2010	Past
Erectile Dysfunction	Erectile dysfunction	2011	Present
Osteoarthritis	Osteoarthritis	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02SEP2020 (1)	11:46
2	BNT162b2	21SEP2020 (20)	09:22

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Bladder cancer	STAGE I Bladder Cancer	02NOV2020 (62)		04NOV2020 (64)		3
2	GENRL	Injection site pain	Injection site pain right arm	21SEP2020 (20)	18:00	22SEP2020 (21)	08:00	2
3	GENRL	Injection site pain	injection site pain right arm	02SEP2020 (1)	16:00	03SEP2020 (2)	12:00	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	Y	Resolved (04NOV2020)	NOT RELATED/OTHER: cancer	2	43	Y

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	1	N	N	Resolved (22SEP2020)	Study Treatment	2	1	N
3	1	N	N	Resolved (03SEP2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.5 cm	68.9 kg	25.2 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sulfa drug allergy (hives)	Urticaria	1988	Present
Degenerative Disc Disease	Intervertebral disc degeneration	2000	Present
Irritable Bowel Syndrome	Irritable bowel syndrome	2005	Present
Spinal Cord stimulator Insertion	Spinal nerve stimulator implantation	2009	Present
Right Hip Replacement	Hip arthroplasty	2010	Past
Seasonal Allergies	Seasonal allergy	2010	Present
Coronary Artery Disease	Coronary artery disease	2012	Present
Hypercholesterolemia	Hypercholesterolaemia	2012	Present
Hypertension	Hypertension	2012	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cervical fusion	Spinal fusion surgery	2012	Past
COPD	Chronic obstructive pulmonary disease	2015	Present
Kidney stones	Nephrolithiasis	2015	Past
Cyst Kidney	Renal cyst	2015	Present
right hip pain	Arthralgia	2017	Present
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2017	Past
Transurethral resection of the prostate	Transurethral prostatectomy	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	12:07
2	Placebo	24SEP2020 (23)	10:45
3	BNT162b2	08JAN2021 (129)	15:11
4	BNT162b2	28JAN2021 (149)	13:14

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	EYE	Eye haemorrhage	ruptured blood vessel behind Left eye	17NOV2020 (77)		18NOV2020 (78)		2
2	MUSC	Osteoporosis	osteoporosis right hip	22SEP2020 (21)		15NOV2020 (75)		55

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/TCN	Y	Resolved (18NOV2020)	NOT RELATED/OTHER: epistexis	2	55	Y
2	2	N	N	Resolved (15NOV2020)	NOT RELATED/OTHER: wear/aging	1	21	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	23OCT2020	
Completed	REPEAT SCREENING 1	08JAN2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	26FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	64	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186 cm	115.2 kg	33.3 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Lichen Planus	Lichen planus	01JAN2009	Present
Hypertension	Hypertension	01FEB2014	Present
Erectile dysfunction	Erectile dysfunction	01JAN2015	Present
Eczema	Eczema	01OCT2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	16:16
2	BNT162b2	24SEP2020 (21)	09:10

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Fatigue	Fatigue	24SEP2020 (21)	16:00	25SEP2020 (22)	14:00	2	1
2	INFEC	Oral herpes	Herpes simplex on lip	17NOV2020 (75)		18DEC2020 (106)		32	1
3	INFEC	Pneumonia	Pneumonia	13NOV2020 (71)		11DEC2020 (99)		29	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (25SEP2020)	Study Treatment	2	1	N
2	TC	N	Resolved (18DEC2020)	NOT RELATED/OTHER: stress	2	55	N
3	TC	Y	Resolved (11DEC2020)	NOT RELATED/OTHER: possible viral illness	2	51	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	22OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	70	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178 cm	102.9 kg	32.5 kg/m2	29SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Prostate cancer	Prostate cancer	2015	Past
Prostatectomy	Prostatectomy	2015	Past
Lymph Node removal	Lymphadenectomy	OCT2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29SEP2020 (1)	10:03
2	BNT162b2	19OCT2020 (21)	10:20

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Injection site pain	injection site pain right arm	19OCT2020 (21)	16:00	20OCT2020 (22)	13:00	2
2	NEOPL	Prostate cancer metastatic	Prostate Cancer with mets	26OCT2020 (28)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (20OCT2020)	Study Treatment	2	1	N
2	3	TC	Y	Yes	NOT RELATED/OTHER: aging/genetics	2	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	29SEP2020	
Completed	VACCINATION	19NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	63	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
194.31 cm	106.09 kg	28 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
sulfa allergy	Drug hypersensitivity	1960	Present
seasonal allegies	Seasonal allergy	1975	Present
vasectomy	Vasectomy	1990	Past
appendectomy	Appendicectomy	2003	Past
appendicitis	Appendicitis	2003	Past
Gastrointestinal perforation	Gastrointestinal perforation	2003	Past
SURGERY FOR SMALL VESSEL	Vascular operation	2003	Past
hernia	Hernia	2008	Past
hyperlipidemia	Hyperlipidaemia	2008	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
right tivia tear	Fracture	2009	Past
hernia repair surgery	Hernia repair	2009	Past
right foot morton's	Morton's neuralgia	2012	Past
Right Knee surgery	Knee operation	2015	Past
torn meniscus in right knee	Meniscus injury	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	13AUG2020 (1)	17:57
2	BNT162b2	01SEP2020 (20)	10:28

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Arthralgia	Right Shoulder Pain	30NOV2020 (110)		ONGOING		
2	INJ&P	Fall	Fall	29NOV2020 (109)		29NOV2020 (109)		1
3	INJ&P	Fractured sacrum	BROKEN SACRUM	29NOV2020 (109)		ONGOING		
4	INJ&P	Head injury	Head Injury	29NOV2020 (109)		17DEC2020 (127)		19
5	MUSC	Neck pain	Neck Pain	30NOV2020 (110)		ONGOING		

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC	N	Yes	NOT RELATED/OTHER: Fall	2	91	N
2	2	N	N	Resolved (29NOV2020)	NOT RELATED/OTHER: Fall at home	2	90	N
3	2	N	N	Yes	NOT RELATED/OTHER: Fall	2	90	N
4	3	TC	Y	Resolved (17DEC2020)	NOT RELATED/OTHER: Fall	2	90	Y
5	2	TC	N	Yes	NOT RELATED/OTHER: Fall	2	91	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
INFLUENZA VACCINE	INFLUENZA VACCINE	30NOV2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13AUG2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	29SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.96 cm	96.36 kg	32.5 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DIABETES MELLITUS TYPE 2	Type 2 diabetes mellitus	1990	Present
ANXIETY	Anxiety	2017	Present
CHRONIC KIDNEY DISEASE	Chronic kidney disease	2017	Present
DEPRESSION	Depression	2017	Present
DIABETIC NEUROPATHY	Diabetic neuropathy	2017	Present
DRUG ABUSE COCAINE	Drug abuse	2017	Past
HYPERLIPIDEMIA	Hyperlipidaemia	2017	Present
HYPERTENSION	Hypertension	2017	Present
INSOMIA	Insomnia	2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SLEEP APNEA	Sleep apnoea syndrome	2017	Present
CONGESTIVE HEART FAILURE	Cardiac failure congestive	04JUL2017	Present
CORONATY ARTERY DISEASE	Coronary artery disease	04JUL2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	12:32
2	Placebo	10SEP2020 (24)	11:10
3	BNT162b2	09FEB2021 (176)	10:15
4	BNT162b2	03MAR2021 (198)	11:11

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INV	Hepatic enzyme increased	Elevated Liver Enzymes	21SEP2020 (35)		12OCT2020 (56)		22

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Resolved (12OCT2020)	NOT RELATED/OTHER: UNKNOWN	2	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	08OCT2020	
Completed	REPEAT SCREENING 1	09FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1938	82	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	83.82 kg	30.7 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
POST MENOPAUSE	Postmenopause	1990	Present
ALLERGY TO TRAMADOL	Drug hypersensitivity	2008	Present
ALLERGY TO LEVOFLOX	Drug hypersensitivity	2010	Present
ALLERGY TO AVELOX	Drug hypersensitivity	2010	Present
Hypercholesterolemia	Hypercholesterolaemia	2010	Present
OSTEOARTHRITIS	Osteoarthritis	2012	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	18AUG2020 (1)	17:38
2	Placebo	10SEP2020 (24)	10:14
3	BNT162b2	05JAN2021 (141)	11:48
4	BNT162b2	26JAN2021 (162)	12:01

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	CONG	Atrial septal defect	Patent Foramen Ovale	23FEB2021 (190)		ONGOING			1
2	NERV	Cerebrovascular accident	Cerebrovascular accident	22FEB2021 (189)		26FEB2021 (193)		5	2
3	GENRL	Fatigue	Fatigue	23FEB2021 (190)		ONGOING			1
4	NERV	Headache	Headache	22FEB2021 (189)		24FEB2021 (191)		3	1
5	VASC	Hypertension	Hypertension	23FEB2021 (190)		26FEB2021 (193)		4	2
6	NERV	Visual field defect	Bilateral Peripheral Vision Loss	22FEB2021 (189)		ONGOING			2

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Yes	NOT RELATED/OTHER: unknown	4	29	N
2	TC	Y	Resolved (26FEB2021)	NOT RELATED/OTHER: unknown	4	28	Y
3	N	N	Yes	NOT RELATED/OTHER: Occipital lobe stroke	4	29	N
4	TC	N	Resolved (24FEB2021)	NOT RELATED/OTHER: Occipital lobe stroke	4	28	N

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
5	N	N	Resolved (26FEB2021)	NOT RELATED/OTHER: unknown	4	29	N
6	N	N	Yes	NOT RELATED/OTHER: Occipital Lobe Stroke	4	28	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccine	INFLUENZA VACCINE	24OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	08OCT2020	
Completed	REPEAT SCREENING 1	05JAN2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	02MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	100.18 kg	29.9 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DEPRESSION	Depression	2002	Present
TONSILLECTOMY	Tonsillectomy	2002	Past
UMBILICAL HERNIA	Umbilical hernia	2002	Past
HYPERLIPIDEMIA	Hyperlipidaemia	2014	Present
HYPERTENSION	Hypertension	2014	Present
ANXIETY	Anxiety	2015	Present
TESTOSTERONE DEFICIENCY	Androgen deficiency	2017	Present
Insomnia	Insomnia	2017	Present
Intermittent lower back pain	Back pain	AUG2019	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Car accident	Road traffic accident	AUG2019	Past
HERNIATED C5-C7 DISC	Intervertebral disc protrusion	FEB2020	Past
C5-C7 FUSION	Spinal fusion surgery	FEB2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	13:14
2	Placebo	09SEP2020 (22)	13:26
3	BNT162b2	14JAN2021 (149)	10:20
4	BNT162b2	03FEB2021 (169)	15:07

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	VASC	Hypertension	worsening of hypertension	14SEP2020 (27)		ONGOING			1	TC	N
2	METAB	Hypokalaemia	HYPOKALEMIA	SEP2020 ()		SEP2020 ()			3	TC	Y
3	MUSC	Muscular weakness	bilateral lower extremity weakness	04OCT2020 (47)	09:00	05OCT2020 (48)		2	3	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: past medical history	2	6	N
2	Resolved (SEP2020)	NOT RELATED/OTHER: PERSONAL ILLNESS, possibly related to con med amlodipine			Y
3	Resolved (05OCT2020)	NOT RELATED/OTHER: unknown	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	07OCT2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	REPEAT SCREENING 1	14JAN2021	
Completed	OPEN LABEL TREATMENT	04MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	120.45 kg	35.9 kg/m2	29AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DIABETES MELLITUS TYPE 2	Type 2 diabetes mellitus	1990	Present
OBESITY	Obesity	2000	Present
DIVERTICULITIS	Diverticulitis	2005	Present
OSTEOARTHRITIS KNEES	Osteoarthritis	2005	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2016	Present
SEASONAL ALLERGIES	Seasonal allergy	2016	Present
ENLARGED PROSTATE	Prostatomegaly	2018	Past
RIGHT KNEE REPLACEMENT	Knee arthroplasty	2019	Past
PROSTATECTOMY	Prostatectomy	2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	29AUG2020 (1)	12:46
2	Placebo	19SEP2020 (22)	09:12
3	BNT162b2	11JAN2021 (136)	15:25
4	BNT162b2	01FEB2021 (157)	16:06

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Acute myocardial infarction	Non-St-Elevation Myocardial Infarction	26FEB2021 (182)		26FEB2021 (182)		1	2
2	RESP	Acute respiratory failure	Acute Hypoxic Respiratory Failure	23FEB2021 (179)		27FEB2021 (183)		5	2
3	CARD	Arteriospasm coronary	Coronary Spasm	08MAR2021 (192)		11MAR2021 (195)		4	3
4	CARD	Cardiovascular disorder	Coronary Blood Stasis	08MAR2021 (192)		12MAR2021 (196)		5	3
5	CARD	Coronary artery disease	Coronary Artery Disease	26FEB2021 (182)		ONGOING			2
6	GENRL	Fatigue	Fatigue	08MAR2021 (192)		ONGOING			2
7	INFEC	Pneumonia	Pneumonia	18FEB2021 (174)		01MAR2021 (185)		12	2
8	INV	Troponin increased	elevated troponin	24FEB2021 (180)		10MAR2021 (194)		15	2
9	INV	Troponin increased	worsening of elevated troponin to 55	10MAR2021 (194)		ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	Y	Resolved (26FEB2021)	NOT RELATED/OTHER: unknown	4	26	Y
2	N	Y	Resolved (27FEB2021)	NOT RELATED/OTHER: Pneumonia	4	23	Y
3	N	Y	Resolved (11MAR2021)	NOT RELATED/OTHER: Coronary Artery Disease	4	36	Y
4	TC	Y	Resolved (12MAR2021)	NOT RELATED/OTHER: coronary artery disease	4	36	Y
5	TC	N	Yes	NOT RELATED/OTHER: unknown	4	26	N
6	N	N	Yes	NOT RELATED/OTHER: unknown	4	36	N
7	TC	N	Resolved (01MAR2021)	NOT RELATED/OTHER: unknown	4	18	N
8	N	N	Resolved (10MAR2021)	NOT RELATED/OTHER: myocardial infarction	4	24	N
9	N	N	Yes	NOT RELATED/OTHER: myocardial infarction	4	38	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	01DEC2020

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	17OCT2020	
Completed	REPEAT SCREENING 1	11JAN2021	
Completed	OPEN LABEL TREATMENT	01MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	97.3 kg	39.1 kg/m2	17SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cesarean section	Caesarean section	30MAY1980	Past
Anxiety	Anxiety	1998	Present
Depression	Depression	1998	Present
Lower back injury	Back injury	2003	Past
Back muscle spasms	Muscle spasms	2003	Present
Hysterectomy (complete)	Hysterectomy	2008	Past
Breast augmentation	Mammoplasty	2008	Past
Post menopausal	Postmenopause	2008	Present
Abnormal uterine bleeding	Uterine haemorrhage	2008	Past
Hypertension	Hypertension	2010	Present
Obesity	Obesity	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17SEP2020 (1)	16:34
2	Placebo	08OCT2020 (22)	15:24
3	BNT162b2	12MAR2021 (177)	13:19

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Fall	fall	31JAN2021 (137)		31JAN2021 (137)		1
2	METAB	Hypokalaemia	hypokalemia	05FEB2021 (142)		ONGOING		
3	INJ&P	Lower limb fracture	Multiple lower extremity fractures	31JAN2021 (137)		ONGOING		
4	INFEC	Urinary tract infection	urinary tract infection	05FEB2021 (142)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	N	Resolved (31JAN2021)	NOT RELATED/OTHER: injury	2	116	N
2	1	TC	N	Yes	NOT RELATED/OTHER: unknown	2	121	N
3	3	TC	Y	Yes	NOT RELATED/OTHER: fall	2	116	Y
4	1	TC	N	Yes	NOT RELATED/OTHER: unknown	2	121	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	22FEB2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17SEP2020	
Completed	VACCINATION	12NOV2020	
Completed	REPEAT SCREENING 1	12MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1941	78	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	99.09 kg	31.3 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Atrial Fibrillation	Atrial fibrillation	09APR2018	Present
BPH	Benign prostatic hyperplasia	09APR2018	Present
Gout	Gout	09APR2018	Present
Hyperlipidemia	Hyperlipidaemia	09APR2018	Present
Hypertension	Hypertension	09APR2018	Present
Diabetes Mellitus Type II	Type 2 diabetes mellitus	09APR2018	Present
Transient Cerebral ischemia	Transient ischaemic attack	09JUL2019	Past
depressive Disorders	Depression	20NOV2019	Present
Obstructive Sleep Apnea	Sleep apnoea syndrome	20NOV2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	15:50
2	BNT162b2	09SEP2020 (21)	09:05

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INFEC	Pneumonia	Pneumonia	20SEP2020 (32)		05OCT2020 (47)	11:00	16	3	TC
2	INJ&P	Skin laceration	HEAD LACERATION	20SEP2020 (32)	16:08	29SEP2020 (41)		10	2	TCN

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (05OCT2020)	NOT RELATED/OTHER: Pt contracted pneumonia from somewhere	2	12	Y
2	N	Resolved (29SEP2020)	NOT RELATED/OTHER: ACCIDENT IN ER	2	12	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	76	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	74.55 kg	22.9 kg/m2	22AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Impotence	Erectile dysfunction	03APR2000	Present
Essential Hypertension	Essential hypertension	03APR2018	Present
Mechanical Heart valve Replacement	Heart valve replacement	03APR2018	Past
Hyperlipidemia	Hyperlipidaemia	03APR2018	Present
Chronic Back Pain1	Back pain	01OCT2018	Present
Neuropathy	Neuropathy peripheral	01OCT2018	Present
Lumbar Radiculopathy	Lumbar radiculopathy	04FEB2019	Present
Gout	Gout	15APR2019	Present
Osteoarthritis	Osteoarthritis	29JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22AUG2020 (1)	11:48
2	Placebo	15SEP2020 (25)	13:37
3	BNT162b2	18JAN2021 (150)	13:27
4	BNT162b2	08FEB2021 (171)	12:33

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Retroperitoneal haematoma	non traumatic retroperitoneal hematoma	13NOV2020 (84)		15NOV2020 (86)		3
2	INFEC	Urinary tract infection	urinary tract infection	19SEP2020 (29)		01NOV2020 (72)		44

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Resolved (15NOV2020)	NOT RELATED/OTHER: unknown	2	60	Y
2	3	TC	N	Resolved (01NOV2020)	NOT RELATED/OTHER: unknown	2	5	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	22AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	18JAN2021	
Completed	OPEN LABEL TREATMENT	08MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	89.09 kg	28.9 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Coronary arteriosclerosis	Arteriosclerosis coronary artery	12JUN2018	Present
Essential Hypertension	Essential hypertension	12JUN2018	Present
Hyperlipidemia	Hyperlipidaemia	12JUN2018	Present
Type II Diabetes	Type 2 diabetes mellitus	12JUN2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	12:48
2	BNT162b2	14SEP2020 (22)	11:52

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Acute myocardial infarction	Non-STEMI	15SEP2020 (23)	12:33	15SEP2020 (23)	12:33	1	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (15SEP2020)	NOT RELATED/OTHER: Three vessel Disease	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	14OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1939	81	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	100 kg	30.7 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Atrial Fibrillation	Atrial fibrillation	10APR2018	Present
GERD	Gastrooesophageal reflux disease	10APR2018	Present
BPH	Benign prostatic hyperplasia	15MAY2018	Present
Depressive Disorder	Depression	15MAY2018	Present
Hyperlipidemia	Hyperlipidaemia	16MAY2018	Present
Normal Pressure hydrocephalus	Normal pressure hydrocephalus	16MAY2018	Present
Right Foot Drop	Peroneal nerve palsy	16MAY2018	Present
Obstructive Sleep Apnea	Sleep apnoea syndrome	16MAY2018	Present
Essential Hypertension	Essential hypertension	27JUN2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Congestive Heart Failure	Cardiac failure congestive	21AUG2018	Present
Hypogonadism	Hypogonadism	09DEC2019	Present
Systolic Heart Failure	Left ventricular failure	13APR2020	Present
Hypothyroidism	Hypothyroidism	15MAY2020	Present
Osteoarthritis	Osteoarthritis	15MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	13:05
2	Placebo	14SEP2020 (22)	11:52
3	BNT162b2	18JAN2021 (148)	12:07
4	BNT162b2	08FEB2021 (169)	11:35

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Cerebrovascular accident	CEREBROVASCULAR ACCIDENT	24FEB2021 (185)		ONGOING		

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	N	Y	Yes	NOT RELATED/OTHER: unknown at this time	4	17	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	18JAN2021	
Completed	OPEN LABEL TREATMENT	08MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	60	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	79.09 kg	28.1 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	JAN2010	Present
Postmenopausal	Postmenopause	2016	Present
Essential Hypertension	Essential hypertension	08MAY2018	Present
Hyperlipidemia	Hyperlipidaemia	08MAY2018	Present
Diabetes Mellitus Type II	Type 2 diabetes mellitus	08MAY2018	Present
Pain in Right Hip	Arthralgia	22OCT2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	09:10
2	Placebo	15SEP2020 (22)	09:25
3	BNT162b2	09FEB2021 (169)	11:57
4	BNT162b2	02MAR2021 (190)	08:27

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Arthralgia	Worsening Chronic right hip pain	03NOV2020 (71)		17NOV2020 (85)		15
2	INFEC	Urinary tract infection	Acute Urinary Tract Infection	19OCT2020 (56)		24OCT2020 (61)		6

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	Y	Resolved (17NOV2020)	NOT RELATED/OTHER: Osteo-arthritis	2	50	Y
2	2	TC	N	Resolved (24OCT2020)	NOT RELATED/OTHER: unknown	2	35	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	09FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	61.36 kg	22.5 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Pulmonary Fibrosis	Pulmonary fibrosis	DEC2015	Present
ADHD	Attention deficit hyperactivity disorder	23MAR2018	Present
COPD	Chronic obstructive pulmonary disease	23MAR2018	Present
Fibromyalgia	Fibromyalgia	23MAR2018	Present
Hyperlipidemia	Hyperlipidaemia	23MAR2018	Present
Hypertension	Hypertension	23MAR2018	Present
Degenerative Lumbar disc	Intervertebral disc degeneration	23MAR2018	Present
Vit D deficiency	Vitamin D deficiency	23MAR2018	Present
Chronic depression	Depression	22APR2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Peripheral Vascular Disease	Peripheral vascular disorder	18FEB2020	Present
Anxiety	Anxiety	23MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28AUG2020 (1)	13:35
2	BNT162b2	17SEP2020 (21)	14:03

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RENAL	Acute kidney injury	Acute kidney injury	22OCT2020 (56)	23:57	25OCT2020 (59)	11:48	4	3
2	NERV	Uraemic encephalopathy	Uremic encephalopathy	22OCT2020 (56)	23:58	25OCT2020 (59)	11:48	4	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (25OCT2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	36	Y
2	TC	Y	Resolved (25OCT2020)	NOT RELATED/OTHER: uremic encaphalopathy due to AKI.	2	36	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	12NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1942	78	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
195.58 cm	124.55 kg	32.5 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteomyelitis	Osteomyelitis	2018	Present
Depressive disorder	Depression	08MAY2018	Present
GOUT	Gout	08MAY2018	Present
Hyperlipidemia	Hyperlipidaemia	08MAY2018	Present
Hypertension	Hypertension	08MAY2018	Present
Hypogonadism	Hypogonadism	08MAY2018	Present
Osteoarthritis	Osteoarthritis	08MAY2018	Present
GERD	Gastrooesophageal reflux disease	30MAY2019	Present
BRONCHOSPASMS	Bronchospasm	31MAY2019	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Muscle spasms	Muscle spasms	31JAN2020	Present
OVERACTIVE BLADDER	Hypertonic bladder	01JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	11:16
2	BNT162b2	24SEP2020 (25)	09:27

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Atrial fibrillation	NEW ONSET ATRIAL FIB	04JAN2021 (127)		06JAN2021 (129)		3
2	CARD	Atrial fibrillation	Persistent Atrial Fibrillation	21JAN2021 (144)		ONGOING		
3	CARD	Cardiac failure congestive	congestive heart failure	22DEC2020 (114)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (06JAN2021)	NOT RELATED/OTHER: unknown	2	103	Y

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	3	TC/TCN	Y	Yes	NOT RELATED/OTHER: unknown	2	120	Y
3	2	TC	N	Yes	NOT RELATED/OTHER: fluid retention	2	90	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	27OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1935	84	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	101.36 kg	36 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Angioplasty	Angioplasty	01OCT2003	Past
Right Knee Replacement	Knee arthroplasty	31MAY2005	Past
Right Rotator Cuff Repair	Rotator cuff repair	30NOV2006	Past
Cardiac Stent Insertion	Coronary arterial stent insertion	01MAY2008	Past
Obstructive Sleep Apnea	Sleep apnoea syndrome	15DEC2008	Present
Bladder stone removal	Bladder calculus removal	21APR2011	Past
Kidney stone removal	Renal stone removal	06JUN2011	Past
Appendectomy	Appendicectomy	19AUG2011	Past
Left Rotator Cuff repair	Rotator cuff repair	05OCT2011	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bladder Cancer	Bladder cancer	01MAY2012	Past
HEART CATHETERIZATION	Catheterisation cardiac	06FEB2013	Past
Cataract removal	Cataract operation	2014	Past
Neuropathy	Neuropathy peripheral	2015	Present
Hyperlipidemia	Hyperlipidaemia	13JUL2015	Present
Hypertension	Hypertension	15DEC2015	Present
Diabetes Mellitus Type II	Type 2 diabetes mellitus	15DEC2015	Present
Left Knee Replacement	Knee arthroplasty	26OCT2016	Past
Depression	Depression	26JUN2018	Present
Hypothyroidism	Hypothyroidism	29JAN2019	Present
GERD	Gastrooesophageal reflux disease	25MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01SEP2020 (1)	16:15
2	BNT162b2	23SEP2020 (23)	10:52

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Bacterial sepsis	Sepsis Bacteremia	29SEP2020 (29)		11OCT2020 (41)		13	3

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
2	NERV	Dizziness	dizziness	13FEB2021 (166)		15FEB2021 (168)		3	2
3	INJ&P	Fall	fall	13FEB2021 (166)		13FEB2021 (166)		1	1
4	INFEC	Urinary tract infection	Urinary Tract Infection	29SEP2020 (29)		11OCT2020 (41)		13	3

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	Y	Resolved (11OCT2020)	NOT RELATED/OTHER: unspecified organism	2	7	Y
2	TC	Y	Resolved (15FEB2021)	NOT RELATED/OTHER: NOT KNOWN AT THIS TIME	2	144	Y
3	N	Y	Resolved (13FEB2021)	NOT RELATED/OTHER: dizziness	2	144	Y
4	TC/TCN	Y	Resolved (11OCT2020)	NOT RELATED/OTHER: Escherichia coli	2	7	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	86.36 kg	27.3 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Appendectomy	Appendicectomy	1978	Past
Gall bladder removal	Cholecystectomy	2003	Past
diabetes mellitus	Diabetes mellitus	2018	Present
Erectile Dysfunction	Erectile dysfunction	02MAR2020	Present
Essential hypertension	Essential hypertension	02MAR2020	Present
GERD	Gastrooesophageal reflux disease	02MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	09:02
2	Placebo	24SEP2020 (23)	10:39
3	BNT162b2	26JAN2021 (147)	09:22
4	BNT162b2	16FEB2021 (168)	08:34

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Tooth infection	Dental Infection	19NOV2020 (79)		07DEC2020 (97)		19

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (07DEC2020)	NOT RELATED/OTHER: Infected tooth	2	57	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	23OCT2020	
Completed	REPEAT SCREENING 1	26JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.69 cm	86.82 kg	29.7 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1980	Present
Myocardial Infarction	Myocardial infarction	1996	Past
A-Fib	Atrial fibrillation	2016	Present
COPD	Chronic obstructive pulmonary disease	2016	Present
Cronary Artery Disease	Coronary artery disease	2016	Present
Depression	Depression	2016	Present
Hyperlipidemia	Hyperlipidaemia	2016	Present
Hypertension	Hypertension	FEB2016	Present
Type 2 Diabetes	Type 2 diabetes mellitus	2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
CHF	Cardiac failure congestive	2018	Present
GERD	Gastrooesophageal reflux disease	03AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	10:41
2	Placebo	24SEP2020 (35)	09:40
3	BNT162b2	03MAR2021 (195)	08:48

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Angina unstable	Unstable Angina Pectoris Moderate	04OCT2020 (45)		05OCT2020 (46)		2	1
2	CARD	Cardiac failure congestive	Diastolic Congestive Heart Failure with acute exacerbation	07OCT2020 (48)		09OCT2020 (50)		3	1
3	GENRL	Chest pain	ChestPain	07OCT2020 (48)	19:30	09OCT2020 (50)	12:00	3	1
4	RESP	Chronic obstructive pulmonary disease	COPD with acute exacerbation	07OCT2020 (48)		09OCT2020 (50)		3	1
5	NERV	Dizziness	Dizziness	07OCT2020 (48)		07OCT2020 (48)		1	1
6	RESP	Dyspnoea	Shortness of Breath	01OCT2020 (42)		07OCT2020 (48)		7	1

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
7	INJ&P	Fall	fall	07OCT2020 (48)		07OCT2020 (48)		1	1
8	INFEC	Pneumonia	Community Acquired Pneumonia	07OCT2020 (48)		09OCT2020 (50)		3	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (05OCT2020)	NOT RELATED/OTHER: unknown	2	11	N
2	N	N	Resolved (09OCT2020)	NOT RELATED/OTHER: unknown	2	14	N
3	TC/TCN	Y	Resolved (09OCT2020)	NOT RELATED/OTHER: Community Acquired Pneumonia	2	14	Y
4	TC	N	Resolved (09OCT2020)	NOT RELATED/OTHER: COPD	2	14	N
5	TC	N	Resolved (07OCT2020)	NOT RELATED/OTHER: Community Acquired Pneumonia	2	14	N
6	N	N	Resolved (07OCT2020)	NOT RELATED/OTHER: Pneomonia	2	8	N
7	TC	N	Resolved (07OCT2020)	NOT RELATED/OTHER: Community Acquired Pneumonia	2	14	N
8	N	Y	Resolved (09OCT2020)	NOT RELATED/OTHER: uknown	2	14	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu vaccine	INFLUENZA VACCINE	09SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	22OCT2020	
Completed	REPEAT SCREENING 1	03MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	73.18 kg	27.6 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
IRRITABLE BOWEL SYNDROME	Irritable bowel syndrome	1989	Present
RAYNAUD'S PHENOMENON	Raynaud's phenomenon	2007	Present
BACTRIM ALLERGY	Drug hypersensitivity	2011	Present
ANXIETY	Anxiety	2014	Present
DEPRESSION	Depression	2014	Present
ACID REFLUX	Gastrooesophageal reflux disease	2014	Present
HAND, SHOULDER AND HIP OSTEOARTHRITIS	Osteoarthritis	2017	Present
NEUROMA R FOOT SURGERTY	Neurectomy	2018	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
RIGHT FOOT NEUROMA	Neuroma	2018	Past
SEASONAL ALLERGIES	Seasonal allergy	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04AUG2020 (1)	15:22
2	BNT162b2	14SEP2020 (42)	14:58

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Colitis	ASCENDING COLITIS	25NOV2020 (114)		13DEC2020 (132)		19

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (13DEC2020)	NOT RELATED/OTHER: UNKNOWN	2	73	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINE	INFLUENZA VACCINE	20AUG2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Completed	VACCINATION	12OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.45 cm	109.36 kg	37.1 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
TUBAL LIGATION	Female sterilisation	2000	Past
HYSTERECTOMY	Hysterectomy	2000	Past
MENORRHAGIA	Menorrhagia	2000	Past
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2015	Present
SEASONAL ALLERGIES	Seasonal allergy	2018	Present
INSOMNIA	Insomnia	2019	Present
DEPRESSION	Depression	JAN2020	Present
CHRONIC RIGHT UPPER QUADRANT PAIN	Abdominal pain upper	MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05AUG2020 (1)	11:28
2	BNT162b2	26AUG2020 (22)	14:05

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Cholelithiasis	CHOLELITHIASIS	11SEP2020 (38)		15SEP2020 (42)		5

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (15SEP2020)	NOT RELATED/OTHER: UNKNOWN	2	17	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	23SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	43	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	133.82 kg	46.1 kg/m2	06AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OVERWEIGHT	Overweight	2010	Present
TRAUMATIC RIGHT ANKLE FRACTURE	Ankle fracture	2017	Past
RIGHT ANKLE REPAIR	Ankle operation	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	06AUG2020 (1)	15:01
2	Placebo	27AUG2020 (22)	07:48

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Microcytic anaemia	MICROCYTIC ANEMIA	09NOV2020 (96)		ONGOING	
2	INV	Red blood cell morphology abnormal	ABNORMAL RBC MORPHOLOGY INCLUDING SICKLE CELLS	09NOV2020 (96)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC/TCN	Y	Yes	NOT RELATED/OTHER: UNKNOWN	2	75	Y
2		3	N	Y	Yes	NOT RELATED/OTHER: UNKNOWN	2	75	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06AUG2020	
Completed	VACCINATION	29SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	18NOV2020	PHYSICIAN DECISION

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	American Indian or Alaska Native	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	115 kg	35.3 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
CHRONIC KIDNEY STONES	Nephrolithiasis	1977	Present
HYPERTENSION	Hypertension	1992	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2014	Present
OVERWEIGHT	Overweight	2014	Present
DIABETES MELLITUS II	Type 2 diabetes mellitus	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	13:59
2	BNT162b2	08SEP2020 (23)	07:33

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RENAL	Nephrolithiasis	RIGHT KIDNEY STONE	25FEB2021 (193)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Yes	NOT RELATED/OTHER: PRIOR HISTORY OF KIDNEY STONES	2	171	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	06OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	70	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	69.09 kg	26.1 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
TUBAL LIGATION	Female sterilisation	1983	Past
POST MENOPAUSAL	Postmenopause	2000	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2015	Present
OSTEOARTHRITIS	Osteoarthritis	2017	Present
2ND TOE- RIGHT FOOT HAMMER TOE	Foot deformity	2018	Past
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2018	Present
RIGHT 2ND TOE HAMMER TOE REPAIR	Toe operation	20JUL2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	09:45
2	Placebo	24SEP2020 (23)	08:36
3	BNT162b2	18JAN2021 (139)	11:10
4	BNT162b2	08FEB2021 (160)	10:05

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Catheter site infection	LEFT ABDOMINAL PORT SITE INFECTION	12JAN2021 (133)		14JAN2021 (135)		3	1
2	VASC	Hypertension	HYPERTENSION	MAR2021 ()		ONGOING			1
3	MUSC	Osteopenia	OSTEOPENIA	DEC2020 ()		ONGOING			1
4	NEOPL	Papillary serous endometrial carcinoma	UTERINE PAPILLARY SEROUS CARCINOMA	NOV2020 ()		30DEC2020 (120)			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (14JAN2021)	NOT RELATED/OTHER: POST SURGICAL INFECTION	2	111	N
2	TC	N	Yes	NOT RELATED/OTHER: CHEMOTHERAPY	4		N
3	TC	N	Yes	NOT RELATED/OTHER: UNKNOWN	2		N
4	TC/TCN	Y	Resolved (30DEC2020)	NOT RELATED/OTHER: UNKNOWN CAUSE	2		Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINE	INFLUENZA VACCINE	09OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	26OCT2020	
Completed	REPEAT SCREENING 1	18JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
181.61 cm	80.45 kg	24.3 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
VASECTOMY	Vasectomy	1990	Past
HYPERTENSION	Hypertension	2010	Present
DIVERTICULOSIS	Diverticulum	2017	Present
TEMPERAL LOBE EPILEPSY	Temporal lobe epilepsy	01AUG2018	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	FEB2020	Present
B12 DEFICIENCY	Vitamin B12 deficiency	05FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03SEP2020 (1)	10:00
2	BNT162b2	23SEP2020 (21)	07:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Diverticulitis	DIVERTICULITIS	DEC2020 ()		22FEB2021 (173)			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (22FEB2021)	NOT RELATED/OTHER: DIVERTICULOSIS	2		Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
FLU SHOT	INFLUENZA VACCINE	10DEC2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	57.73 kg	24 kg/m2	31JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Irritable Bowel Syndrome-Diarrhea	Irritable bowel syndrome	JAN1975	Present
Cholecystectomy	Cholecystectomy	JAN2001	Past
Hernia Surgery	Hernia repair	JAN2002	Past
Bladder surgery	Bladder operation	JAN2004	Present
Cardiac Ablation	Cardiac ablation	JAN2005	Past
SEASONAL Allergy	Seasonal allergy	JAN2014	Present
Atrial fibrillation	Atrial fibrillation	JAN2015	Present
Hypertension	Hypertension	JAN2015	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	JAN2018	Present
Acid reflux	Gastrooesophageal reflux disease	JAN2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31JUL2020 (1)	15:14
2	Placebo	20AUG2020 (21)	14:09
3	BNT162b2	15JAN2021 (169)	13:47
4	BNT162b2	05FEB2021 (190)	14:28

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	COVID-19 pneumonia	Pneumonia COVID-19 illness	04DEC2020 (127)		21DEC2020 (144)		18
2	GENRL	Injection site pain	INJECTION SITE PAIN	06FEB2021 (191)		08FEB2021 (193)		3

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	TC	Y	Resolved (21DEC2020)	NOT RELATED/OTHER: Infection	2	107	Y
2	1	N	N	Resolved (08FEB2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31JUL2020	
Completed	VACCINATION	17SEP2020	
Completed	REPEAT SCREENING 1	15JAN2021	
Completed	OPEN LABEL TREATMENT	05MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	72.73 kg	23.6 kg/m2	01AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ALLERGY TO LATEX	Rubber sensitivity	2000	Present
POST MENOPAUSAL	Postmenopause	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01AUG2020 (1)	10:21

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	21AUG2020 (21)	14:37
3	BNT162b2	31DEC2020 (153)	09:57
4	BNT162b2	18FEB2021 (202)	09:28

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	MUSC	Arthralgia	LEFT MIDDLE FINGER PIP TENDERNESS	01AUG2020 (1)	14:00	28AUG2020 (28)		28	1	N
2	NEOPL	Malignant melanoma	REGIONALLY ADVANCED MELANOMA OF THE RIGHT INGUINAL AREA	26NOV2020 (118)		ONGOING			4	TC/TCN

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Resolved (28AUG2020)	NOT RELATED/OTHER: osteoarthritis possibly tendonitis or age	1	1	N
2	Y	Yes	NOT RELATED/OTHER: Melanoma	2	98	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01AUG2020	
Completed	VACCINATION	18SEP2020	
Completed	REPEAT SCREENING 1	31DEC2020	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	83.64 kg	33.7 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Appendectomy	Appendicectomy	JAN1962	Past
Appendicitis	Appendicitis	JAN1962	Past
Tubal Ligation	Female sterilisation	JAN1988	Past
Depression	Depression	JAN1995	Present
Carpel Tunnel Syndrome, Bi-lateral	Carpal tunnel syndrome	JAN1997	Past
Diverticulosis	Diverticulum	JAN1998	Present
Hemorrhoids	Haemorrhoids	JAN1998	Present
Hypertension	Hypertension	JAN2000	Present
Obesity	Obesity	JAN2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteoarthritis, Hip, Hands	Osteoarthritis	JAN2000	Present
Hand Surgery, Bi-lateral Thumb	Limb operation	JAN2002	Past
Hand Surgery, Bi-lateral Thumb	Limb operation	JAN2006	Past
Hypercholesterolemia	Hypercholesterolaemia	JAN2010	Present
HYPERTRIGLYCERIDEMIA	Hypertriglyceridaemia	JAN2010	Present
Deep Vein Thrombosis	Deep vein thrombosis	JAN2014	Present
Hot Flashes	Hot flush	JAN2017	Present
PTSD	Post-traumatic stress disorder	JUN2018	Present
Anxiety	Anxiety	01JUN2018	Present
Seasonal Allergies	Seasonal allergy	01AUG2019	Present
Cataract Surgery	Cataract operation	OCT2019	Past
Cystocele	Cystocele	OCT2019	Present
Rectocele	Rectocele	OCT2019	Present
Colonoscopy	Colonoscopy	JAN2020	Present
Polyp removal	Polypectomy	JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03AUG2020 (1)	11:00
2	BNT162b2	23AUG2020 (21)	10:18

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	RESP	Cough	COUGH	20AUG2020 (18)	08:00	04SEP2020 (33)		16	1	N
2	INFEC	Diverticulitis	Diverticulitis flair-up	08NOV2020 (98)	18:00	13NOV2020 (103)		6	4	TC

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Resolved (04SEP2020)	NOT RELATED/OTHER: POST NASAL DRIP	1	18	N
2	Y	Resolved (13NOV2020)	NOT RELATED/OTHER: Previous medical history of diverticulosis	2	78	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	29SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	111.82 kg	46.5 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OSTEOARTHRITIS BILATERAL KNEES	Osteoarthritis	2000	Present
Anxiety	Anxiety	JAN2010	Present
Obesity	Obesity	2015	Present
Postmenopausal	Postmenopause	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04AUG2020 (1)	15:51
2	Placebo	24AUG2020 (21)	11:32
3	BNT162b2	15FEB2021 (196)	14:39
4	BNT162b2	08MAR2021 (217)	14:14

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GENRL	Chills	CHILLS	08MAR2021 (217)	16:00	08MAR2021 (217)	16:00	1	1	N	N
2	VASC	Deep vein thrombosis	Deep Vein Thrombosis	07SEP2020 (35)		ONGOING			4	TC	Y
3	GENRL	Fatigue	FATIGUE	08MAR2021 (217)	16:00	08MAR2021 (217)	22:00	1	1	N	N
4	MUSC	Myalgia	MYALGIA	08MAR2021 (217)	16:00	08MAR2021 (217)	22:22	1	1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (08MAR2021)	Study Treatment	4	1	N
2	Yes	NOT RELATED/OTHER: Right Total Knee Replacement on 31 Aug 2020	2	15	Y

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	Resolved (08MAR2021)	Study Treatment	4	1	N
4	Resolved (08MAR2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	04AUG2020	
Completed	VACCINATION	21SEP2020	
Completed	REPEAT SCREENING 1	15FEB2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1942	77	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	104.55 kg	37.1 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
bipolar disorder	Bipolar disorder	01JAN1972	Present
sleep disorder	Sleep disorder	01JAN1972	Present
post menopausal	Postmenopause	01JAN1995	Present
hypercholesterolemia	Hypercholesterolaemia	01JAN1999	Present
hypothyroidism	Hypothyroidism	01JAN2000	Present
memory loss	Amnesia	01JAN2018	Present
hypertension	Hypertension	01APR2019	Present
sinus ballon surgery	Sinus operation	13MAY2019	Past
uterine fibroid's	Uterine leiomyoma	01JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	17:17
2	Placebo	10SEP2020 (25)	12:08
3	BNT162b2	05JAN2021 (142)	12:00
4	BNT162b2	26JAN2021 (163)	12:17

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Cerebrovascular accident	CVA	17NOV2020 (93)		05JAN2021 (142)		50	3
2	GENRL	Injection site pain	INJECTION SITE PAIN	26JAN2021 (163)		28JAN2021 (165)		3	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (05JAN2021)	NOT RELATED/OTHER: CEREBREAL ISCHEMIAH	2	69	Y
2	N	N	Resolved (28JAN2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	08OCT2020	
Completed	REPEAT SCREENING 1	05JAN2021	
Completed	OPEN LABEL TREATMENT	01MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152.4 cm	50 kg	21.5 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SEASONAL ALLERGIES	Seasonal allergy	1990	Present
ANXIETY	Anxiety	2000	Present
HYSTERECTOMY	Hysterectomy	2000	Past
POSTMENOPAUSAL	Postmenopause	2000	Present
RIGHT HIP ARTHROPLASTY	Hip arthroplasty	DEC2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	11:34
2	Placebo	15SEP2020 (26)	15:47
3	BNT162b2	04MAR2021 (196)	11:17

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	SKIN	Dermatitis contact	CONTACT DERMATITIS FROM THE CREAM USED TO TREAT SHINGLES	12FEB2021 (176)		25FEB2021 (189)		14	2
2	INFEC	Herpes zoster	SHINGLES lOWER BACK	07JAN2021 (140)		22JAN2021 (155)		16	2
3	RENAL	Hydronephrosis	Acute Left Hydro Nephrosis	16NOV2020 (88)	05:30	23DEC2020 (125)		38	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (25FEB2021)	NOT RELATED/OTHER: Medication	2	151	N
2	TC	N	Resolved (22JAN2021)	NOT RELATED/OTHER: VARICELLA INFECTION	2	115	N
3	TC/TCN	Y	Resolved (23DEC2020)	NOT RELATED/OTHER: Inflammation	2	63	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	16OCT2020	
Completed	REPEAT SCREENING 1	04MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	82.27 kg	30.1 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
VASECTOMY	Vasectomy	1997	Past
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2010	Present
HYPOTHYROIDISM	Hypothyroidism	2010	Present
OSTEOARTHRITIS-RIGHT KNEE	Osteoarthritis	2014	Present
SLEEP APNEA	Sleep apnoea syndrome	2015	Present
ROSACEA	Rosacea	2017	Present
ENLARGED PROSTATE	Prostatomegaly	2018	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	01SEP2020 (1)	13:21
2	BNT162b2	22SEP2020 (22)	14:40

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	VASC	Deep vein thrombosis	Deep Vein Thrombosis (Right Leg)	20OCT2020 (50)		ONGOING			3
2	MUSC	Osteoarthritis	Worsening osteoarthritis of the right knee	14OCT2020 (44)	09:00	15OCT2020 (45)		2	4

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Yes	NOT RELATED/OTHER: Knee surgery (right)	2	29	N
2	TC/TCN	Y	Resolved (15OCT2020)	NOT RELATED/OTHER: Previous medical history	2	23	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	23OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	82.73 kg	29.4 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
FIBROMYALGIA	Fibromyalgia	1990	Present
ALLERGY TO KEFLEX	Drug hypersensitivity	1995	Present
ALLERGY TO AUGMENTIN	Drug hypersensitivity	1995	Present
ALLERGY TO BIAXIN	Drug hypersensitivity	2005	Present
ALLERGY TO LATEX	Rubber sensitivity	2005	Present
HYSTERECTOMY	Hysterectomy	2006	Past
POSTMENOPAUSAL	Postmenopause	2006	Present
ALLERGY TO SEPTRA	Drug hypersensitivity	2008	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Headaches	Headache	2010	Present
Hemiplegic Migraine	Hemiplegic migraine	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	15:07
2	Placebo	28SEP2020 (21)	08:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Hemiplegic migraine	Hemiplegic Migraine	20OCT2020 (43)		ONGOING			4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Yes	NOT RELATED/OTHER: Related to subjects history of headaches	2	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	28OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	111.36 kg	40.8 kg/m2	05OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HEPATITIS C	Hepatitis C	2005	Past
DEPRESION	Depression	2010	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2010	Present
HYPERTENSION	Hypertension	2010	Present
ALLERGIES SEASONAL	Seasonal allergy	2010	Present
COPD	Chronic obstructive pulmonary disease	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05OCT2020 (1)	15:51
2	BNT162b2	24OCT2020 (20)	14:44

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	RESP	Chronic obstructive pulmonary disease	EXACERBATION OF COPD	06NOV2020 (33)		20NOV2020 (47)		15	3	TC
2	RESP	Chronic obstructive pulmonary disease	RE-EXACERBATION OF COPD	30NOV2020 (57)	09:00	23DEC2020 (80)		24	3	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (20NOV2020)	NOT RELATED/OTHER: Inflammation	2	14	Y
2	Y	Resolved (23DEC2020)	NOT RELATED/OTHER: UNDERLINEING LUNG CONDITION	2	38	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05OCT2020	
Completed	VACCINATION	23NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	95.25 kg	33.3 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERTENSION	Hypertension	2000	Present
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2005	Present
Coronary Artery Disease	Coronary artery disease	2015	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2015	Present
Diabetes Mellitus Type 2	Type 2 diabetes mellitus	2018	Present
NEPHROLITHIASIS	Nephrolithiasis	JAN2019	Present
SLEEP DISTURBANCE	Sleep disorder	JAN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04AUG2020 (1)	12:37
2	Placebo	25AUG2020 (22)	10:51
3	BNT162b2	25JAN2021 (175)	09:27
4	BNT162b2	15FEB2021 (196)	09:34

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	METAB	Diabetes mellitus inadequate control	Uncontrolled Diabetes Mellitus Type 2	10NOV2020 (99)		13NOV2020 (102)		4	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (13NOV2020)	NOT RELATED/OTHER: diabetes mellitus type 2 uncontrolled	2	78	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	04AUG2020	
Completed	VACCINATION	23SEP2020	
Completed	REPEAT SCREENING 1	25JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	71.4 kg	25.6 kg/m2	29AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hyperlipidemia	Hyperlipidaemia	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29AUG2020 (1)	10:35
2	BNT162b2	21SEP2020 (24)	11:52

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Chest pain	Chest Pain	15DEC2020 (109)		16DEC2020 (110)		2

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC	Y	Resolved (16DEC2020)	NOT RELATED/OTHER: Unknown.	2	86	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	75	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	66.64 kg	23.7 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
post menopausal	Postmenopause	14NOV1991	Present
osteoporosis	Osteoporosis	2005	Present
hypercholesterolemia	Hypercholesterolaemia	2010	Present
generalized anxiety disorder	Generalised anxiety disorder	2014	Present
hypertension	Hypertension	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	11:52
2	Placebo	21SEP2020 (22)	11:22
3	BNT162b2	16DEC2020 (108)	11:45
4	BNT162b2	05JAN2021 (128)	11:04

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Transient ischaemic attack	Transient Ischemic Attack	03NOV2020 (65)	15:00	06NOV2020 (68)		4

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (06NOV2020)	NOT RELATED/OTHER: unknown	2	44	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	21OCT2020	
Completed	REPEAT SCREENING 1	16DEC2020	
Completed	OPEN LABEL TREATMENT	03FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	28	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.6 cm	65.71 kg	24.9 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ATTENTION DEFICIT DISORDER	Attention deficit hyperactivity disorder	1999	Present
LATEX ALLERGY	Rubber sensitivity	2008	Present
SLEEP DISORDER	Sleep disorder	2014	Present
PEPTIC ULCER DISEASE	Peptic ulcer	FEB2017	Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	11SEP2020 (1)	15:49
2	BNT162b2	02OCT2020 (22)	15:27

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GASTR	Abdominal discomfort	Abdominal Discomfort	14NOV2020 (65)		16NOV2020 (67)		3
2	MUSC	Back pain	back pain	31OCT2020 (51)	01:01	08NOV2020 (59)		9
3	EYE	Eye pruritus	Bilateral Eye Itchiness	14NOV2020 (65)	23:30	16NOV2020 (67)		3
4	GENRL	Fatigue	Fatigue	14NOV2020 (65)	23:30	01FEB2021 (144)		80
5	EYE	Ocular hyperaemia	Bilateral Eye redness	14NOV2020 (65)	23:30	16NOV2020 (67)		3
6	SKIN	Rash	Generalize Rash	05JAN2021 (117)	05:30	06JAN2021 (118)	03:00	2
7	SKIN	Rash	rash to legs	08OCT2020 (28)		05MAR2021 (176)		149
8	RESP	Throat irritation	Throat Itchiness	14NOV2020 (65)	23:30	16NOV2020 (67)		3
9	EYE	Visual impairment	change in vision	06DEC2020 (87)		07DEC2020 (88)		2

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (16NOV2020)	NOT RELATED/OTHER: unknown	2	44	N
2	1	TC	N	Resolved (08NOV2020)	NOT RELATED/OTHER: unknown	2	30	N
3	1	N	N	Resolved (16NOV2020)	NOT RELATED/OTHER: Unknown	2	44	N
4	1	N	N	Resolved (01FEB2021)	NOT RELATED/OTHER: unknown	2	44	N

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
5	1	N	N	Resolved (16NOV2020)	NOT RELATED/OTHER: Unknown	2	44	N
6	1	N	N	Resolved (06JAN2021)	NOT RELATED/OTHER: unknown	2	96	N
7	1	N	N	Resolved (05MAR2021)	NOT RELATED/OTHER: unknown	2	7	N
8	1	N	N	Resolved (16NOV2020)	NOT RELATED/OTHER: Unknown	2	44	N
9	2	N	Y	Resolved (07DEC2020)	NOT RELATED/OTHER: Unknown	2	66	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	06NOV2020	

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	70.45 kg	22.9 kg/m2	24SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
gastroesophageal reflux disease	Gastrooesophageal reflux disease	2016	Present
hypercholesterolemia	Hypercholesterolaemia	2017	Present
coronary artery disease	Coronary artery disease	APR2017	Present
heart bypass surgery	Coronary artery surgery	APR2017	Past
diabetes mellitus type II	Type 2 diabetes mellitus	JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24SEP2020 (1)	14:02
2	BNT162b2	15OCT2020 (22)	11:20

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Procedural pain	post op pain	22FEB2021 (152)		08MAR2021 (166)		15
2	NEOPL	Tonsil cancer	tonsil cancer	15FEB2021 (145)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (08MAR2021)	NOT RELATED/OTHER: surgery	2	131	Y
2	1	N	Y	Yes	NOT RELATED/OTHER: Unknown.	2	124	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24SEP2020	
Completed	VACCINATION	13NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166.1 cm	82.1 kg	29.8 kg/m2	21OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Diabetes Mellitus Type II	Type 2 diabetes mellitus	29JUL2011	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21OCT2020 (1)	15:33

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	19NOV2020 (30)	13:02
3	BNT162b2	12MAR2021 (143)	10:23

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	MUSC	Back pain	lower back pain	17NOV2020 (28)		10JAN2021 (82)		55	2
2	INV	Blood glucose abnormal	uncontrolled blood sugar (glucose)	20NOV2020 (31)		23NOV2020 (34)		4	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (10JAN2021)	NOT RELATED/OTHER: unknown	1	28	N
2	TC	Y	Resolved (23NOV2020)	NOT RELATED/OTHER: uncontrolled diabetes mellitus type 2	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21OCT2020	
Completed	VACCINATION	17DEC2020	
Completed	REPEAT SCREENING 1	12MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1945	75	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.96 cm	103.73 kg	29.3 kg/m2	31JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hernia repair	Hernia repair	1982	Past
Erectile dysfunction	Erectile dysfunction	2000	Present
Low libido	Libido decreased	2000	Present
nearsighted	Myopia	2000	Present
Type II Diabetes Mellitus	Type 2 diabetes mellitus	2000	Present
diabetic neuropathy	Diabetic neuropathy	2005	Present
Left knee torn meiniscus	Meniscus injury	2014	Past
osteoarthritis Right knee and shoulder	Osteoarthritis	2014	Present
depression	Depression	2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypertension	Hypertension	2017	Present
replaced mitral valve	Mitral valve replacement	2017	Past
transient ischemic attack	Transient ischaemic attack	2017	Past
Chronic Kidney Disease	Chronic kidney disease	FEB2017	Present
hernia repair	Hernia repair	2018	Past
Colon polyps-benign	Large intestine polyp	2019	Past
mediastinal masses (benign)	Mediastinal mass	2019	Present
lung masses (benign)	Pulmonary mass	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31JUL2020 (1)	15:36
2	Placebo	21AUG2020 (22)	11:12
3	BNT162b2	05JAN2021 (159)	10:55
4	BNT162b2	26JAN2021 (180)	13:03

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Acute respiratory failure	Acute hypoxic respiratory failure	11JAN2021 (165)		15JAN2021 (169)		5	3

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
2	RENAL	Chronic kidney disease	Acute kidney injury on chronic kidney disease stage III	11JAN2021 (165)		15JAN2021 (169)		5	2
3	INFEC	Clostridium difficile infection	clostridium difficile infection	13MAR2021 (226)		ONGOING			2
4	NEOPL	Non-small cell lung cancer stage III	Nonsmall cell lung carcinoma stage 3	25FEB2021 (210)		ONGOING			3
5	INFEC	Urosepsis	Urosepsis	11JAN2021 (165)		15JAN2021 (169)		5	3

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TCN	Y	Resolved (15JAN2021)	NOT RELATED/OTHER: Urosepsis	3	7	Y
2	TCN	N	Resolved (15JAN2021)	NOT RELATED/OTHER: Kidney disease	3	7	N
3	TC	Y	Yes	NOT RELATED/OTHER: antibiotic use	4	47	Y
4	TC	Y	Yes	NOT RELATED/OTHER: history of lung masses	4	31	Y
5	TC	Y	Resolved (15JAN2021)	NOT RELATED/OTHER: unknown	3	7	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
FLUAD Quadrivalent	INFLUENZA VACCINE INACT SAG 4V	22SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31JUL2020	
Completed	VACCINATION	18SEP2020	
Completed	REPEAT SCREENING 1	05JAN2021	
Completed	OPEN LABEL TREATMENT	23FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	91.64 kg	28.1 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tonsillectomy	Tonsillectomy	1959	Past
broken leg	Lower limb fracture	1970	Past
broken arm	Upper limb fracture	1970	Past
head injury	Head injury	2000	Past
swelling in left leg	Peripheral swelling	2010	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03AUG2020 (1)	12:00
2	Placebo	25AUG2020 (23)	08:34
3	BNT162b2	05JAN2021 (156)	16:12
4	BNT162b2	26JAN2021 (177)	15:40

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Atrial fibrillation	Atrial Fibrillation	07JAN2021 (158)		08JAN2021 (159)		2	1
2	RESP	Pulmonary embolism	Pulmonary emboli	07JAN2021 (158)		08JAN2021 (159)		2	3
3	VASC	Thrombosis	Occlusive thrombus in the right calf	07JAN2021 (158)		08JAN2021 (159)		2	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (08JAN2021)	NOT RELATED/OTHER: Pulmonary embolism	3	3	N
2	TC	Y	Resolved (08JAN2021)	NOT RELATED/OTHER: Prolonged travel in the car	3	3	Y
3	TC	Y	Resolved (08JAN2021)	NOT RELATED/OTHER: Prolonged travel in the car	3	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Fluzone High-Dose (Influenza vaccine)	INFLUENZA VACCINE INACT SPLIT 3V	02OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	22SEP2020	
Completed	REPEAT SCREENING 1	05JAN2021	
Completed	OPEN LABEL TREATMENT	23FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	57.55 kg	21.7 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to codeine	Drug hypersensitivity	1972	Present
Postmenopausal	Postmenopause	1987	Present
Hypercholesterolemia	Hypercholesterolaemia	2010	Present
Farsighted	Hypermetropia	2010	Present
Hypertension	Hypertension	2010	Present
Hypothyroidism	Hypothyroidism	2010	Present
Melanoma (left forearm)	Malignant melanoma	2010	Past
Mohs surgery	Micrographic skin surgery	2010	Past
Muscle spasms	Muscle spasms	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	13:31
2	BNT162b2	01SEP2020 (22)	12:34

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	PSYCH	Mental disorder	Undiagnosed Mental Disorder (not otherwise specified)	25SEP2020 (46)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	N	Y	Yes	NOT RELATED/OTHER: mental instability	2	25	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Withdrawn	VACCINATION	07DEC2020	LOST TO FOLLOW-UP
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	07DEC2020	LOST TO FOLLOW-UP

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	97.45 kg	32.6 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
dyslipidemia	Dyslipidaemia	1997	Present
farsighted	Hypermetropia	2004	Present
nearsighted	Myopia	2004	Present
vitamin d deficiency	Vitamin D deficiency	2010	Present
fungus toenail	Onychomycosis	2012	Present
total hip replacement right	Hip arthroplasty	2013	Past
osteoarthritis-hips	Osteoarthritis	2013	Present
diverticulosis	Diverticulum	2015	Present
hypothyroidism	Hypothyroidism	2015	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
benign prostatic hypertrophy	Benign prostatic hyperplasia	2017	Present
total hip replacement left	Hip arthroplasty	2019	Past
low libido	Libido decreased	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	18:46
2	BNT162b2	31AUG2020 (21)	08:55

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	BLOOD	Anaemia	Anemia	12OCT2020 (63)		ONGOING			1
2	INFEC	Bacteraemia	Bacteremia	16FEB2021 (190)		27FEB2021 (201)		12	3
3	RESP	Dyspnoea exertional	Dyspnea on exertion	FEB2021 ()		27FEB2021 (201)			3
4	INFEC	Endocarditis	Endocarditis	16FEB2021 (190)		27FEB2021 (201)		12	2
5	INV	Liver function test increased	Elevated liver function tests	NOV2020 ()		27FEB2021 (201)			2
6	GENRL	Oedema peripheral	Lower extremity edema	OCT2020 ()		27FEB2021 (201)			1
7	SKIN	Purpura	Purpuric rash on lower extremity	OCT2020 ()		27FEB2021 (201)			1
8	BLOOD	Splenic infarction	Splenic infarcts	16FEB2021 (190)		ONGOING			3

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Yes	NOT RELATED/OTHER: unknown etiology	2	43	N
2	TC	Y	Resolved (27FEB2021)	NOT RELATED/OTHER: unknown etiology	2	170	Y
3	TC	Y	Resolved (27FEB2021)	NOT RELATED/OTHER: endocarditis	2		Y
4	TC	Y	Resolved (27FEB2021)	NOT RELATED/OTHER: bacteremia	2	170	Y
5	N	N	Resolved (27FEB2021)	NOT RELATED/OTHER: unknown etiology	2		N
6	N	N	Resolved (27FEB2021)	NOT RELATED/OTHER: bacteremia	2		N
7	N	N	Resolved (27FEB2021)	NOT RELATED/OTHER: Bacteremia	2		N
8	N	N	Yes	NOT RELATED/OTHER: Bacteremia	2	170	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	28SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	75.91 kg	26.2 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Overweight	Overweight	1970	Present
Hypertension	Hypertension	1997	Present
Kidney stones	Nephrolithiasis	1997	Past
Tubal ligation	Female sterilisation	1998	Past
Diverticulosis	Diverticulum	2010	Present
Cholecystectomy	Cholecystectomy	2012	Past
Gallstones	Cholelithiasis	2012	Past
Disseminated porokeratosis	Porokeratosis	2013	Present
Sleep apnea	Sleep apnoea syndrome	2013	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Carpal tunnel syndrome (right)	Carpal tunnel syndrome	2014	Past
Farsighted	Hypermetropia	2015	Present
Uterine ablation	Endometrial ablation	2016	Past
Post-menopause	Postmenopause	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14AUG2020 (1)	13:26
2	BNT162b2	04SEP2020 (22)	16:56

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Pyelonephritis	Pyelonephritis	28SEP2020 (46)		02OCT2020 (50)		5	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (02OCT2020)	NOT RELATED/OTHER: kidney stones/nephrolithiasis	2	25	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	05OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	American Indian or Alaska Native	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.29 cm	66.73 kg	25.6 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	1987	Present
Back Pain	Back pain	2000	Present
Vitamin D deficiency	Vitamin D deficiency	2010	Present
Farsighted	Hypermetropia	2012	Present
Low libido	Libido decreased	2012	Present
Seasonal allergies	Seasonal allergy	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18AUG2020 (1)	15:18
2	BNT162b2	24SEP2020 (38)	11:38

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Subarachnoid haemorrhage	Subarachnoid hemorrhage	26AUG2020 (9)		03SEP2020 (17)		9

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/TCN	Y	Resolved (03SEP2020)	NOT RELATED/OTHER: unknown	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	22OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1942	77	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	70.55 kg	22.6 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Alcohol use	Alcohol use		Present
High cholesterol	Blood cholesterol increased	2010	Present
Indigestion (acid)	Dyspepsia	2010	Present
Hypertension	Hypertension	2010	Present
Type II Diabetes Mellitus	Type 2 diabetes mellitus	2010	Present
Transient ischemic attack	Transient ischaemic attack	2016	Past
Transient ischemic attack	Transient ischaemic attack	2017	Past
Low libido	Libido decreased	2018	Present
Constipation	Constipation	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15OCT2020 (1)	09:58
2	Placebo	05NOV2020 (22)	09:11
3	BNT162b2	05JAN2021 (83)	08:39
4	BNT162b2	26JAN2021 (104)	08:19

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Pancreatitis acute	Acute Pancreatitis	19OCT2020 (5)		21OCT2020 (7)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (21OCT2020)	NOT RELATED/OTHER: Alcohol use	1	5	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15OCT2020	
Completed	VACCINATION	03DEC2020	
Completed	REPEAT SCREENING 1	05JAN2021	
Completed	OPEN LABEL TREATMENT	23FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	37	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	87.27 kg	30.1 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Abnormal Uterine bleeding	Uterine haemorrhage	2016	Past
Intramural and Subserous Leiomyoma of Uterus	Uterine leiomyoma	2016	Past
Intrauterine Device Placement	Intra-uterine contraceptive device insertion	2017	Present
Rosacea	Rosacea	01JAN2017	Present
Obesity	Obesity	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	17:59
2	Placebo	01SEP2020 (22)	17:18
3	BNT162b2	22JAN2021 (165)	09:59
4	BNT162b2	11FEB2021 (185)	18:22

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	REPRO	Uterine haemorrhage	Worsening of Abnormal Uterine Bleeding	14SEP2020 (35)		18NOV2020 (100)		66	3
2	NEOPL	Uterine leiomyoma	Worsening INTRAMURAL AND SUBSEROUS LEIOMYOMA OF UTERUS	14SEP2020 (35)		18NOV2020 (100)		66	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	N	Resolved (18NOV2020)	NOT RELATED/OTHER: history of uterine fibroids	2	14	N
2	TCN	Y	Resolved (18NOV2020)	NOT RELATED/OTHER: Unknown	2	14	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	01OCT2020	
Completed	REPEAT SCREENING 1	22JAN2021	
Completed	OPEN LABEL TREATMENT	11MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177 cm	87.5 kg	27.9 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteoarthritis Generalized	Osteoarthritis	JAN1967	Present
Angina Recurrent	Angina pectoris	2005	Present
Coronary Artery Disease	Coronary artery disease	AUG2005	Present
Acute Myocardial Infarction	Acute myocardial infarction	01AUG2005	Past
Allergic to Phenergren	Drug hypersensitivity	01AUG2005	Present
Hyperlipidemia	Hyperlipidaemia	01AUG2005	Present
Hypertension	Hypertension	01AUG2005	Present
Seasonal Allergies	Seasonal allergy	APR2010	Present
Ejection Fraction Less then 30% Abnormal	Ejection fraction abnormal	2011	Past
Automatic Implantable Cardioverter Defibrillators Implant Insertion	Implantable defibrillator insertion	2011	Past
Benign prostatic hyperplasia	Benign prostatic hyperplasia	JAN2014	Present
Bursitis Right Shoulder	Bursitis	01JUN2018	Past
Subcutaneous Cyst Oculus Dexter	Eye disorder	AUG2019	Past
Cataract Oculus Sinister	Cataract	JAN2020	Present

Medical History

Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Total knee replacement, left	Knee arthroplasty	JAN2020	Past
Right Eye periorbital ecchymosis	Periorbital haemorrhage	12AUG2020	Present
Cyst removal of Subcutaneous cyst, right eye	Skin cyst excision	12AUG2020	Past

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	12AUG2020 (1)	19:26
2	BNT162b2	01SEP2020 (21)	11:28

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	BLOOD	Coagulopathy	Blood coagulation disorder	07JAN2021 (149)		ONGOING			2	TC/TCN	N
2	METAB	Hypokalaemia	Hypokalemia	12DEC2020 (123)		20DEC2020 (131)		9	1	TC/TCN	N
3	RESP	Pulmonary embolism	pulmonary embolism	07JAN2021 (149)		10JAN2021 (152)		4	2	TC	N
4	CARD	Ventricular tachycardia	Ventricular Tachycardia	11DEC2020 (122)		15DEC2020 (126)		5	4	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: BLOOD COUGULATION DISORDER	2	129	N
2	Resolved (20DEC2020)	NOT RELATED/OTHER: Metabolic	2	103	N
3	Resolved (10JAN2021)	NOT RELATED/OTHER: blood coagulation disorder	2	129	N
4	Resolved (15DEC2020)	NOT RELATED/OTHER: Related to his coronary artery disease, has defibrillation.	2	102	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	06OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.5 cm	127.7 kg	37.1 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Neuropathy	Neuropathy peripheral	JAN1986	Present
Type 2 Diabetes Mellitus	Type 2 diabetes mellitus	01JAN1986	Present
Trauma Left Leg	Limb injury	01JAN2005	Past
Trama Right Leg	Limb injury	01JAN2005	Past
Anxiety	Anxiety	01JAN2010	Present
Amputed Right Leg	Leg amputation	01NOV2012	Past
Depression	Depression	01JAN2013	Present
Asthma	Asthma	OCT2015	Present
Recurrent Methicillin-resistant Staphylococcus aureus Infections	Staphylococcal infection	JAN2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	03NOV2017	Present
Amputed Left Leg	Leg amputation	01JAN2018	Past
Hyperlipidemia	Hyperlipidaemia	14NOV2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	15:03
2	BNT162b2	30SEP2020 (38)	09:15

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RENAL	Acute kidney injury	acute kidney injury	12SEP2020 (20)		02NOV2020 (71)		52
2	CARD	Atrial fibrillation	Atrial fibrillation	14SEP2020 (22)	10:00	ONGOING		
3	GENRL	Chest pain	chest pain	14SEP2020 (22)	10:00	14SEP2020 (22)	11:00	1
4	CARD	Left ventricular hypertrophy	Left Ventricular Hypertrophy	14SEP2020 (22)	10:00	ONGOING		
5	CARD	Mitral valve incompetence	mitral valve regurgitation	14SEP2020 (22)	10:00	ONGOING		
6	MUSC	Pain in extremity	bilateral hand pain	12SEP2020 (20)		13SEP2020 (21)		2
7	RESP	Pulmonary hypertension	Pulmonary Hypertension	14SEP2020 (22)	10:00	ONGOING		
8	INJ&P	Skin injury	skin avulsion, left finger	12SEP2020 (20)		12SEP2020 (20)		1

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
9	INFEC	Staphylococcal infection	MRSA infection Right Stump	12SEP2020 (20)	08:00	08OCT2020 (46)		27
10	CARD	Tricuspid valve incompetence	Tricuspid regurgitation	14SEP2020 (22)	10:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Resolved (02NOV2020)	NOT RELATED/OTHER: MRSA infection	1	20	N
2	2	N	N	Yes	NOT RELATED/OTHER: Hypertension	1	22	N
3	2	N	N	Resolved (14SEP2020)	NOT RELATED/OTHER: Hypertension	1	22	N
4	1	N	N	Yes	NOT RELATED/OTHER: hypertension	1	22	N
5	1	N	N	Yes	NOT RELATED/OTHER: hypertension	1	22	N
6	1	N	N	Resolved (13SEP2020)	NOT RELATED/OTHER: Musculoskeletal	1	20	N
7	1	N	N	Yes	NOT RELATED/OTHER: hypertension	1	22	N
8	2	N	N	Resolved (12SEP2020)	NOT RELATED/OTHER: Musculoskeletal	1	20	N
9	2	TC	Y	Resolved (08OCT2020)	NOT RELATED/OTHER: Infection	1	20	Y
10	1	N	N	Yes	NOT RELATED/OTHER: Hypertension	1	22	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Pneumonia vaccine	PNEUMOCOCCAL VACCINE	26AUG2020
Influenza Vaccine	INFLUENZA VACCINE	23SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	29OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	82.36 kg	26.8 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Shoulder Pain	Arthralgia	2016	Past
Rectal Bleeding/Gastrointestinal bleed	Rectal haemorrhage	MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	12:48
2	Placebo	18SEP2020 (22)	11:12

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	BLOOD	Anaemia	Anemia	27OCT2020 (61)		ONGOING			3
2	GASTR	Haemorrhoids	External Hemorrhoids	OCT2020 ()		27OCT2020 (61)			1
3	GASTR	Hiatus hernia	Hiatal Hernia	09NOV2020 (74)		ONGOING			1
4	VASC	Hypertension	Hypertension	27OCT2020 (61)		ONGOING			1
5	GASTR	Large intestine polyp	Multiple Colon Polyps	09NOV2020 (74)		09NOV2020 (74)		1	1
6	INFEC	Oesophageal candidiasis	Candida Esophagitis	10NOV2020 (75)		ONGOING			2
7	CARD	Sinus bradycardia	Sinus Bradycardia	28OCT2020 (62)		30OCT2020 (64)		3	2
8	BLOOD	Thrombocytopenia	Thrombocytopenia	27OCT2020 (61)		11NOV2020 (76)		16	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	N	Yes	NOT RELATED/OTHER: Rectal Bleeding	2	40	N
2	N	N	Resolved (27OCT2020)	NOT RELATED/OTHER: Natural Occurrence	2		N
3	N	N	Yes	NOT RELATED/OTHER: Natural Occurrence	2	53	N
4	TC	N	Yes	NOT RELATED/OTHER: Smoking	2	40	N
5	N	N	Resolved (09NOV2020)	NOT RELATED/OTHER: Natural Occurrence	2	53	N

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
6	TC	N	Yes	NOT RELATED/OTHER: Unknown	2	54	N
7	N	N	Resolved (30OCT2020)	NOT RELATED/OTHER: history of anemia and GI bleed	2	41	N
8	N	Y	Resolved (11NOV2020)	NOT RELATED/OTHER: Unknown at this time	2	40	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1999	20	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
151.13 cm	91.73 kg	40.1 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	2019	Present
Abdominal Pain undiagonised origin	Abdominal pain	AUG2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	11:54
2	BNT162b2	22SEP2020 (23)	14:40

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	HEPAT	Bile duct stone	Choledocholithiasis	13SEP2020 (14)	19:00	19SEP2020 (20)	01:01	7	3	TC/TCN	Y
2	SOCCI	High risk sexual behaviour	unprotected, heterosexual intercourse	23NOV2020 (85)		23NOV2020 (85)	22:00	1	1	N	N
3	INJ&P	Maternal exposure before pregnancy	maternal exposure before pregnancy	09NOV2020 (71)		ONGOING			1	N	N
4	GASTR	Obstructive pancreatitis	Gall Stone Pancreatitis	13SEP2020 (14)		18SEP2020 (19)		6	3	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (19SEP2020)	NOT RELATED/OTHER: Patient had underlying, undiagnosed condition	1	14	Y
2	Resolved (23NOV2020)	NOT RELATED/OTHER: unprotected, heterosexual intercourse	2	63	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	Yes	NOT RELATED/OTHER: unprotected heterosexual intercourse	2	49	N
4	Resolved (18SEP2020)	NOT RELATED/OTHER: Undiagnosed preexisiting condition	1	14	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	90.55 kg	27 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tonsillectomy	Tonsillectomy	1958	Past
Tonsillitis	Tonsillitis	1958	Past
Appendectomy	Appendicectomy	1960	Past
Appendicitis	Appendicitis	1960	Past
Urinary incontinence	Urinary incontinence	2008	Present
Pacemaker Implanted	Cardiac pacemaker insertion	2010	Past
Cataracts Bilateral	Cataract	2010	Past
Cataract bilateral eye surgery	Cataract operation	2010	Past
Tachy Brady Heart Rate	Sinus node dysfunction	2010	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SA Node Sysfunction	Sinus node dysfunction	2010	Present
No cartilage in knees	Chondropathy	2014	Past
Bilateral Knee Replacement	Knee arthroplasty	2014	Past
Erectile Dysfunction	Erectile dysfunction	2015	Present
osteoarthritis	Osteoarthritis	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	17:25
2	Placebo	29SEP2020 (20)	17:04
3	BNT162b2	13JAN2021 (126)	13:00
4	BNT162b2	03FEB2021 (147)	11:18

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INJ&P	Delayed recovery from anaesthesia	slow to recover from anesthesia	02DEC2020 (84)		03DEC2020 (85)		2	2	N
2	RESP	Pulmonary embolism	PULMONARY EMBOLISM/ BLOOD CLOTS IN UPPER RIGHT LOBE	22DEC2020 (104)		22DEC2020 (104)		1	3	TC

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (03DEC2020)	NOT RELATED/OTHER: complication to shoulder surgery	2	65	Y
2	Y	Resolved (22DEC2020)	NOT RELATED/OTHER: complication from shoulder surgery	2	85	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	27OCT2020	
Completed	REPEAT SCREENING 1	13JAN2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	03MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
194.56 cm	122.36 kg	32.3 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
FISH ALLERGY	Food allergy	1979	Present
ALCOHOLISM	Alcoholism	2005	Past
BIPOLAR DISORDER	Bipolar disorder	2016	Present
HYPERTENSION	Hypertension	2016	Present
MAJOR DEPRESSIVE DISORDER	Major depression	2016	Present
SCHIZOPHRENIA	Schizophrenia	2016	Present
ANXIETY	Anxiety	2017	Present
INSOMNIA	Insomnia	2017	Present
CONSTIPATION	Constipation	2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DIABETES MELLITUS TYPE II	Type 2 diabetes mellitus	2019	Present
Chronic Kidney Disease, Stage 2	Chronic kidney disease	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	16:02
2	Placebo	10SEP2020 (22)	13:12

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	RENAL	Acute kidney injury	ACUTE KIDNEY INJURY	26AUG2020 (7)		30AUG2020 (11)		5	1	TC	N
2	RENAL	Chronic kidney disease	CHRONIC KIDNEY DISEASE, STAGE 2, WORSENING	31DEC2020 (134)		ONGOING			2	N	N
3	METAB	Diabetes mellitus	WORSENING DIABETES MELLITUS TYPE 2	10NOV2020 (83)		ONGOING			2	TC	N
4	VASC	Hypertension	WORSENING HYPERTENSION	SEP2020 ()		ONGOING			2	TC	N
5	METAB	Hypocalcaemia	HYPOCALCEMIA	SEP2020 ()		ONGOING			2	TC	N
6	PSYCH	Insomnia	WORSENING INSOMNIA	SEP2020 ()		ONGOING			2	N	N

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
7	PSYCH	Major depression	MODERATE EPISODE OF MAJOR DEPRESSIVE DISORDER W/ PSYCHOSIS	30DEC2020 (133)		01JAN2021 (135)		3	3	TC/TCN	Y
8	MUSC	Musculoskeletal stiffness	NECK STIFFNESS	21SEP2020 (33)	08:00	24OCT2020 (66)		34	1	N	N
9	MUSC	Pain in extremity	ARM SORENESS, LEFT	22SEP2020 (34)	08:00	02OCT2020 (44)		11	2	N	N
10	MUSC	Rhabdomyolysis	RHABDOMYOLYSIS	26AUG2020 (7)		30AUG2020 (11)		5	1	TC	N
11	RESP	Snoring	SNORING	SEP2020 ()		ONGOING			2	N	N
12	PSYCH	Suicidal ideation	SUICIDAL IDEATION	20NOV2020 (93)		25NOV2020 (98)		6	4	TC/TCN	Y
13	PSYCH	Suicidal ideation	Suicidal ideation	27AUG2020 (8)		30AUG2020 (11)		4	4	TC	Y
14	NERV	Syncope	Syncopal Episode	26AUG2020 (7)		30AUG2020 (11)		5	4	N	Y

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (30AUG2020)	NOT RELATED/OTHER: HEAT RELATED EVENT	1	7	N
2	Yes	NOT RELATED/OTHER: DIABETES MELLITUS II DISEASE PROGRESSION	2	113	N
3	Yes	NOT RELATED/OTHER: DISEASE PROGRESSION	2	62	N
4	Yes	NOT RELATED/OTHER: NON COMPLIANCE WITH PLAN OF CARE			N

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	Yes	NOT RELATED/OTHER: ETIOLOGY UNKNOWN			N
6	Yes	NOT RELATED/OTHER: ETIOLOGY UNKNOWN			N
7	Resolved (01JAN2021)	NOT RELATED/OTHER: BIPOLAR DISORDER	2	112	Y
8	Resolved (24OCT2020)	NOT RELATED/OTHER: ETIOLOGY UNKNOWN PER INVESTIGATOR	2	12	N
9	Resolved (02OCT2020)	NOT RELATED/OTHER: ETIOLOGY NOT KNOWN PER INVESTIGATOR	2	13	N
10	Resolved (30AUG2020)	NOT RELATED/OTHER: HEAT RELATED EVENT	1	7	N
11	Yes	NOT RELATED/OTHER: ETIOLOGY UNKNOWN			N
12	Resolved (25NOV2020)	NOT RELATED/OTHER: MENTAL HEALTH DISORDER	2	72	Y
13	Resolved (30AUG2020)	NOT RELATED/OTHER: Per participant: "due to being in the hospital"	1	8	Y
14	Resolved (30AUG2020)	NOT RELATED/OTHER: Due to heat, acute kidney injury, rhabdomyolysis	1	7	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINE	INFLUENZA VACCINE	14SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	08OCT2020	
Withdrawn	REPEAT SCREENING 1	28JAN2021	NO LONGER MEETS ELIGIBILITY CRITERIA
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	68	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	104.91 kg	39.6 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PENICILLIN ALLERGY	Drug hypersensitivity	1956	Present
OBESITY	Obesity	1961	Present
Tobacco Use - Smoker	Tobacco user	1967	Past
BILATERAL VISION IMPAIRMENT	Visual impairment	1976	Present
MITRAL VALVE PROLAPSE	Mitral valve prolapse	1981	Present
DEPRESSION	Depression	2000	Present
ENVIRONMENTAL ALLERGIES	Hypersensitivity	2000	Present
HYPERTENSION	Hypertension	2005	Present
GENERALIZED OSTEOARTHRITIS	Osteoarthritis	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
RIGHT HIP OSTEOARTHRITIS	Osteoarthritis	2013	Past
RIGHT HIP REPLACEMENT	Hip arthroplasty	MAR2014	Past
TOTAL HYSTERECTOMY	Hysterectomy	OCT2014	Past
UTERINE CANCER	Uterine cancer	OCT2014	Past
ASTHMA	Asthma	2017	Present
HIGH CHOLESTEROL	Blood cholesterol increased	2017	Present
LEFT HIP OSTEOARTHRITIS	Osteoarthritis	2017	Past
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2018	Present
LEFT HIP REPLACEMENT	Hip arthroplasty	FEB2018	Past
CERVICAL DISC COMPRESSION	Intervertebral disc compression	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27AUG2020 (1)	17:41
2	BNT162b2	15SEP2020 (20)	12:16

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	NERV	Cervical radiculopathy	C7 RADICULOPATHY	11MAR2021 (197)		ONGOING			2	TC/TCN
2	CARD	Myocardial infarction	MYOCARDIAL INFARCTION	28JAN2021 (155)		29JAN2021 (156)		2	3	TC/TCN

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Yes	NOT RELATED/OTHER: CERVICAL DISC DEGENERATION	2	178	N
2	Y	Resolved (29JAN2021)	NOT RELATED/OTHER: ETIOLOGY UNKNOWN	2	136	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
FLU VACCINE	INFLUENZA VACCINE	06OCT2020

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	15OCT2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.61 cm	53.55 kg	19.5 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
CIGARETTE SMOKER	Tobacco user	1960	Present
MARIJUANA USE	Substance use	1968	Past
HEPATITIS C	Hepatitis C	1987	Past
DILAUDID ALLERGY	Drug hypersensitivity	2010	Present
PULMONARY HYPERTENSION	Pulmonary hypertension	2010	Present
BILATERAL VISION IMPAIRMENT	Visual impairment	2010	Present
POST TRAUMATIC STRESS SYNDROME	Post-traumatic stress disorder	2012	Present
CHOLECYSTECTOMY	Cholecystectomy	2016	Past
CHOLELITHIASIS	Cholelithiasis	2016	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HERNIA, INGUINAL, RIGHT	Inguinal hernia	2016	Past
HERNIA REPAIR, INGUINAL, RIGHT	Inguinal hernia repair	2016	Past
CRACK COCAINE USE	Substance use	2016	Past
DIVERTICULOSIS	Diverticulum	FEB2016	Present
HEMORRHOIDS, INTERNAL	Haemorrhoids	FEB2016	Present
CONGESTIVE HEART FAILURE	Cardiac failure congestive	2017	Present
CORONARY ARTERY DISEASE	Coronary artery disease	2017	Present
IMPAIRED GLUCOSE TOLERANCE	Glucose tolerance impaired	2017	Present
AORTIC ANEURYSM	Aortic aneurysm	DEC2017	Past
CAROTID SUBCLAVIAN TRANSPOSITION, LEFT	Carotid artery bypass	18DEC2017	Past
AORTIC ARCH RECONSTRUCTION	Aortic surgery	19DEC2017	Past
CORONARY ARTERY BYPASS GRAFTING	Coronary artery bypass	19DEC2017	Past
DYSPHAGIA	Dysphagia	20DEC2017	Present
HOARSE VOICE	Dysphonia	20DEC2017	Present
BENIGN PROSTATE HYPERPLASIA	Benign prostatic hyperplasia	2018	Present
HIGH CHOLESTEROL	Blood cholesterol increased	2018	Present
EPITHELIAL BASEMENT MEMBRANE DYSTROPHY	Corneal dystrophy	2018	Present
PERIPHERAL OPACITY OF CORNEA	Corneal opacity	2018	Present
FRACTURE, ORBITAL, LEFT	Facial bones fracture	MAR2018	Past
CHRONIC OBSTRUCTIVE PULMONARY DISEASE	Chronic obstructive pulmonary disease	DEC2018	Present
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR INSERTION	Implantable defibrillator insertion	DEC2018	Past
INSOMNIA	Insomnia	2019	Present
ACUTE HEART FAILURE	Cardiac failure acute	28MAR2019	Past
PNEUMONIA	Pneumonia	28MAR2019	Past
HEADACHES	Headache	FEB2020	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
BASAL CELL CARCINOMA FOREHEAD	Basal cell carcinoma	13JUL2020	Past
BASAL CELL CARCINOMA FOREHEAD REMOVAL	Skin neoplasm excision	13JUL2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03SEP2020 (1)	14:13
2	BNT162b2	22SEP2020 (20)	11:40

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Cardiac failure congestive	CARDIAC FAILURE, CONGESTIVE	14FEB2021 (165)		19FEB2021 (170)		6	3	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (19FEB2021)	NOT RELATED/OTHER: MEDICAL HISTORY OF COPD AND CHF	2	146	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
FLU VACCINE	INFLUENZA VACCINE	14OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1940	79	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.94 cm	84.55 kg	28.9 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SEASONAL ALLERGIES	Seasonal allergy	1948	Present
BILATERAL VISUAL IMPAIRMENT	Visual impairment	1948	Present
LEFT KNEE SURGERY	Knee operation	1962	Past
LEFT KNEE BREAK	Lower limb fracture	1962	Past
ACID REFLUX	Gastrooesophageal reflux disease	1990	Present
MYCARDIAL INFARCT	Myocardial infarction	2001	Past
CARDIAC BYPASS	Coronary artery bypass	JUL2001	Past
CHRONIC THROMBOCYTOPENIA	Thrombocytopenia	JUL2001	Present
SULFA ALLERGY	Drug hypersensitivity	2005	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERLIPIDEMIA	Hyperlipidaemia	2005	Present
HYPERTENSION	Hypertension	2005	Present
RIGHT KNEE REPLACEMENT	Knee arthroplasty	APR2014	Past
RIGHT KNEE DEGENERATION	Osteoarthritis	APR2014	Past
LEFT KNEE REPLACEMENT	Knee arthroplasty	APR2015	Past
LEFT KNEE DEGENERATION	Osteoarthritis	APR2015	Past
RIGHT HIP REPLACEMENT	Hip arthroplasty	APR2016	Past
RIGHT HIP DEGENERATION	Osteoarthritis	APR2016	Past
BENIGN PROSTATIC HYPERPLASIA	Benign prostatic hyperplasia	2017	Present
ANEMIA	Anaemia	2018	Present
ATRIAL FIBRILLATION	Atrial fibrillation	2018	Present
ACUTE COLITIS	Colitis	2018	Present
CORONARY ARTERY DISEASE	Coronary artery disease	2018	Present
ELEVATED PROSTATE SPECIFIC ANTIGEN	Prostatic specific antigen increased	2018	Present
SICK SINUS SYNDROME	Sinus node dysfunction	2018	Present
CARDIAC PACEMAKER PLACEMENT	Cardiac pacemaker insertion	AUG2018	Present
CHOLECYSTECTOMY	Cholecystectomy	AUG2018	Past
GALLBLADDER OBSTRUCTION	Gallbladder obstruction	AUG2018	Past
GLAUCOMA	Glaucoma	2019	Present
BILATERAL EYE CATARACTS	Cataract	JAN2019	Past
BILATERAL EYE CATARACT SURGERY	Cataract operation	JAN2019	Past
LEFT EYE CAPSULOTOMY PROCEDURE	Lens capsulotomy	17AUG2020	Past
LEFT EYE CLOUDING MEMBRANE	Vision blurred	17AUG2020	Past
RIGHT EYE CAPSULOTOMY LASER PROCEDURE	Lens capsulotomy	31AUG2020	Past
RIGHT EYE CLOUDING MEMBRANE	Vision blurred	31AUG2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03SEP2020 (1)	16:07
2	BNT162b2	23SEP2020 (21)	14:05

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	GENRL	Non-cardiac chest pain	NON CARDIAC CHEST PAIN	14NOV2020 (73)		16NOV2020 (75)		3	3	TC/TCN

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (16NOV2020)	NOT RELATED/OTHER: PRIOR CARDIAC MEDICAL HISTORY	2	53	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
FLU VACCINE	INFLUENZA VACCINE	21OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.5 cm	75.82 kg	30.1 kg/m2	22SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ALLERGY, PENCILLIN	Drug hypersensitivity	1959	Present
ALLERGY, SEASONAL	Seasonal allergy	1965	Present
ALCOHOL USE, 7 DRINKS/WEEK	Alcohol use	1968	Present
UTERINE FIBROIDS	Uterine leiomyoma	1990	Past
VISION IMPAIRMENT, BILATERAL	Visual impairment	1990	Present
MENOPAUSE	Menopause	2000	Present
MUSCLE SPASM	Muscle spasms	2010	Present
VENTRICULAR ENLARGEMENT, RIGHT	Ventricular enlargement	22JAN2010	Present
HEARING IMPAIRMENT, BILATERAL	Hypoacusis	2012	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OSTEOPOROSIS	Osteoporosis	2012	Present
HYSTERECTOMY, TOTAL	Hysterectomy	2014	Past
ULCERS, GASTRIC	Gastric ulcer	2015	Present
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2015	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2015	Present
NEUROPATHY, LOWER EXTREMITY, BILATERAL	Neuropathy peripheral	2015	Present
OSTEOARTHRITIS, THUMB, BILATERAL	Osteoarthritis	2015	Present
OSTEOARTHRITIS, HIP, BILATERAL	Osteoarthritis	2015	Present
PEPTIC ULCERS	Peptic ulcer	2015	Past
VERTIGO	Vertigo	2015	Present
BONE SPUR REMOVAL, SHOULDER, RIGHT	Bone lesion excision	2016	Past
BONE SPUR, SHOULDER, RIGHT	Exostosis	2016	Past
OSTEOARTHRITIS, KNEE, BILATERAL	Osteoarthritis	2017	Present
VITAMIN D DEFICIENCY	Vitamin D deficiency	2017	Present
IRREGULAR HEART BEAT	Heart rate irregular	2018	Present
KIDNEY STONE	Nephrolithiasis	2018	Past
AORTIC ANEURYSM	Aortic aneurysm	22JAN2018	Present
ATHEROSCLEROTIC DISEASE	Arteriosclerosis	22JAN2018	Present
PULMONARY ARTERIAL HYPERTENSION	Pulmonary arterial hypertension	22JAN2018	Present
HYPERTENSION	Hypertension	JUN2018	Present
SLEEP APNEA	Sleep apnoea syndrome	SEP2018	Present
DEEP VEIN THROMBOSIS, LOWER EXTREMITY, BILATERAL	Deep vein thrombosis	2019	Past
CELLULITIS, ANKLE, RIGHT	Cellulitis	31JAN2019	Past
CATARACTS, BILATERAL	Cataract	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22SEP2020 (1)	15:57
2	Placebo	12OCT2020 (21)	14:13
3	BNT162b2	19JAN2021 (120)	14:55
4	BNT162b2	09FEB2021 (141)	14:45

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	EYE	Cataract	CATARACTS, WORSENING CONDITION	03FEB2021 (135)		ONGOING			1	N
2	VASC	Deep vein thrombosis	DEEP VEIN THROMBOSIS, LOWER EXTREMITY, RIGHT	21JAN2021 (122)		23JAN2021 (124)		3	2	TC
3	GASTR	Hiatus hernia	HIATAL HERNIA	21JAN2021 (122)		ONGOING			1	N
4	RESP	Pulmonary embolism	PULMONARY EMBOLI	21JAN2021 (122)		23JAN2021 (124)		3	1	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Yes	NOT RELATED/OTHER: PRE EXISTING CONDITON	3	16	N
2	Y	Resolved (23JAN2021)	NOT RELATED/OTHER: PRIOR HISTORY OF DVT	3	3	Y
3	N	Yes	NOT RELATED/OTHER: ETIOLOGY UNKNOWN	3	3	N
4	Y	Resolved (23JAN2021)	NOT RELATED/OTHER: CURRENT DVT, PRIOR HX OF DVT	3	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	22SEP2020	
Completed	VACCINATION	12NOV2020	
Completed	REPEAT SCREENING 1	19JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1938	82	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.97 cm	84.36 kg	28.1 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ALCOHOL USE, SOCIAL	Social alcohol drinker	1956	Present
CHOLECYSTECTOMY	Cholecystectomy	1999	Past
CHOLECYSTITIS	Cholecystitis	1999	Past
HYPERTENSION	Hypertension	2000	Present
ROTATOR CUFF REPAIR, RIGHT	Rotator cuff repair	2001	Past
ROTATOR CUFF TEAR, RIGHT	Rotator cuff syndrome	2001	Past
CORONARY ARTERY DISEASE	Coronary artery disease	2010	Present
ELEVATED PROSTATE SPECIFIC ANTIGEN	Prostatic specific antigen increased	2014	Present
HERNIA, ABDOMINAL	Abdominal hernia	2015	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
BENIGN PROSTATE HYPERPLASIA	Benign prostatic hyperplasia	2015	Present
ADENOMATOUS COLON POLYPS	Colon adenoma	2015	Past
CARDIAC ARTERY BLOCKAGE	Coronary artery occlusion	2015	Past
COLON POLYP REMOVAL	Large intestinal polypectomy	2015	Past
STENT PLACEMENT, CARDIAC	Coronary arterial stent insertion	01SEP2018	Past
HYPERLIPIDEMIA	Hyperlipidaemia	2019	Present
WOUND, INSECT BITE	Arthropod bite	09SEP2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25SEP2020 (1)	14:51
2	BNT162b2	14OCT2020 (20)	15:47

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	EAR	Vertigo	VERTIGO	06NOV2020 (43)		09NOV2020 (46)		4	3

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	Y	Resolved (09NOV2020)	NOT RELATED/OTHER: ETIOLOGY UNKNOWN	2	24	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
FLU VACCINE	INFLUENZA VACCINE	30OCT2020

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25SEP2020	
Completed	VACCINATION	11NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.3 cm	79.7 kg	30.6 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERTENSION	Hypertension	18APR2008	Present
HYPOTHYROIDISM	Hypothyroidism	21MAR2013	Present
HYPERLIPIDEMIA	Hyperlipidaemia	15MAY2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	14:23
2	BNT162b2	01SEP2020 (22)	10:35

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Hypertension	WORSENING OF HYPERTENSION	19JAN2021 (162)	18:15	ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Yes	NOT RELATED/OTHER: WORSENING OF HYPERTENSION	2	141	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	29SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1942	78	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166.5 cm	49.7 kg	17.9 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPOTHYROIDISM	Hypothyroidism	1967	Present
CODEING ALLERGY	Drug hypersensitivity	1970	Present
NICKEL ALLERGY	Allergy to metals	1980	Present
MIGRAINE HEADACHES	Migraine	1980	Past
oophorectomy	Oophorectomy	1981	Past
POST MENOPAUSAL	Postmenopause	1992	Present
OSTEOARTHRITIS	Osteoarthritis	2000	Present
SPINAL STENOSIS	Spinal stenosis	2010	Present
ANGINA	Angina pectoris	2011	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
MINOR CORONARY ARTERY DISEASE	Coronary artery disease	2011	Present
HYPERLIPIDEMIA	Hyperlipidaemia	2012	Present
MITRAL VALVE PROLAPSE	Mitral valve prolapse	2012	Past
OSTEOPOROSIS	Osteoporosis	2013	Present
RENAL INSUFFICIENCY	Renal failure	2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14AUG2020 (1)	09:23
2	BNT162b2	04SEP2020 (22)	08:33

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Angina pectoris	cardiac chest pain	24NOV2020 (103)	09:00	26NOV2020 (105)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Resolved (26NOV2020)	NOT RELATED/OTHER: chest pain	2	82	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	30SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	91.3 kg	35.7 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PSORIASIS	Psoriasis	1957	Present
ALLERGY TO IODINE	Iodine allergy	1976	Present
BRONCHIAL ASTHMA	Asthma	1990	Present
ENVIRONMENTAL ALLERGIES	Hypersensitivity	1990	Present
HYPERTENSION	Hypertension	1990	Present
OSTEOARTHRITIS BILATERAL KNEE, HIP	Osteoarthritis	1990	Present
OSTEOARTHRITIS SPINE	Spinal osteoarthritis	1990	Present
HYPERLIPIDEMIA	Hyperlipidaemia	2010	Present
CORONARY ARTERY DISEASE	Coronary artery disease	2011	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	14:15
2	Placebo	08SEP2020 (23)	14:15
3	BNT162b2	26JAN2021 (163)	11:54
4	BNT162b2	16FEB2021 (184)	13:58

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Pulmonary embolism	bilateral pulmonary embolism	11NOV2020 (87)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Yes	NOT RELATED/OTHER: pulmonary embolism	2	65	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	08OCT2020	
Completed	REPEAT SCREENING 1	26JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.3 cm	52.9 kg	20.1 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
migraines	Migraine	1977	Present
dermatitis	Dermatitis	1990	Present
metamucil allergy	Drug hypersensitivity	1990	Present
hypertension	Hypertension	2009	Present
hypothyroidism	Hypothyroidism	2009	Present
post menopausal	Postmenopause	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18AUG2020 (1)	15:32
2	BNT162b2	10SEP2020 (24)	12:18

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Diverticulitis	Sigmoid diverticulitis	04SEP2020 (18)		18SEP2020 (32)	00:00	15	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (18SEP2020)	NOT RELATED/OTHER: Sigmoid diverticulosis	1	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	08OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.6 cm	80.5 kg	30.4 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DEPRESSION	Depression	1990	Present
sarcoidosis	Sarcoidosis	2010	Present
HYPERLIPIDEMIA	Hyperlipidaemia	2014	Present
SEASONAL ALLERGIES	Seasonal allergy	2018	Present
RHINITIS	Rhinitis	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	13:26
2	Placebo	11SEP2020 (23)	11:37
3	BNT162b2	26JAN2021 (160)	11:20
4	BNT162b2	18FEB2021 (183)	14:10

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Bradycardia	BRADYCARDIA	14SEP2020 (26)	10:30	03NOV2020 (76)		51	2
2	METAB	Gout	GOUT RIGHT FOOT	06OCT2020 (48)	00:00	ONGOING			1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (03NOV2020)	NOT RELATED/OTHER: BRADYCARDIA	2	4	Y
2	TC	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	26	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	16OCT2020	
Completed	REPEAT SCREENING 1	26JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	110 kg	40.3 kg/m2	22OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
GENERALIZED GOUT	Gout	2000	Present
TYPE 2 DIABETES	Type 2 diabetes mellitus	2005	Present
MILD ASTHMA	Asthma	2010	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2014	Present
HYPERTENSION	Hypertension	2015	Present
STROKE	Cerebrovascular accident	16FEB2016	Past
DIABETIC NEUROPATHY	Diabetic neuropathy	2018	Present
DEPRESSION	Depression	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22OCT2020 (1)	13:31
2	Placebo	12NOV2020 (22)	11:14
3	BNT162b2	20JAN2021 (91)	13:52
4	BNT162b2	18FEB2021 (120)	12:05

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	GASTR	Pancreatitis acute	IDIOPATHIC ACUTE PANCREATITIS	06FEB2021 (108)	19:30	12FEB2021 (114)	16:20	7	3	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (12FEB2021)	NOT RELATED/OTHER: IDIOPATHIC ACUTE PANCREATITIS	3	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	22OCT2020	
Completed	VACCINATION	10DEC2020	
Completed	REPEAT SCREENING 1	20JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	64	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	86 kg	31.6 kg/m2	29JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Diabetes Mellitus Type II	Type 2 diabetes mellitus	1986	Present
Hypertension	Hypertension	1995	Present
Hypercholesterolemia	Hypercholesterolaemia	2010	Present
Laminectomy Lumbar	Spinal laminectomy	07FEB2020	Past
Onychomycosis toe nails	Onychomycosis	APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	29JUL2020 (1)	20:33
2	Placebo	19AUG2020 (22)	11:57

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Uterine leiomyoma	fibroids	27DEC2020 (152)		26JAN2021 (182)		31

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/TCN	Y	Resolved (26JAN2021)	NOT RELATED/OTHER: unknown	2	131	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
BNT162B2	BNT162B2	27JAN2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29JUL2020	
Completed	VACCINATION	16SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	64	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	74.9 kg	30 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
endometriosis	Endometriosis	1991	Past
hysterectomy	Hysterectomy	1994	Past
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	1997	Present
post traumatic stress disorder	Post-traumatic stress disorder	2001	Present
hypothyroidism	Hypothyroidism	2014	Present
cataract	Cataract	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05AUG2020 (1)	13:02
2	BNT162b2	26AUG2020 (22)	11:31

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Breast cancer	breast cancer	05NOV2020 (93)		02DEC2020 (120)		28

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (02DEC2020)	NOT RELATED/OTHER: unknown	2	72	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	95.1 kg	31.1 kg/m2	20OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
congestive heart failure	Cardiac failure congestive	1992	Present
hypertension	Hypertension	1992	Present
heart attack	Myocardial infarction	1992	Past
quadruple bypass surgery	Coronary artery bypass	DEC1992	Past
insomnia	Insomnia	1994	Present
chronic back pain	Back pain	2007	Present
chronic neck pain	Neck pain	2009	Present
low testosterone	Blood testosterone decreased	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
pacemaker difibulator implant	Implantable defibrillator insertion	2010	Past
generalized body pain	Pain	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20OCT2020 (1)	16:20
2	BNT162b2	20JAN2021 (93)	14:51

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	SURG	Cardiac pacemaker replacement	PACE MAKER BATTERY CHARGE	17NOV2020 (29)		17NOV2020 (29)		1	1
2	VASC	Haematoma	HEMATOMA	23NOV2020 (35)		23NOV2020 (35)		1	3
3	INFEC	Postoperative wound infection	Postoperative wound infection to left upper chest	23NOV2020 (35)		04JAN2021 (77)		43	1
4	SURG	Wound drainage	WOUND PUMP DRAINAGE	07DEC2020 (49)		ONGOING			1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (17NOV2020)	NOT RELATED/OTHER: HISTORY PACE MAKER	1	29	N
2	N	N	Resolved (23NOV2020)	NOT RELATED/OTHER: UNKNOWN	1	35	N
3	TC	Y	Resolved (04JAN2021)	NOT RELATED/OTHER: Pacemaker replacement	1	35	Y
4	N	N	Yes	NOT RELATED/OTHER: UNKNOWN	1	49	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20OCT2020	
Completed	VACCINATION	24FEB2021	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1945	75	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	84.2 kg	29.5 kg/m2	30OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
INSOMNIA	Insomnia	2008	Present
BACK SPASMS	Muscle spasms	2008	Present
SEASONAL ALLERGIES	Seasonal allergy	2012	Present
HYPERLIPIDEMIA	Hyperlipidaemia	2018	Present
BILATERAL ANKLES OSTEOARTHRITIS	Osteoarthritis	2018	Present
HYPERTENSION	Hypertension	14FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30OCT2020 (1)	14:23
2	Placebo	20NOV2020 (22)	11:10

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Pancreatic carcinoma	Pancreatic cancer	04DEC2020 (36)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		4	N	Y	Yes	NOT RELATED/OTHER: unknown	2	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30OCT2020	
	VACCINATION		
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	47	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	85.95 kg	29.6 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERTHYROIDISM	Hyperthyroidism	2014	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2015	Present
HYPERTENSION	Hypertension	2016	Present
TYPE 2 DIABETES	Type 2 diabetes mellitus	AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	10:01
2	Placebo	29SEP2020 (20)	09:15

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	COVID-19	COVID-19	24OCT2020 (45)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Yes	NOT RELATED/OTHER: Possibly covid related.	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	27OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	48	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	86.36 kg	26.5 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
High Cholesterol	Blood cholesterol increased	2001	Present
Vasectomy	Vasectomy	2001	Past
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2004	Present
Lower back pain	Back pain	2009	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	14:53
2	BNT162b2	16SEP2020 (22)	08:58

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	CARD	Acute myocardial infarction	ST elevation myocardial infarction	27SEP2020 (33)		13OCT2020 (49)		17	4	N
2	INJ&P	Fall	Fall from Bicycle	27SEP2020 (33)		27SEP2020 (33)		1	2	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (13OCT2020)	NOT RELATED/OTHER: related to cardiovascular risk	2	12	Y
2	N	Resolved (27SEP2020)	NOT RELATED/OTHER: Due to SAE of Myocardial Infarction	2	12	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	96.36 kg	32.2 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	2000	Present
Caesarean section	Caesarean section	2007	Past
Anxiety	Anxiety	2018	Present
Nexplanon placement	Contraceptive implant	2018	Past
Hypertension	Hypertension	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13AUG2020 (1)	12:17
2	Placebo	04SEP2020 (23)	15:16
3	BNT162b2	25FEB2021 (197)	15:44

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Cervical vertebral fracture	Cervical Spine fracture	23DEC2020 (133)		21JAN2021 (162)		30
2	INJ&P	Craniocerebral injury	traumatic brain injury	23DEC2020 (133)		21JAN2021 (162)		30
3	INJ&P	Fall	Fall from Stairs	23DEC2020 (133)		23DEC2020 (133)		1
4	INJ&P	Rib fracture	Rib Fractures	23DEC2020 (133)		21JAN2021 (162)		30
5	INJ&P	Skull fracture	Skull Fracture	23DEC2020 (133)		21JAN2021 (162)		30

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (21JAN2021)	NOT RELATED/OTHER: Fall	2	111	N
2	3	TC	Y	Resolved (21JAN2021)	NOT RELATED/OTHER: fall	2	111	Y
3	3	N	N	Resolved (23DEC2020)	NOT RELATED/OTHER: injury	2	111	N
4	2	N	N	Resolved (21JAN2021)	NOT RELATED/OTHER: Fall	2	111	N
5	2	N	N	Resolved (21JAN2021)	NOT RELATED/OTHER: fall	2	111	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	08OCT2020	
Completed	REPEAT SCREENING 1	25FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	104.09 kg	31.9 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	FEB2000	Present
Angina pectoris	Angina pectoris	2015	Present
Hypercholesterolemia	Hypercholesterolaemia	2015	Present
OSteoArthritis	Osteoarthritis	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	09:39
2	Placebo	22SEP2020 (20)	08:51

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	COVID-19	Covid-19	20JAN2021 (140)		14FEB2021 (165)		26

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (14FEB2021)	NOT RELATED/OTHER: infection	2	121	Y

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
bamlanivimab	BAMLANIVIMAB	24JAN2021	24JAN2021	INTRAVENOUS

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	23OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	70	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	77.1 kg	31.3 kg/m2	30JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
urinary Tract Infection - Recurrent	Urinary tract infection	1951	Present
Bronchitis - Recurrent	Bronchitis	1960	Present
Seasonal Allergies	Seasonal allergy	1960	Present
Myopia	Myopia	1962	Present
Migraines	Migraine	1980	Present
Allergy to Non-Steroidal Anti-Inflammatory drugs	Drug hypersensitivity	1990	Present
hypothyroidism	Hypothyroidism	1992	Present
Hypertension	Hypertension	1993	Present
Asthma	Asthma	1995	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Insomnia	Insomnia	1995	Present
Hyperlipidemia	Hyperlipidaemia	1998	Present
postmenopausal	Postmenopause	2000	Present
Uterine polyps	Uterine polyp	2002	Past
Hysterectomy	Hysterectomy	2005	Past
osteoarthritis - Bilateral Hips	Osteoarthritis	2008	Present
osteoarthritis - Generalized	Osteoarthritis	2008	Present
Osteoarthritis - Left Shoulder	Osteoarthritis	2018	Present
Hearing Loss Bilateral	Deafness bilateral	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30JUL2020 (1)	17:52
2	BNT162b2	18AUG2020 (20)	10:39

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	RESP	Asthma	worsening of asthma	01OCT2020 (64)		ONGOING	
2	NEOPL	Invasive ductal breast carcinoma	Malignant invasive ductal carcinoma left breast	05NOV2020 (99)	11:55	ONGOING	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		1	TC	N	Yes	NOT RELATED/OTHER: allergy	2	45	N
2		3	N	Y	Yes	NOT RELATED/OTHER: malignancy	2	80	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
Influenza vaccination	INFLUENZA VACCINE	08SEP2020

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30JUL2020	
Completed	VACCINATION	15SEP2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1941	79	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	90.64 kg	29 kg/m2	31JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillectomy	Tonsillectomy	1953	Past
Tonsillitis	Tonsillitis	1953	Past
Appendectomy	Appendicectomy	1956	Past
Appendicitis	Appendicitis	1956	Past
Vasectomy	Vasectomy	1974	Past
Anxiety	Anxiety	1995	Present
Diabetes Type 2	Type 2 diabetes mellitus	2005	Present
Prostate Cancer, malignant	Prostate cancer	2008	Past
Prostectomy	Prostatectomy	2008	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
elevated cholesterol	Blood cholesterol increased	2010	Present
Glaucoma	Glaucoma	2010	Present
Acid Reflux	Gastrooesophageal reflux disease	2012	Present
Low Vitamin D	Vitamin D decreased	2015	Present
Arthritis	Arthritis	DEC2017	Present
Muscle Fatigue	Muscle fatigue	2019	Present
Hypotension	Hypotension	AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31JUL2020 (1)	17:51
2	Placebo	27AUG2020 (28)	12:59
3	BNT162b2	30DEC2020 (153)	13:52
4	BNT162b2	18JAN2021 (172)	15:03

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Fall	Fall	28AUG2020 (29)	09:30	20SEP2020 (52)		24
2	INJ&P	Skin laceration	FACIAL LACERATIONS	28AUG2020 (29)	09:30	28AUG2020 (29)	09:30	1

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TCN	Y	Resolved (20SEP2020)	NOT RELATED/OTHER: Fall	2	2	Y
2	2	N	N	Resolved (28AUG2020)	NOT RELATED/OTHER: Hypotension	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31JUL2020	
Completed	VACCINATION	24SEP2020	
Completed	REPEAT SCREENING 1	30DEC2020	
Completed	OPEN LABEL TREATMENT	25FEB2021	
	FOLLOW-UP		

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	54.64 kg	22 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
low back pain	Back pain	1987	Present
migraines	Migraine	1987	Present
restless leg syndrome	Restless legs syndrome	1988	Present
total hysterectomy	Hysterectomy	2002	Past
polycystic ovarian disorder	Polycystic ovaries	2002	Past
seizure disorder	Seizure	2003	Present
muscle spasms	Muscle spasms	2008	Present
anxiety	Anxiety	2010	Present
depression	Depression	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
osteopenia	Osteopenia	2015	Present
seasonal allergies	Seasonal allergy	2015	Present
bipolar disorder	Bipolar disorder	2018	Present
shortness of breath	Dyspnoea	2018	Present
hyperlipidemia	Hyperlipidaemia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12AUG2020 (1)	14:33
2	BNT162b2	01SEP2020 (21)	13:22

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Escherichia urinary tract infection	Escherichia coli urinary tract infection	03OCT2020 (53)		22OCT2020 (72)		20	2
2	METAB	Hypokalaemia	Severe Hypokalemia	03OCT2020 (53)		22OCT2020 (72)		20	2
3	RENAL	Nephrolithiasis	Kidney Stones	03OCT2020 (53)		22OCT2020 (72)		20	2

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	Y	Resolved (22OCT2020)	NOT RELATED/OTHER: BACTERIAL INFECTION	2	33	Y
2	TC	Y	Resolved (22OCT2020)	NOT RELATED/OTHER: HYPOKALEMIA	2	33	Y
3	TC	Y	Resolved (22OCT2020)	NOT RELATED/OTHER: RENAL CALCULUS	2	33	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	30SEP2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.96 cm	83.14 kg	23.5 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hpv p-16 OROPHARYNGEAL cancer	Oropharyngeal cancer	2018	Past
HPV P-16 OROPHARYNGEAL cancer	Oropharyngeal cancer	2018	Past
lymph node removal	Lymphadenectomy	14AUG2018	Past
tonsillectomy	Tonsillectomy	14AUG2018	Past
diabetes mellitus II	Type 2 diabetes mellitus	SEP2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	16:09
2	Placebo	10SEP2020 (24)	12:21

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Oropharyngeal cancer recurrent	Recurrence of Oropharyngeal Cancer, Left side	12NOV2020 (87)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC	Y	Yes	NOT RELATED/OTHER: Cancer	2	64	Y

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Carboplatin	CARBOPLATIN	17DEC2000	ONGOING	ORAL
Flourouracil (5FU)	FLUOROURACIL	17DEC2000	ONGOING	ORAL
CISPLATIN	CISPLATIN	17DEC2020	ONGOING	INTRAVENOUS

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINE	INFLUENZA VACCINE	02OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	08OCT2020	
Completed	REPEAT SCREENING 1	19JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	40	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	70 kg	25.6 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
general myalgia	Myalgia	1992	Present
depression	Depression	1995	Present
stargardt's disease, both eyes	Stargardt's disease	1998	Present
Appendectomy	Appendicectomy	2002	Past
Appendicitis	Appendicitis	2002	Past
drug allergy: demerol	Drug hypersensitivity	2002	Present
bipolar depression disorder type 3	Bipolar disorder	2005	Present
Attention deficit disorder	Attention deficit hyperactivity disorder	2008	Present
insomnia	Insomnia	2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	17:39
2	Placebo	09SEP2020 (22)	17:06
3	BNT162b2	25JAN2021 (160)	16:02
4	BNT162b2	24FEB2021 (190)	16:45

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	HEPAT	Hepatocellular injury	Hepatocellular injury	04NOV2020 (78)		13NOV2020 (87)		10	3
2	GENRL	Injection site pain	Injection Site Soreness, left arm	24FEB2021 (190)	18:00	26FEB2021 (192)	00:30	3	1
3	INFEC	Sepsis	Sepsis	04NOV2020 (78)		13NOV2020 (87)		10	3
4	INFEC	Viral infection	VIRAL SYNDROME	04NOV2020 (78)		13NOV2020 (87)		10	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (13NOV2020)	NOT RELATED/OTHER: Hepatocellular injury	2	57	Y
2	N	N	Resolved (26FEB2021)	Study Treatment	4	1	N
3	TC	Y	Resolved (13NOV2020)	NOT RELATED/OTHER: VIRAL SYNDROME	2	57	Y
4	TC	N	Resolved (13NOV2020)	NOT RELATED/OTHER: virus	2	57	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINE	INFLUENZA VACCINE	12NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	25JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1942	78	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	101.77 kg	35.1 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
menorrhagia	Menorrhagia	1977	Past
obesity	Obesity	1977	Past
hysterectomy	Hysterectomy	1981	Past
cholecystectomy	Cholecystectomy	1989	Past
gallstones	Cholelithiasis	1989	Past
osteoarthritis, bilateral knees and bilateral hips	Osteoarthritis	1992	Present
lasix surgery, bilateral eyes	Keratomileusis	1998	Past
urinary incontinence	Urinary incontinence	1998	Present
prolapsed bladder	Bladder prolapse	2000	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
bladder suspension surgery	Urinary bladder suspension	2000	Past
left ulnar nerve decompression	Peripheral nerve decompression	2005	Past
left ulnar nerve damage	Ulnar nerve injury	2005	Past
cataracts, bilateral eyes	Cataract	2006	Past
cataract surgery bilateral eyes	Cataract operation	2006	Past
gastric bypass surgery	Gastric bypass	2008	Past
acid reflux	Gastrooesophageal reflux disease	2008	Present
implantation of bladder stimulator	Urinary control neurostimulator implantation	2013	Past
broken pelvis	Pelvic fracture	2015	Past
broken left wrist (ulnar and radius bones)	Wrist fracture	2018	Past
battery replacement, bladder stimulator procedure	Medical device battery replacement	2019	Past
broken right shoulder humerous	Humerus fracture	FEB2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	17:23
2	Placebo	16SEP2020 (23)	15:59
3	BNT162b2	21JAN2021 (150)	12:12
4	BNT162b2	09FEB2021 (169)	12:19

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Injection site pain	Injection Site Soreness, Left arm	21JAN2021 (150)	17:00	22JAN2021 (151)		2
2	MUSC	Osteoarthritis	worsening of right hip osteoarthritis	23FEB2021 (183)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (22JAN2021)	Study Treatment	3	1	N
2	3	TCN	Y	Yes	NOT RELATED/OTHER: osteoarthritis	4	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccination	INFLUENZA VACCINE	15OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	21JAN2021	
Completed	OPEN LABEL TREATMENT	09MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	66	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.99 cm	77.41 kg	25.5 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2010	Present
Post Menopausal	Postmenopause	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	14:09

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Other_AEI_SAE/profile Date of Generation: 07APR2021 (21:52)

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	30SEP2020 (30)	13:54
3	BNT162b2	12JAN2021 (134)	12:49
4	BNT162b2	03FEB2021 (156)	14:58

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Breast cancer	Breast Cancer	27DEC2020 (118)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	N	Y	Yes	NOT RELATED/OTHER: Breast Cancer	2	89	Y

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Chemotherapy	ANTINEOPLASTIC AGENTS	20FEB2021	ONGOING	INTRAVENOUS

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccine	INFLUENZA VACCINE	23OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	27OCT2020	
Completed	REPEAT SCREENING 1	12JAN2021	
Completed	OPEN LABEL TREATMENT	03MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	93.19 kg	37.5 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SEASONAL ALLERGIES	Seasonal allergy	2005	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	12:55
2	Placebo	23SEP2020 (22)	16:56

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	11JAN2021 (132)	16:57
4	BNT162b2	03FEB2021 (155)	16:29

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	MUSC	Arthralgia	Joint Pain	02SEP2020 (1)	15:00	03SEP2020 (2)		2	1
2	MUSC	Arthralgia	Joint Pain	05SEP2020 (4)		06SEP2020 (5)		2	2
3	GENRL	Fatigue	Fatigue	07SEP2020 (6)	15:00	08SEP2020 (7)		2	2
4	MUSC	Myalgia	Body Ache (muscle pain)	04SEP2020 (3)	15:00	04SEP2020 (3)		1	2
5	MUSC	Myalgia	Body Aches (Muscle pain)	05SEP2020 (4)		06SEP2020 (5)		2	3
6	REPRO	Rectocele	Rectocele	17DEC2020 (107)		18DEC2020 (108)		2	3
7	REPRO	Vaginal prolapse	Vaginal Prolapse	01DEC2020 (91)		18DEC2020 (108)		18	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (03SEP2020)	Study Treatment	1	1	N
2	N	N	Resolved (06SEP2020)	Study Treatment	1	4	N
3	N	N	Resolved (08SEP2020)	Study Treatment	1	6	N
4	N	N	Resolved (04SEP2020)	Study Treatment	1	3	N
5	N	N	Resolved (06SEP2020)	Study Treatment	1	4	N

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
6	TCN	Y	Resolved (18DEC2020)	NOT RELATED/OTHER: rectocele	2	86	Y
7	TCN	Y	Resolved (18DEC2020)	NOT RELATED/OTHER: Vaginal Prolapse	2	70	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	22OCT2020	
Completed	REPEAT SCREENING 1	11JAN2021	
Completed	OPEN LABEL TREATMENT	03MAR2021	
	FOLLOW-UP		

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1945	74	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
153.67 cm	78.41 kg	33.1 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hysterectomy	Hysterectomy	1974	Past
Polysystic Ovaries	Polycystic ovaries	1974	Past
Diabetes Mellitus II	Type 2 diabetes mellitus	1995	Present
Diabetic Neuropathy	Diabetic neuropathy	2005	Present
Gastroesophogeal Reflux Disease	Gastrooesophageal reflux disease	2005	Present
Hyperlipidemia	Hyperlipidaemia	2005	Present
Hypertension	Hypertension	2005	Present
Insomnia	Insomnia	2005	Present
Restless Leg Syndrome	Restless legs syndrome	2005	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Coronary Artery Disease	Coronary artery disease	2009	Present
right rotator cuff tear	Rotator cuff syndrome	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	12:54
2	Placebo	29SEP2020 (22)	16:45
3	BNT162b2	04JAN2021 (119)	13:07
4	BNT162b2	25JAN2021 (140)	10:14

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	BLOOD	Anaemia	anemia	23DEC2020 (107)		ONGOING			2
2	MUSC	Arthralgia	severe right shoulder pain	23DEC2020 (107)		ONGOING			2
3	NERV	Headache	soreness to back of head	23DEC2020 (107)		25DEC2020 (109)		3	2
4	INJ&P	Post-traumatic pain	post traumatic pain	23DEC2020 (107)		02JAN2021 (117)		11	2
5	INJ&P	Road traffic accident	MOTOR VEHICLE ACCIDENT	23DEC2020 (107)		25DEC2020 (109)		3	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Yes	NOT RELATED/OTHER: IRON DEFFICIENCY	2	86	N
2	TC	N	Yes	NOT RELATED/OTHER: automotive accident	2	86	N
3	TC	N	Resolved (25DEC2020)	NOT RELATED/OTHER: automotive accident	2	86	N
4	TC	Y	Resolved (02JAN2021)	NOT RELATED/OTHER: automotive accident	2	86	Y
5	TC/TCN	Y	Resolved (25DEC2020)	NOT RELATED/OTHER: AUTOMOBILE ACCIDENT	2	86	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccination	INFLUENZA VACCINE	22OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	27OCT2020	
Completed	REPEAT SCREENING 1	04JAN2021	
Completed	OPEN LABEL TREATMENT	22FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	49	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	104.36 kg	36 kg/m2	29JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
nearsighted	Myopia	1970	Present
dermatitis of the scalp	Dermatitis	1980	Present
Seasonal Allergies	Seasonal allergy	1980	Present
right Carpal tunnel syndrome	Carpal tunnel syndrome	1990	Present
overweight	Overweight	1995	Present
smoker	Tobacco user	2002	Past
Fatty Liver Disease	Hepatic steatosis	2005	Present
vasectomy	Vasectomy	2005	Past
right bundle branch block	Bundle branch block right	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ST depression	Electrocardiogram ST segment depression	2010	Present
Sleep apnea	Sleep apnoea syndrome	2010	Present
Trigger finger	Trigger finger	2010	Present
Hemorrhoids	Haemorrhoids	2015	Present
Diabetic neuropathy	Diabetic neuropathy	2017	Present
type ii diabetes mellitus	Type 2 diabetes mellitus	2017	Present
High cholesterol	Blood cholesterol increased	2018	Present
Vitamin B12 deficiency	Vitamin B12 deficiency	2018	Present
vitamin D deficiency	Vitamin D deficiency	2018	Present
macular dystrophy left eye	Maculopathy	2019	Present
repaired hole in retina	Retinal operation	2019	Present
hole in Retina	Retinal tear	2019	Present
anxiety	Anxiety	JAN2019	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	MAR2020	Present
Roux-en-Y gastric bypass	Gastric bypass	20MAR2020	Past
constipation	Constipation	MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29JUL2020 (1)	14:29
2	BNT162b2	18AUG2020 (21)	16:12

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Internal hernia	Internal Hernia	21JAN2021 (177)	10:55	22JAN2021 (178)		2	3
2	GASTR	Intestinal obstruction	bowel obstruction	21JAN2021 (177)		22JAN2021 (178)		2	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	N	Resolved (22JAN2021)	NOT RELATED/OTHER: etiology previous surgery	2	157	N
2	TC/TCN	Y	Resolved (22JAN2021)	NOT RELATED/OTHER: unknown	2	157	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29JUL2020	
Completed	VACCINATION	15SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	72	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	103 kg	32.5 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
asthma	Asthma	1960	Past
seasonal allergies	Seasonal allergy	1960	Present
right fibula fracture	Fibula fracture	1963	Past
fracture right tibia	Tibia fracture	1963	Past
Chronic major depression	Major depression	1970	Present
overweight	Overweight	1980	Present
bilateral arthroscopic knee surgery x2	Arthroscopy	1999	Past
bilateral knee replacement	Knee arthroplasty	2002	Past
intermittent gout	Gout	2005	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Neck pain	Neck pain	2007	Past
abnormal electrocardiogram	Electrocardiogram abnormal	2010	Present
osteoarthritis	Osteoarthritis	2010	Present
surgical fixture c-3-4-5	Spinal operation	2010	Past
smoker	Tobacco user	2010	Present
bilateral shoulder surgery	Shoulder operation	2015	Past
high cholesterol	Blood cholesterol increased	2016	Present
high blood pressure	Hypertension	2016	Present
bilateral cataracts	Cataract	2017	Past
right shoulder replacement	Shoulder arthroplasty	2017	Past
type 2 diabetes	Type 2 diabetes mellitus	2018	Present
kidney stones	Nephrolithiasis	FEB2019	Past
bilateral cataract surgery	Cataract operation	DEC2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03AUG2020 (1)	10:50
2	Placebo	24AUG2020 (22)	12:21
3	BNT162b2	04JAN2021 (155)	15:55
4	BNT162b2	25JAN2021 (176)	13:16

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GENRL	Chills	chills	25JAN2021 (176)		25JAN2021 (176)		1	1
2	GENRL	Fatigue	fatigue	25JAN2021 (176)		25JAN2021 (176)		1	3
3	MUSC	Osteoarthritis	worsened degenerative joint disease left shoulder	16FEB2021 (198)		17FEB2021 (199)		2	3
4	GENRL	Pain	generalized body ache	25JAN2021 (176)		31JAN2021 (182)		7	3
5	GENRL	Pyrexia	mild fever	25JAN2021 (176)		25JAN2021 (176)		1	1
6	GASTR	Vomiting	vomiting	25JAN2021 (176)		25JAN2021 (176)		1	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (25JAN2021)	Study Treatment	4	1	N
2	N	N	Resolved (25JAN2021)	Study Treatment	4	1	N
3	TC/TCN	Y	Resolved (17FEB2021)	NOT RELATED/OTHER: degenerative joint disease	4	23	Y
4	N	N	Resolved (31JAN2021)	Study Treatment	4	1	N
5	N	N	Resolved (25JAN2021)	Study Treatment	4	1	N
6	N	N	Resolved (25JAN2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	21SEP2020	
Completed	REPEAT SCREENING 1	04JAN2021	
Completed	OPEN LABEL TREATMENT	22FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	92.82 kg	28.5 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergy to Penicillin	Drug hypersensitivity	1970	Present
smoker	Tobacco user	1979	Past
appendectomy	Appendicectomy	1985	Past
Appendicitis	Appendicitis	1985	Past
seasonal allergies	Seasonal allergy	1987	Present
farsighted	Hypermetropia	2010	Present
osteoarthritis bilateral knee	Osteoarthritis	2010	Present
left knee surgery	Knee operation	2011	Past
left meniscus tear	Meniscus injury	2011	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
colon polyps	Large intestine polyp	2014	Past
benign neoplasm of prostate	Benign neoplasm of prostate	2015	Present
insomnia	Insomnia	2015	Present
allergic rhinitis	Rhinitis allergic	24APR2017	Present
acid reflux	Gastrooesophageal reflux disease	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03AUG2020 (1)	14:44
2	Placebo	24AUG2020 (22)	13:13

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Squamous cell carcinoma of head and neck	Metastatic Squamous Cell Carcinoma of head and neck	30NOV2020 (120)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Yes	NOT RELATED/OTHER: SCCA Head and Neck	2	99	Y

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
cisplatin	CISPLATIN	28DEC2020	ONGOING	INTRAVENOUS

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Moderna Covid-19 Vaccine	COVID-19 VACCINE MRNA (MRNA 1273)	16FEB2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	19NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	16FEB2021	PROTOCOL DEVIATION

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	83.82 kg	26.5 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Herpes Simplex	Herpes simplex	2000	Present
Allergy Pollen	Seasonal allergy	2000	Present
Anxiety	Anxiety	2010	Present
Attention Deficit Hyperactivity Disorder	Attention deficit hyperactivity disorder	2010	Present
Depression	Depression	2010	Present
Insomnia	Insomnia	2010	Present
Asthma	Asthma	2012	Past
Hypertension	Hypertension	2015	Present
Farsighted	Hypermetropia	2016	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
High Cholesterol	Blood cholesterol increased	2017	Present
Diverticulosis	Diverticulum	2017	Past
Hernia	Hernia	2017	Past
Hernia Repair	Hernia repair	2017	Past
Vitamin D Deficiency	Vitamin D deficiency	2017	Present
Allergy Contrast Dye	Contrast media allergy	2018	Present
Erectile Dysfunction	Erectile dysfunction	2018	Present
Left Shoulder Melanoma	Malignant melanoma	04APR2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04AUG2020 (1)	11:43
2	BNT162b2	25AUG2020 (22)	11:23

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Fall	fall	31JAN2021 (181)		31JAN2021 (181)		1	2
2	INJ&P	Wrist fracture	compound fracture left wrist	31JAN2021 (181)		ONGOING			2

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (31JAN2021)	NOT RELATED/OTHER: tripped	2	160	N
2	TCN	Y	Yes	NOT RELATED/OTHER: patient fell playing tennis	2	160	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	04AUG2020	
Completed	VACCINATION	22SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	70	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159.39 cm	91.36 kg	35.9 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tonsillectomy	Tonsillectomy	1953	Present
tonsillitis	Tonsillitis	1953	Past
farsighted	Hypermetropia	1962	Present
smoker	Tobacco user	1969	Past
adenoidectomy	Adenoidectomy	1971	Past
Food allergy	Food allergy	1971	Present
allergy morphine	Drug hypersensitivity	1974	Present
allergy dilaudid	Drug hypersensitivity	1974	Present
allergy demerol	Drug hypersensitivity	1974	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tubal ligation	Female sterilisation	1984	Present
excessive uterine bleeding related to endometriosis	Endometriosis	1987	Present
endometriosis	Endometriosis	1989	Past
hysterectomy	Hysterectomy	1989	Past
rosacea	Rosacea	1989	Present
seasonal allergy	Seasonal allergy	1989	Present
gastroesophageal reflux disease	Gastrooesophageal reflux disease	1990	Present
high blood pressure	Hypertension	1995	Present
high cholesterol	Blood cholesterol increased	2000	Present
hyperlipidemia	Hyperlipidaemia	2000	Present
overweight	Overweight	2000	Present
restless leg	Restless legs syndrome	2000	Present
abdominal hernia repairs	Abdominal hernia repair	2001	Past
appendicitis	Appendicitis	2002	Past
abdominal hernia	Abdominal hernia	2003	Past
left knee torn meniscus	Meniscus injury	2005	Past
left knee torn meniscus repair	Meniscus operation	2005	Past
left meniscectomy	Meniscus removal	2005	Past
diarrhea	Diarrhoea	2010	Present
urination problems	Micturition disorder	2014	Present
overactive bladder	Hypertonic bladder	2015	Present
stress incontinence	Stress urinary incontinence	2015	Present
reactive airway	Bronchial hyperreactivity	2016	Present
multiple deep vein thrombosis	Deep vein thrombosis	2016	Past
multiple pulmonary embolisms	Pulmonary embolism	2016	Past
synovial cyst right popliteal space	Synovial cyst	2016	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
back pain	Back pain	2017	Past
left carpal tunnel syndrome	Carpal tunnel syndrome	2017	Past
carpal tunnel syndrome left wrist	Carpal tunnel syndrome	2017	Past
sciatica	Sciatica	2017	Past
fusion l5-s1	Spinal fusion surgery	2017	Past
vitamin d deficiency	Vitamin D deficiency	2017	Present
type II diabetes	Type 2 diabetes mellitus	2018	Present
hypercalcemia	Hypercalcaemia	APR2018	Past
carpal tunnel repair	Carpal tunnel decompression	2019	Past
cataracts	Cataract	2019	Present
osteoarthritis	Osteoarthritis	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04AUG2020 (1)	12:15
2	BNT162b2	24AUG2020 (21)	11:52

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Intracranial aneurysm	Aneurysm x3 Mid lateral Cranial Artery	22JAN2021 (172)		09FEB2021 (190)		19	3
2	NERV	Vocal cord paralysis	right vocal cord paralysis	22JAN2021 (172)		ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (09FEB2021)	NOT RELATED/OTHER: Unknown Etiology	2	152	Y
2	TC	N	Yes	NOT RELATED/OTHER: unknown etiology	2	152	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Completed	VACCINATION	21SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1936	84	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.96 cm	83.91 kg	23.7 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
nearsighted	Myopia	(b) (6) 1936	Present
hypercholesterolemia	Hypercholesterolaemia	1950	Present
drug allergy: penicillin	Drug hypersensitivity	1958	Present
tobacco smoker	Tobacco user	1960	Past
hypertriglyceridemia	Hypertriglyceridaemia	2000	Present
cataracts-bilateral	Cataract	2010	Past
Left hip replacement surgery	Hip arthroplasty	2010	Past
Intraocular Lens Replacement-Bilateral	Intraocular lens implant	2010	Past
left leg weakness	Muscular weakness	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
osteoarthritis left hip	Osteoarthritis	2010	Present
allergic rhinitis-seasonal	Seasonal allergy	2010	Present
mitral valve replacement	Mitral valve replacement	2012	Past
coronary artery disease	Coronary artery disease	2013	Past
mitral valve disease	Mitral valve disease	2013	Past
basal cell skin cancer	Basal cell carcinoma	2015	Past
vertigo	Vertigo	2015	Present
mild memory loss	Amnesia	2018	Present
atrial fibrillation	Atrial fibrillation	2018	Past
cholecystectomy	Cholecystectomy	2018	Past
Cholelithiasis	Cholelithiasis	2018	Past
clostridium difficile infection	Clostridium difficile infection	2018	Past
hemicolectomy	Colectomy	2018	Past
diverticulosis	Diverticulum	2018	Past
seborrhea-face/scalp	Seborrhoea	2018	Present
vena cava thrombosis	Vena cava thrombosis	2018	Past
deep vein thrombosis	Deep vein thrombosis	JUN2018	Past
ivc filter insertion	Vena cava filter insertion	JUN2018	Past
erectile dysfunction	Erectile dysfunction	2019	Present
abnormal gait	Gait disturbance	14JAN2020	Present
bilateral foot edema	Oedema peripheral	14JAN2020	Past
cough variant asthma	Cough variant asthma	MAY2020	Present
short bowel syndrome	Short-bowel syndrome	18MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10AUG2020 (1)	11:44
2	BNT162b2	31AUG2020 (22)	10:11

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	EYE	Diplopia	double vision	21AUG2020 (12)		22AUG2020 (13)		2	3	N
2	EAR	Vertigo	Worsened Vertigo	21AUG2020 (12)		24AUG2020 (15)		4	3	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (22AUG2020)	NOT RELATED/OTHER: related to vertigo	1	12	Y
2	Y	Resolved (24AUG2020)	NOT RELATED/OTHER: subject history of vertigo exacerbation	1	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10AUG2020	
Completed	VACCINATION	28SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	90 kg	31 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tonsillectomy	Tonsillectomy	1953	Past
tonsillitis	Tonsillitis	1953	Past
insomnia	Insomnia	1970	Present
constipation	Constipation	1975	Present
diarrhea	Diarrhoea	1975	Present
irritable bowel syndrome	Irritable bowel syndrome	1975	Present
GERD	Gastrooesophageal reflux disease	1980	Present
acid reflux	Gastrooesophageal reflux disease	1980	Present
sleep apnea	Sleep apnoea syndrome	1980	Present
hysterectomy	Hysterectomy	1984	Past
low libido	Libido decreased	1984	Present
scoliosis	Scoliosis	1985	Present
overweight	Overweight	1989	Present
depression	Depression	1995	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
multiple basal cell carcinoma	Basal cell carcinoma	2000	Past
osteoarthritis	Osteoarthritis	2000	Present
bladder tuck-retrocele repair	Rectocele repair	2007	Past
urinary frequency	Pollakiuria	2008	Present
allergy:aspirin	Drug hypersensitivity	2009	Present
gastric bypass	Gastric bypass	2009	Past
osteoporosis	Osteoporosis	2009	Present
sciatica	Sciatica	2010	Past
reduction mammoplasty	Mammoplasty	2012	Past
tummy tuck	Abdominoplasty	2013	Past
face lift	Face lift	2015	Past
knee pain-left	Arthralgia	JUN2020	Present
basal cell carcinoma mohs surgery	Skin neoplasm excision	JUN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	12:24
2	BNT162b2	31AUG2020 (21)	11:43

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Osteoarthritis	worsened left knee degenerative joint disease	05OCT2020 (56)		06OCT2020 (57)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Resolved (06OCT2020)	NOT RELATED/OTHER: osteoarthritis	2	36	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	28SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	85.82 kg	27.9 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
drug allergies: restoril	Drug hypersensitivity	1989	Present
tobacco user	Tobacco user	1990	Present
insomnia	Insomnia	2010	Present
post traumatic stress disorder	Post-traumatic stress disorder	2010	Present
gout	Gout	2013	Present
atrial fibrillation	Atrial fibrillation	2015	Present
near sighted	Myopia	2015	Present
diabetes type 2	Type 2 diabetes mellitus	2017	Present
diverticulitis	Diverticulitis	2019	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
GERD	Gastrooesophageal reflux disease	2019	Present
anemia	Anaemia	MAR2020	Present
hemorrhoids	Haemorrhoids	MAY2020	Present
colon polyps	Large intestine polyp	18MAY2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18AUG2020 (1)	16:04
2	BNT162b2	08SEP2020 (22)	14:46

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	MUSC	Back pain	intermittent lower back pain	16JAN2021 (152)		16JAN2021 (152)		1	2	TC
2	HEPAT	Cholelithiasis	Gallstones	22JAN2021 (158)		ONGOING			1	N
3	GASTR	Gastritis erosive	erosive gastropathy	22JAN2021 (158)		ONGOING			2	TC
4	VASC	Hypertension	worsened hypertension	20JAN2021 (156)		ONGOING			1	TC
5	MUSC	Neck pain	neck pain	16JAN2021 (152)		26JAN2021 (162)		11	1	TC
6	GASTR	Pancreatic calcification	Pancreatic Calculus	20JAN2021 (156)		ONGOING			1	N
7	BLOOD	Pancytopenia	Pancytopenia	20JAN2021 (156)		ONGOING			3	N

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
8	INFEC	Sepsis	Sepsis	16JAN2021 (152)		26JAN2021 (162)		11	3	TC/TCN
9	BLOOD	Splenomegaly	Splenomegaly	20JAN2021 (156)		ONGOING			1	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Resolved (16JAN2021)	NOT RELATED/OTHER: unknown	2	131	N
2	N	Yes	NOT RELATED/OTHER: etiology unknown	2	137	N
3	N	Yes	NOT RELATED/OTHER: history of Gastroesophageal reflux disease	2	137	N
4	N	Yes	NOT RELATED/OTHER: unknown etiology	2	135	N
5	N	Resolved (26JAN2021)	NOT RELATED/OTHER: medical history of neck muscle spasms	2	131	N
6	N	Yes	NOT RELATED/OTHER: etiology unknown	2	135	N
7	Y	Yes	NOT RELATED/OTHER: Due to sepsis	2	135	Y
8	Y	Resolved (26JAN2021)	NOT RELATED/OTHER: Unknown Etiology	2	131	Y
9	N	Yes	NOT RELATED/OTHER: etiology unknown	2	135	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	06OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	83.27 kg	27.1 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Strawberry allergy	Food allergy	1953	Present
Penicillin allergy	Drug hypersensitivity	1958	Present
asthma	Asthma	1961	Past
right wrist fracture	Wrist fracture	1965	Past
Prednisone allergy	Drug hypersensitivity	1973	Present
Kenalog allergy	Drug hypersensitivity	1973	Present
Nut allergy	Food allergy	1975	Present
jawbone cyst removal	Bone cyst excision	1979	Past
arthroscopy right knee	Arthroscopy	1985	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
arthroscopy left knee	Arthroscopy	1993	Past
hypercholesterolemia	Hypercholesterolaemia	1995	Present
left anterior cruciate ligament reconstruction	Ligament operation	JUL1996	Past
left knee osteoarthritis	Osteoarthritis	1998	Present
iliotibial band friction syndrome	Iliotibial band syndrome	2000	Present
removal of bottom screw left knee	Knee operation	2000	Past
left knee repair	Knee operation	2000	Past
antiphospholipid syndrome	Antiphospholipid syndrome	2002	Present
anxiety	Anxiety	2002	Present
depression	Depression	2002	Present
encephalitis	Encephalitis	2002	Past
right sided hemiplegia	Hemiplegia	2002	Present
hypertension	Hypertension	2002	Present
viral meningitis	Meningitis viral	2002	Past
seasonal allergies	Seasonal allergy	2003	Present
Fatty liver disease	Hepatic steatosis	11FEB2003	Present
spasmodic dysphonia	Spasmodic dysphonia	04AUG2003	Present
sleep apnea	Sleep apnoea syndrome	2004	Present
temporomandibular joint dysfunction	Temporomandibular joint syndrome	26JUL2004	Present
gout	Gout	2005	Present
arthroscopy left knee	Arthroscopy	21NOV2005	Past
right radial styloid tenosynovitis surgical release	Tenotomy	05APR2006	Past
type 2 diabetes	Type 2 diabetes mellitus	2009	Present
left radial styloid tenosynovitis release	Tenotomy	20JUL2009	Past
diabetic neuropathy bilateral hands	Diabetic neuropathy	27OCT2009	Present
diabetic neuropathy bilateral feet	Diabetic neuropathy	27OCT2009	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
left total knee repair	Knee operation	13MAY2010	Past
right iritis	Iritis	22NOV2010	Past
acute lymes disease	Lyme disease	08AUG2011	Past
partial detached retina left eye	Retinal detachment	12APR2012	Past
revision left total knee replacement	Knee arthroplasty	15AUG2013	Past
revision left total knee replacement	Knee arthroplasty	10OCT2014	Past
laser surgery left eye	Eye laser surgery	19NOV2014	Past
Upper respiratory infection	Upper respiratory tract infection	27JAN2015	Past
iliotibial band release	Fascia release	07JUL2015	Past
left knee pyogenic granuloma removal	Skin neoplasm excision	13NOV2015	Past
right inner thigh fungal infection	Fungal skin infection	28SEP2016	Past
allergy induced edema	Allergic oedema	2017	Present
Norvasc allergy	Drug hypersensitivity	2017	Present
patella femur realignment surgery	Bone operation	14JUN2017	Past
unstable medial collateral ligament left knee	Ligament disorder	26JUL2017	Present
left sided cataracts	Cataract	2018	Past
cataract removal left eye	Cataract operation	2018	Past
Ocular ischemic syndrome	Ocular ischaemic syndrome	2018	Present
Open angle glaucoma	Open angle glaucoma	2018	Present
rosacea	Rosacea	2018	Present
lumbar fusion	Spinal fusion surgery	2018	Past
lumbar laminectomy	Spinal laminectomy	2018	Past
steroid responder	Therapy responder	29OCT2018	Present
lesion removal right elbow	Elbow operation	30JAN2019	Past
Tropical ulcer right elbow	Tropical ulcer	15JUL2019	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
revision left total knee replacement	Knee arthroplasty	20AUG2019	Past
injection left iliotibial band	Injection	17APR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	11:45
2	Placebo	15SEP2020 (22)	12:02
3	BNT162b2	05JAN2021 (134)	11:23
4	BNT162b2	26JAN2021 (155)	11:07

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Osteomyelitis	osteomyelitis distal phalanx right 3rd toe	31AUG2020 (7)		26SEP2020 (33)		27	3
2	EYE	Retinal detachment	detached left retina	26OCT2020 (63)		28OCT2020 (65)		3	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (26SEP2020)	NOT RELATED/OTHER: related to bacterial infection	1	7	Y
2	TC/TCN	N	Resolved (28OCT2020)	NOT RELATED/OTHER: worsening of past medical history	2	42	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
flu vaccine	INFLUENZA VACCINE	09OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	13OCT2020	
Completed	REPEAT SCREENING 1	05JAN2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	23FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	77.27 kg	25.8 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
episodic smoke induced reactive airways	Respiratory fume inhalation disorder	1965	Present
tobacco smoker	Tobacco user	1965	Past
back pain	Back pain	1990	Present
hyperopia	Hypermetropia	1995	Present
acid reflux	Gastrooesophageal reflux disease	2010	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2010	Present
enlarged prostate	Prostatomegaly	2010	Present
right rotator cuff repair	Rotator cuff repair	2010	Past
neck osteoarthritis	Spinal osteoarthritis	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
back osteoarthritis	Spinal osteoarthritis	2010	Present
heart catheterization	Catheterisation cardiac	2011	Past
cardiac stent insertion	Coronary arterial stent insertion	2011	Past
Coronary Artery disease	Coronary artery disease	2011	Present
right hip replacement	Hip arthroplasty	2012	Past
left hip replacement	Hip arthroplasty	2014	Past
type 2 diabetes	Type 2 diabetes mellitus	2014	Present
mild hearing loss right ear	Hypoacusis	2015	Present
heart catheterization	Catheterisation cardiac	2016	Past
cardiac stent insertion	Coronary arterial stent insertion	2016	Past
kidney stones	Nephrolithiasis	2016	Present
Bilateral cataracts	Cataract	2018	Present
Vitamin B12 deficiency	Vitamin B12 deficiency	2018	Present
heart catheterization	Catheterisation cardiac	2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	13:45
2	Placebo	22SEP2020 (22)	13:30
3	BNT162b2	21DEC2020 (112)	13:36
4	BNT162b2	11JAN2021 (133)	10:28

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GENRL	Chills	chills	11JAN2021 (133)		12JAN2021 (134)		2	1
2	CARD	Coronary artery disease	worsening coronary artery disearse	01DEC2020 (92)		18JAN2021 (140)		49	3
3	MUSC	Muscular weakness	muscle weakness	11JAN2021 (133)		12JAN2021 (134)		2	1
4	MUSC	Myalgia	myalgia	11JAN2021 (133)		12JAN2021 (134)		2	1
5	GENRL	Pyrexia	mild fever	11JAN2021 (133)		12JAN2021 (134)		2	1
6	MUSC	Rotator cuff syndrome	left rotator cuff tear	21NOV2020 (82)		ONGOING			1

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (12JAN2021)	Study Treatment	4	1	N
2	TC/TCN	Y	Resolved (18JAN2021)	NOT RELATED/OTHER: preexisting Coronary artery disease	2	71	Y
3	N	N	Resolved (12JAN2021)	Study Treatment	4	1	N
4	N	N	Resolved (12JAN2021)	Study Treatment	4	1	N
5	N	N	Resolved (12JAN2021)	Study Treatment	4	1	N
6	N	N	Yes	NOT RELATED/OTHER: muscle related to painting	2	61	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	20OCT2020	
Completed	REPEAT SCREENING 1	21DEC2020	
Completed	OPEN LABEL TREATMENT	08FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	61	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	94.27 kg	28.9 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Atrial fibrillation	Atrial fibrillation	2003	Present
cardiac ablation	Cardiac ablation	2003	Past
systolic ejection murmur	Cardiac murmur	2003	Present
mechanical heart valve replacement	Heart valve replacement	2003	Past
Seasonal allergies	Seasonal allergy	2015	Present
cardiac ablation	Cardiac ablation	2016	Past
Enlarged prostate	Prostatomegaly	2017	Present
reactive airway	Bronchial hyperreactivity	2018	Present
hyperopia	Hypermetropia	2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
myopia	Myopia	2018	Present
Varicose vein stripping right leg	Varicose vein operation	2019	Past
overweight	Overweight	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15SEP2020 (1)	16:24
2	Placebo	06OCT2020 (22)	16:13
3	BNT162b2	25JAN2021 (133)	17:12
4	BNT162b2	15FEB2021 (154)	16:23

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	MUSC	Arthralgia	bilateral shoulder pain	06OCT2020 (22)	20:00	15OCT2020 (31)		10	2
2	MUSC	Arthralgia	left shoulder soreness	18SEP2020 (4)		19SEP2020 (5)		2	2
3	REPRO	Benign prostatic hyperplasia	Worsened BPH	09MAR2021 (176)		ONGOING			2
4	GENRL	Chills	chills	15FEB2021 (154)		16FEB2021 (155)		2	2
5	GENRL	Fatigue	fatigue	06OCT2020 (22)	20:00	15OCT2020 (31)		10	1
6	NERV	Headache	headache	15FEB2021 (154)		17FEB2021 (156)		3	2

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
7	MUSC	Myalgia	bilateral upper extremity muscle pain	06OCT2020 (22)	20:00	15OCT2020 (31)		10	2
8	RENAL	Urinary tract obstruction	Urinary Obstruction	09MAR2021 (176)		10MAR2021 (177)		2	3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (15OCT2020)	Study Treatment	2	1	N
2	TC	N	Resolved (19SEP2020)	Study Treatment	1	4	N
3	TC	N	Yes	NOT RELATED/OTHER: Etiology Medical History	4	23	N
4	N	N	Resolved (16FEB2021)	Study Treatment	4	1	N
5	N	N	Resolved (15OCT2020)	Study Treatment	2	1	N
6	N	N	Resolved (17FEB2021)	Study Treatment	4	1	N
7	TC	N	Resolved (15OCT2020)	Study Treatment	2	1	N
8	TCN	Y	Resolved (10MAR2021)	NOT RELATED/OTHER: Etiology BPH	4	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu Vaccine	INFLUENZA VACCINE	01SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	06NOV2020	
Completed	REPEAT SCREENING 1	25JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1939	81	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152.4 cm	50.8 kg	21.9 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	24MAR1995	Present
Right Breast Cancer	Breast cancer	2000	Past
Lumpectomy Right breast	Breast conserving surgery	2000	Past
OSTEOARTHRITIS bilateral hands	Osteoarthritis	25FEB2000	Present
Chronic RHINOSINUSITIS	Chronic sinusitis	02MAR2000	Present
ROSACEA	Rosacea	17NOV2000	Present
BASAL CELL CARCINOMA, FACE LEFT FOREHEAD ABOVE EYEBROW	Basal cell carcinoma	05FEB2002	Past
Mohs micrographic surgery to Left face basal cell carcinoma	Skin neoplasm excision	05FEB2002	Past

Medical History

Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
SPONDYLOSIS CERVICAL JOINT Without MYELOPATHY	Spinal osteoarthritis	26NOV2003	Present
Left Breast Cancer	Breast cancer	2005	Past
Lumpectomy, Left breast	Breast conserving surgery	2005	Past
Osteoporosis of back	Osteoporosis	25APR2007	Present
Bilateral hands, PERIPHERAL NEUROPATHY	Neuropathy peripheral	17DEC2009	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	26APR2016	Present
HYPOTHYROIDISM	Hypothyroidism	14AUG2017	Present
SPINAL STENOSIS OF LUMBAR SPINE	Lumbar spinal stenosis	30JUL2019	Present
ATHEROSCLEROSIS OF AORTA (Chronic)	Aortic arteriosclerosis	09NOV2019	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	02SEP2020 (1)	14:18
2	Placebo	21SEP2020 (20)	10:24
3	BNT162b2	20JAN2021 (141)	10:29
4	BNT162b2	09FEB2021 (161)	10:26

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GENRL	Injection site rash	Rash - injection site	09FEB2021 (161)	19:00	19FEB2021 (171)		11	1

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
2	SKIN	Rash	Rash- various places on body	09FEB2021 (161)	19:00	19FEB2021 (171)		11	1
3	NERV	Transient ischaemic attack	Transient Ischemic Attack	07MAR2021 (187)	08:00	07MAR2021 (187)	10:07	1	2
4	INFEC	Urinary tract infection	Urinary Tract Infection	07MAR2021 (187)	09:48	ONGOING			1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (19FEB2021)	Study Treatment	4	1	N
2	N	N	Resolved (19FEB2021)	Study Treatment	4	1	N
3	TC	Y	Resolved (07MAR2021)	NOT RELATED/OTHER: Related to hypercholesterolemia	4	27	Y
4	TC	N	Yes	NOT RELATED/OTHER: Bacteria in the Urinary Tract	4	27	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
INFs Pres Free High Dose (FLUZONE) (influenza)	INFLUENZA VACCINE INACT SPLIT 3V	15OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	19OCT2020	
Completed	REPEAT SCREENING 1	20JAN2021	
Completed	OPEN LABEL TREATMENT	09MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169.5 cm	97.4 kg	33.9 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillectomy, surgery	Tonsillectomy	1953	Past
Deviated septum	Nasal septum deviation	1973	Past
Auto accident	Road traffic accident	1973	Past
Blood transfusion	Transfusion	1973	Past
Denture wearer, partial lower	Denture wearer	1974	Present
Dermatitis, bilateral arms	Dermatitis	1980	Present
Dermatitis, back	Dermatitis	1980	Present
Deviated septum surgical repair	Nasal septal operation	1980	Past
eye glass wearer	Corrective lens user	1982	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hyperopia	Hypermetropia	1982	Present
Migraine headaches	Migraine	1985	Present
Osteoarthritis, bilateral knees	Osteoarthritis	1985	Present
Osteoarthritis, bilateral hands	Osteoarthritis	1985	Present
High blood pressure	Hypertension	2014	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	10:28
2	BNT162b2	09SEP2020 (24)	08:25

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	VASC	Aortic aneurysm	Aortic Aneurysm	02MAR2021 (198)		ONGOING		
2	VASC	Deep vein thrombosis	Deep Vein Thrombosis	02MAR2021 (198)		ONGOING		
3	RESP	Pulmonary embolism	Pulmonary Embolism	02MAR2021 (198)		ONGOING		

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	N	Y	Yes	NOT RELATED/OTHER: Hypertension	2	175	Y
2	3	N	Y	Yes	NOT RELATED/OTHER: Uncertain etiology	2	175	Y
3	3	N	Y	Yes	NOT RELATED/OTHER: Deep vein thrombosis	2	175	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.5 cm	98.9 kg	34 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
rheumatoid arthritis, juvenile in remission since 1982	Juvenile idiopathic arthritis	1980	Present
Allergic Rhinitis, seasonal	Seasonal allergy	1980	Present
tobacco use, 20 cigarettes per day	Tobacco user	1984	Present
amputation right below the right knee	Leg amputation	2002	Past
motor vehicle accident	Road traffic accident	2002	Past
sleep apnea without C-PAP usage	Sleep apnoea syndrome	2010	Present
eye glass wearer for reading	Corrective lens user	2012	Present
total left knee replacement	Knee arthroplasty	2017	Past
high blood pressure	Hypertension	2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
osteoporosis	Osteoporosis	2018	Present
recurrent heartburn	Dyspepsia	2019	Present
wheezing	Wheezing	01AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	15:37
2	Placebo	11SEP2020 (22)	09:06
3	BNT162b2	11MAR2021 (203)	10:31

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Peripheral artery stenosis	Right femoral artery stenosis	19NOV2020 (91)		NOV2020 ()			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	Y	Resolved (NOV2020)	NOT RELATED/OTHER: peripheral vascular disease	2	70	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	09OCT2020	
Completed	REPEAT SCREENING 1	11MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.1 cm	95.9 kg	30.6 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
inguinal hernia	Inguinal hernia	1981	Past
inguinal hernia surgical repair	Inguinal hernia repair	1981	Past
anxiety	Anxiety	JAN2010	Present
hyperlipidemia	Hyperlipidaemia	2014	Present
contact lens wearer	Corrective lens user	2015	Present
Myopia	Myopia	2015	Present
erectile dysfunction	Erectile dysfunction	AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	16:20
2	Placebo	16SEP2020 (21)	16:47
3	BNT162b2	10FEB2021 (168)	09:19
4	BNT162b2	08MAR2021 (194)	14:30

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	PSYCH	Anxiety	Increased Anxiety	02MAR2021 (188)		ONGOING			3	TC	Y
2	PSYCH	Major depression	Major Depressive Disorder, single episode	03MAR2021 (189)		ONGOING			3	TC	Y
3	PSYCH	Suicide attempt	Suicidal Attempt	03MAR2021 (189)		05MAR2021 (191)		3	3	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: Stress related to pandemic	3	21	Y

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	Yes	NOT RELATED/OTHER: Situational stress due to pandemic	3	22	Y
3	Resolved (05MAR2021)	NOT RELATED/OTHER: Worsening anxiety and depression due to pandemic	3	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	15OCT2020	
Completed	REPEAT SCREENING 1	10FEB2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	77	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
189.1 cm	96.4 kg	27 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tonsillectomy and adenoidectomy	Adenotonsillectomy	1949	Past
eye glass wearer	Corrective lens user	1949	Present
left knee meniscus surgical repair	Meniscus operation	2000	Past
laser vision correction surgery	Eye laser surgery	2005	Past
wet age-related macular degeneration	Neovascular age-related macular degeneration	2007	Present
interstitial cystitis	Cystitis interstitial	2010	Present
high blood pressure	Hypertension	2010	Present
prostate tumors, malignant	Prostate cancer	2016	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
aortic valve defect	Aortic valve disease	2017	Past
cataracts, bilaterally	Cataract	2017	Past
cataract surgery, bilaterally	Cataract operation	2018	Past
elevated LDL cholesterol	Low density lipoprotein increased	2018	Present
aortic valve replacement	Aortic valve replacement	JUN2020	Past
coronary artery disease	Coronary artery disease	JUN2020	Present
double cardiac bypass surgery	Coronary artery bypass	01JUN2020	Past
recurrent lower back pain from injury	Back injury	06AUG2020	Present
hole in right ear drum	Tympanic membrane perforation	18AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	10:28
2	BNT162b2	24SEP2020 (21)	09:43

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	MUSC	Arthralgia	generalized joint pain	25SEP2020 (22)		28OCT2020 (55)		34	2	TC	N

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
2	NEOPL	Breast cancer	Breast Cancer, Right Breast	08DEC2020 (96)		ONGOING			2	TCN	Y
3	NERV	Headache	headache	24SEP2020 (21)	22:00	28SEP2020 (25)		5	2	TC	N
4	MUSC	Myalgia	muscle pain	24SEP2020 (21)	22:00	28SEP2020 (25)		5	2	TC	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (28OCT2020)	Study Treatment	2	2	N
2	Yes	NOT RELATED/OTHER: Probable pre-existing malignant changes right breast	2	76	Y
3	Resolved (28SEP2020)	Study Treatment	2	1	N
4	Resolved (28SEP2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	22OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	75	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186.2 cm	92 kg	26.5 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
eye glass wearer	Corrective lens user	1949	Present
benign prostatic hyperplasia	Benign prostatic hyperplasia	1990	Past
eczema, bilaterally in arms and legs	Eczema	1990	Present
transurethral resection of prostate	Transurethral prostatectomy	1990	Past
elevated cholesterol, specific level unknown	Blood cholesterol increased	2010	Present
diabetes type II without any history of ketoacidosis	Type 2 diabetes mellitus	2010	Present
diabetic neuropathy of feet, bilaterally	Diabetic neuropathy	2011	Present
insomnia	Insomnia	2011	Present
atrial fibrillation	Atrial fibrillation	2012	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
coronary artery disease	Coronary artery disease	2012	Present
high blood pressure	Hypertension	2012	Present
full denture wearer	Denture wearer	2015	Present
edema in both legs	Oedema peripheral	2016	Present
edema in ankles	Oedema peripheral	2016	Present
osteoporosis	Osteoporosis	2016	Present
bilateral cataracts	Cataract	2018	Past
heart failure with reserved ejection fraction	Cardiac failure	2019	Present
decreased hearing in both ears	Hypoacusis	2019	Present
chronic obstructive pulmonary disease, severe	Chronic obstructive pulmonary disease	JAN2019	Present
peripheral neuropathy of feet, bilaterally	Neuropathy peripheral	APR2019	Present
urinary incontinence, urge	Urge incontinence	AUG2019	Present
chronic kidney disease, stage 3	Chronic kidney disease	OCT2019	Present
dizziness	Dizziness	JAN2020	Past
cataract surgery in both eyes	Cataract operation	MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	13:32

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RENAL	Acute kidney injury	acute kidney injury	08OCT2020 (31)		13OCT2020 (36)		6	2
2	RENAL	Acute kidney injury	acute kidney injury	18OCT2020 (41)		25OCT2020 (48)		8	2
3	GENRL	Asthenia	generalized weakness, intermittent	SEP2020 ()		ONGOING			2
4	CARD	Atrial fibrillation	Atrial fibrillation with rapid ventricular response	08OCT2020 (31)		13OCT2020 (36)		6	2
5	SKIN	Diabetic foot	diabetic foot ulcer, right foot	18OCT2020 (41)		ONGOING			2
6	INJ&P	Fall	Frequent falls	SEP2020 ()		ONGOING			2
7	METAB	Hypovolaemia	hypovolemia	08OCT2020 (31)		13OCT2020 (36)		6	2
8	METAB	Hypovolaemia	hypovolemia	18OCT2020 (41)		25OCT2020 (48)		8	2
9	VASC	Orthostatic hypotension	Hypotension, orthostatic	18OCT2020 (41)		25OCT2020 (48)		8	3
10	NERV	Paraesthesia	tingling of bilateral limbs, intermittent	SEP2020 ()		ONGOING			1
11	INJ&P	Skin abrasion	abrasion of right forearm	SEP2020 ()		ONGOING			1
12	NERV	Syncope	Syncope	08OCT2020 (31)		13OCT2020 (36)		6	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (13OCT2020)	NOT RELATED/OTHER: hypovolemia	1	31	N
2	TC	N	Resolved (25OCT2020)	NOT RELATED/OTHER: hypovolemia	1	41	N
3	N	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT			N
4	TC	N	Resolved (13OCT2020)	NOT RELATED/OTHER: Hypovolemia	1	31	N
5	TC	N	Yes	NOT RELATED/OTHER: Infection	1	41	N
6	N	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT			N
7	TC	N	Resolved (13OCT2020)	NOT RELATED/OTHER: due to poor intake	1	31	N

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
8	N	N	Resolved (25OCT2020)	NOT RELATED/OTHER: Inadequate intake	1	41	N
9	TC	Y	Resolved (25OCT2020)	NOT RELATED/OTHER: Hypovolemia due to poor oral intake	1	41	Y
10	N	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT			N
11	N	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT			N
12	TC	Y	Resolved (13OCT2020)	NOT RELATED/OTHER: Hypovolemia	1	31	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08SEP2020	
Withdrawn	VACCINATION	07DEC2020	LOST TO FOLLOW-UP

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	07DEC2020	LOST TO FOLLOW-UP

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1937	83	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.4 cm	78 kg	29.9 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
myopia	Myopia	1953	Present
tobacco use, past, cigarettes, 0.5 pack per day	Ex-tobacco user	1958	Past
hearing loss in both ears	Deafness bilateral	1970	Present
deviated septum repair	Nasal septal operation	1970	Past
allergic rhinitis, seasonal	Seasonal allergy	1970	Present
moderate intermittent asthma	Asthma	1985	Present
high blood pressure	Hypertension	1990	Present
heart attack	Myocardial infarction	1990	Past
mixed hyperlipdemia	Type V hyperlipidaemia	1990	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
benign prostatic hypertrophy with urinary obstruction	Benign prostatic hyperplasia	2010	Present
chronic kidney disease, stage 3	Chronic kidney disease	2010	Present
erectile dysfunction	Erectile dysfunction	2010	Present
chronic anemia	Anaemia	2011	Present
prostate cancer	Prostate cancer	2011	Past
prostatectomy	Prostatectomy	2011	Past
urinary incontinence	Urinary incontinence	2011	Present
hearing device wearer in both ears	Hearing aid user	2014	Present
chronic dry eye	Dry eye	2015	Present
glaucoma	Glaucoma	2015	Present
cataract surgery in both eyes	Cataract operation	2016	Past
edema in both feet	Oedema peripheral	2016	Present
atherosclerosis in both carotid arteries	Carotid arteriosclerosis	2018	Present
recurrent heartburn	Dyspepsia	2018	Present
transient ischemic attacks, more than one per subject, but not clear on specific number	Transient ischaemic attack	2018	Past
osteoarthritis in both hands	Osteoarthritis	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	08SEP2020 (1)	21:17
2	BNT162b2	29SEP2020 (22)	13:38

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	CARD	Atrioventricular block complete	complete heart block	08DEC2020 (92)		19DEC2020 (103)		12	4	TC/TCN
2	CARD	Bradycardia	symptomatic bradycardia	08DEC2020 (92)		19DEC2020 (103)		12	2	TCN
3	CARD	Cardiomegaly	mild cardiomegaly	17DEC2020 (101)		ONGOING			1	N
4	VASC	Hypertensive urgency	hypertensive urgency	17DEC2020 (101)		19DEC2020 (103)		3	2	TC
5	METAB	Hypokalaemia	hypokalemia	17DEC2020 (101)		18DEC2020 (102)		2	1	TC/TCN

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (19DEC2020)	NOT RELATED/OTHER: A-V conduction block	2	71	Y
2	N	Resolved (19DEC2020)	NOT RELATED/OTHER: complete heart block	2	71	N
3	N	Yes	NOT RELATED/CONCOMITANT NON-DRUG TREATMENT	2	80	N
4	N	Resolved (19DEC2020)	NOT RELATED/OTHER: Heart Block	2	80	N
5	N	Resolved (18DEC2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	80	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	03NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179.3 cm	79.5 kg	24.7 kg/m2	24SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
inguinal hernia repair	Inguinal hernia repair	1986	Past
hyperlipidemia	Hyperlipidaemia	1987	Present
benign prostatic hypertrophy	Benign prostatic hyperplasia	1988	Present
hypogonadism on left	Hypogonadism	1996	Present
scrotum cyst on left side	Scrotal cyst	1996	Past
basal cell carcinoma, multiple locations	Basal cell carcinoma	1999	Past
hypothyroidism	Hypothyroidism	1999	Present
scrotum cystectomy	Scrotal cystectomy	1999	Past
erectile dysfunction	Erectile dysfunction	2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
high blood pressure	Hypertension	2000	Present
anxiety	Anxiety	2001	Present
cataract in right eye	Cataract	2005	Past
cataract in left eye	Cataract	2005	Past
gastroesophageal reflux disease	Gastrooesophageal reflux disease	2005	Present
allergic rhinitis, seasonal	Seasonal allergy	2007	Present
chronic obstructive pulmonary disease, mild	Chronic obstructive pulmonary disease	2008	Present
cataract surgery in right eye	Cataract operation	2010	Past
right lens implant	Intraocular lens implant	2010	Past
Peyronie's Disease	Peyronie's disease	2011	Present
vertigo, intermittent	Vertigo	2011	Past
tenosynovitis in both thumbs	Tenosynovitis	2012	Present
cataract surgery in left eye	Cataract operation	2013	Past
left lens implant, left	Intraocular lens implant	2013	Past
recurrent neck pain	Neck pain	2013	Present
actinic keratosis	Actinic keratosis	2015	Present
difficulty swallowing	Dysphagia	2015	Past
esophageal dilation	Oesophageal dilation procedure	2015	Past
persistent rash on extremities	Rash	2015	Present
carpal tunnel syndrome, right hand	Carpal tunnel syndrome	2016	Past
carpal tunnel syndrome, left hand	Carpal tunnel syndrome	2016	Present
inguinal hernia repair	Inguinal hernia repair	2016	Past
retractile testis right	Testicular retraction	2016	Present
inguinal hernia	Inguinal hernia	2017	Past
melanoma on lower right back, excision	Skin neoplasm excision	2017	Past
carpal tunnel right hand repair	Carpal tunnel decompression	2018	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
enlarged prostate	Prostatomegaly	APR2019	Present
urolift procedure	Prostatic urethral lift procedure	MAY2019	Past
left bicep tear	Muscle rupture	DEC2019	Past
left bicep tear surgical repair	Muscle operation	JAN2020	Past
basal cell excision, multiple locations	Skin lesion removal	JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24SEP2020 (1)	20:04
2	Placebo	15OCT2020 (22)	11:45
3	BNT162b2	18FEB2021 (148)	14:15
4	BNT162b2	11MAR2021 (169)	14:25

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GENRL	Injection site pain	injection site pain	19FEB2021 (149)		24FEB2021 (154)		6	2	TC	N
2	INJ&P	Post procedural haematoma	Post-op Hematoma	30DEC2020 (98)		31DEC2020 (99)		2	3	N	Y

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
3	EAR	Vertigo	reoccurrence of vertigo	04OCT2020 (11)		06OCT2020 (13)		3	1	N	N
4	EAR	Vertigo	reoccurrence of vertigo	12NOV2020 (50)	11:00	12NOV2020 (50)	13:00	1	1	N	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (24FEB2021)	Study Treatment	3	2	N
2	Resolved (31DEC2020)	NOT RELATED/OTHER: Post-op orichiectomy	2	77	Y
3	Resolved (06OCT2020)	NOT RELATED/OTHER: Per physician, subject has history of vertigo; perhaps side eff of medications	1	11	N
4	Resolved (12NOV2020)	NOT RELATED/OTHER: history of vertigo, perhaps side effect medications	2	29	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24SEP2020	
Completed	VACCINATION	16NOV2020	
Completed	REPEAT SCREENING 1	18FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	Asian	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	50 kg	19.5 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
eye glass wearer	Corrective lens user	1979	Present
myopia	Myopia	1979	Present
postmenopausal state	Postmenopause	2016	Present
recurrent heartburn	Dyspepsia	2019	Present
palpitations	Palpitations	JUL2020	Present
cervical spine degeneration	Spinal osteoarthritis	JUL2020	Present
vitamin D deficiency	Vitamin D deficiency	JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25SEP2020 (1)	13:35
2	BNT162b2	16OCT2020 (22)	15:23

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Anaemia postoperative	post surgery anemia	11NOV2020 (48)		12NOV2020 (49)		2	1
2	CONG	Heart disease congenital	congenital heart anomaly	02NOV2020 (39)		15NOV2020 (52)		14	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	N	Resolved (12NOV2020)	NOT RELATED/OTHER: due to heart surgery	2	27	N
2	TC/TCN	Y	Resolved (15NOV2020)	NOT RELATED/OTHER: Congenital heart anomaly	2	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
Completed	VACCINATION	20NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	62	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179 cm	112 kg	35 kg/m2	30JUL2020 (-1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ETOH abuse	Alcohol abuse	2000	Past
Coronary Artery Disease	Coronary artery disease	2008	Present
Hyperlipidemia	Hyperlipidaemia	2008	Present
Hypertension	Hypertension	2008	Present
Open Heart Surgery	Cardiac operation	2009	Past
Benign Prostate Hyperplasia	Benign prostatic hyperplasia	2012	Present
Congestive Hearth Failure (CHF)	Cardiac failure congestive	2012	Present
Strock (CVA)	Cerebrovascular accident	2014	Past
Ischemic colitis	Colitis ischaemic	2017	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Colectomy Hartman	Colostomy	2017	Past
Bipolar Disorder	Bipolar disorder	2018	Present
Schizophrenia with paranoia	Schizophrenia	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31JUL2020 (1)	10:08
2	Placebo	21AUG2020 (22)	11:11
3	BNT162b2	22JAN2021 (176)	10:30
4	BNT162b2	12FEB2021 (197)	09:47

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PSYCH	Bipolar disorder	Worsening Bipolar Disorder	24AUG2020 (25)	08:00	04SEP2020 (36)	14:00	12	3
2	NERV	Syncope	Syncope	05OCT2020 (67)	10:00	05OCT2020 (67)	10:00	1	3
3	INFEC	Urinary tract infection	Urinary tract infection	05OCT2020 (67)	10:00	14OCT2020 (76)	10:00	10	3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN	Y	Resolved (04SEP2020)	NOT RELATED/OTHER: Psychiatric illness	2	4	Y
2	TC	N	Resolved (05OCT2020)	NOT RELATED/OTHER: Urinary tract Infection	2	46	N
3	N	Y	Resolved (14OCT2020)	NOT RELATED/OTHER: Escherichia coli	2	46	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30JUL2020	
Completed	VACCINATION	05OCT2020	
Completed	REPEAT SCREENING 1	22JAN2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	68	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
155.5 cm	63.5 kg	26.3 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Right knee meniscus tear	Meniscus injury	1999	Past
Right knee meniscus tear repair	Meniscus operation	1999	Past
Right knee meniscus tear repair	Meniscus operation	2004	Past
right knee meniscus tear repair	Meniscus operation	2009	Past
Allergy to dogs	Allergy to animal	2010	Present
ALLERGY TO DUST	Dust allergy	2010	Present
Postmenopausal	Postmenopause	2011	Present
Breast cancer	Breast cancer	2015	Past
knee replacement	Knee arthroplasty	13MAY2015	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Breast reconstruction	Breast reconstruction	2017	Past
Breast reduction	Mammoplasty	2017	Past
Hyperlipidemia	Hyperlipidaemia	2019	Present
Benign Pancreatic lesion	Pancreatic disorder	JUL2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	11:28
2	Placebo	04SEP2020 (22)	10:52
3	BNT162b2	04JAN2021 (144)	09:47
4	BNT162b2	25JAN2021 (165)	09:42

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INFEC	Asymptomatic bacteriuria	Asyntomatic Bacteriuria	22JAN2021 (162)	19:00	22JAN2021 (162)	19:00	1	2	TC
2	GASTR	Pancreatitis acute	Acute Pancreatitis	21JAN2021 (161)	19:00	22JAN2021 (162)	09:00	2	2	TC

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Resolved (22JAN2021)	NOT RELATED/OTHER: Bacteria	3	19	N
2	Y	Resolved (22JAN2021)	NOT RELATED/OTHER: Endoscopic retrograde cholangiopanc	3	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	02OCT2020	
Completed	REPEAT SCREENING 1	04JAN2021	
Completed	OPEN LABEL TREATMENT	25FEB2021	
	FOLLOW-UP		

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	75 kg	25.4 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
MYOPIA	Myopia	2000	Present
NEARSIGHTED	Myopia	2000	Present
SURGERY - VASECTOMY	Vasectomy	DEC2013	Past
RIGHT INGUINAL HERNIA	Inguinal hernia	2016	Past
SURGERY - RIGHT INGUINAL HERNIA REPAIR	Inguinal hernia repair	JAN2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28AUG2020 (1)	13:01
2	BNT162b2	23SEP2020 (27)	12:13

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Brain cancer metastatic	Metastatic Brain Tumor	08FEB2021 (165)	09:00	24FEB2021 (181)	09:00	17

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (24FEB2021)	NOT RELATED/OTHER: colon cancer	2	139	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINE	INFLUENZA VACCINE	NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	28OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1938	81	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	97.55 kg	29.9 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic Lower Back Pain	Back pain	1972	Present
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2008	Present
Elevated Cholesterol	Blood cholesterol increased	2008	Present
Hypertension	Hypertension	2008	Present
Osteoarthritis (Both Knees and Hands)	Osteoarthritis	2016	Present
Perennial Allergic Rhinitis	Rhinitis perennial	2017	Present
Right Partial Knee replacement	Knee arthroplasty	MAY2017	Past
Prostatitis	Prostatitis	11APR2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	17:00
2	Placebo	01SEP2020 (21)	10:18
3	BNT162b2	15JAN2021 (157)	10:45
4	BNT162b2	03FEB2021 (176)	10:23

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Intestinal obstruction	Intestinal Obstruction	20AUG2020 (9)		03SEP2020 (23)		15

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	Y	Resolved (03SEP2020)	NOT RELATED/OTHER: Unknown	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	29SEP2020	
Completed	REPEAT SCREENING 1	15JAN2021	
Completed	OPEN LABEL TREATMENT	04MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	105 kg	40.9 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OSTEOARTHRITIS (UPPER AND LOWER EXTREMITY)	Osteoarthritis	1980	Present
(RIGHT) HIP REPLACEMENT	Hip arthroplasty	1998	Past
(LEFT) PARTIAL HIP REPLACEMENT	Hip arthroplasty	2008	Past
DEPRESSION	Depression	2010	Present
ALLERGY TO SULFER	Drug hypersensitivity	2010	Present
ALLERGY TO NAPROXEN	Drug hypersensitivity	2010	Present
ALLERGY TO CODEINE	Drug hypersensitivity	2010	Present
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2010	Present
EDEMA (UPPER AND LOWER EXTREMITY)	Oedema peripheral	2010	Present

Medical History

Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
HYSTERECTOMY	Hysterectomy	2011	Past
POST MENOPAUSAL	Postmenopause	2011	Present
ALLERGY TO SHELL FISH	Food allergy	2014	Present
ATRIAL FIBRILLATION	Atrial fibrillation	2017	Present
ABLAtion	Exeresis	2018	Past
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2018	Present
HYPERTENSION	Hypertension	2018	Present
(RIGHT) SHOULDER SURGERY	Shoulder operation	2018	Past

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	17AUG2020 (1)	10:26
2	BNT162b2	08SEP2020 (23)	08:50

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	MUSC	Intervertebral disc compression	COMPRESSED CERVICAL DISC	15DEC2020 (121)		31DEC2020 (137)		17

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC	Y	Resolved (31DEC2020)	NOT RELATED/OTHER: IDIOPATHIC	2	99	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
shingles vaccine	VARICELLA ZOSTER VACCINE	FEB2021

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	12OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	76	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152.4 cm	54.09 kg	23.2 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	1949	Past
appendicitis	Appendicitis	1949	Past
tonsillectomy	Tonsillectomy	1953	Past
tonsillitis	Tonsillitis	1953	Past
rheumatoid arthritis	Rheumatoid arthritis	1970	Present
left fractured femur repair	Fracture treatment	01DEC1971	Past
right hammer toe	Foot deformity	1979	Past
bunions to left foot	Foot deformity	1979	Past
hammer toe repair to right foot	Toe operation	1979	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
left hand carpal tunnel syndrome	Carpal tunnel syndrome	1983	Past
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	1990	Present
post menopausal	Postmenopause	1994	Present
anxiety	Anxiety	2009	Present
bilateral cataracts	Cataract	2015	Present
left fractured femur	Femur fracture	01DEC2017	Past
gout	Gout	MAR2018	Present
left inner ear infection	Labyrinthitis	12SEP2018	Past
kidney stones	Nephrolithiasis	AUG2020	Past
ER visit for kidney stones	Nephrolithiasis	AUG2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03SEP2020 (1)	10:06
2	BNT162b2	24SEP2020 (22)	09:37

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Adrenal gland cancer	ADRENAL ADENOCARCINOMA	20OCT2020 (48)		ONGOING	
2	GENRL	Pain	right side pain	14SEP2020 (12)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		4	TC	Y	Yes	NOT RELATED/OTHER: IDIOPATHIC	2	27	Y
2		3	TC	N	Yes	NOT RELATED/OTHER: idiopathic	1	12	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
flu vaccine	INFLUENZA VACCINE	OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	10NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1999	21	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	85.5 kg	29.6 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
inguinal hernia repair	Inguinal hernia repair	1999	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11SEP2020 (1)	09:23
2	BNT162b2	02OCT2020 (22)	07:54

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INFEC	Pneumonia	DOUBLE PNEUMONIA	10MAR2021 (181)	12:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC	Y	Yes	NOT RELATED/OTHER: bacterial	2	160	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	06NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
191.77 cm	107.64 kg	29.2 kg/m2	19OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
abscess surgery	Abscess drainage	2000	Past
right broken ankle	Ankle fracture	2000	Past
right ankle surgery	Ankle operation	2000	Past
hypertension	Hypertension	2000	Present
perirectal abscess	Perirectal abscess	2000	Past
gout	Gout	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19OCT2020 (1)	11:07
2	BNT162b2	11NOV2020 (24)	10:52

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Overdose	HEROINE OVERDOSE	26NOV2020 (39)		28NOV2020 (41)		3	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (28NOV2020)	NOT RELATED/OTHER: SUBSTANCE ABUSE	2	16	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
FLU VACCINE	INFLUENZA VACCINE	28NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19OCT2020	
Completed	VACCINATION	09DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	63	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	83.3 kg	29.9 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
keloid scar (left knee)	Keloid scar	1966	Present
depression	Depression	1995	Present
cataplexy	Cataplexy	2000	Present
inguinal hernia	Inguinal hernia	2000	Past
inguinal hernia repair	Inguinal hernia repair	2000	Past
narcolepsy	Narcolepsy	2000	Present
obese	Obesity	2000	Present
overweight	Overweight	2000	Present
low testosterone	Blood testosterone decreased	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
erectile dysfunction	Erectile dysfunction	2010	Present
left shoulder injury	Limb injury	2011	Past
left shoulder replacement	Shoulder arthroplasty	2011	Past
pre-diabetic	Glucose tolerance impaired	2013	Present
hypertension	Hypertension	2015	Present
circadian rhythm sleep disorder	Circadian rhythm sleep disorder	2018	Present
reading glasses	Corrective lens user	2018	Present
sleep apnea	Sleep apnoea syndrome	2018	Present
hyperlipidemia	Hyperlipidaemia	FEB2020	Present
pulmonary nodule	Pulmonary mass	APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	14:57
2	Placebo	09SEP2020 (24)	13:19
3	BNT162b2	09FEB2021 (177)	10:15
4	BNT162b2	01MAR2021 (197)	11:26

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	HEPAT	Cholecystitis acute	acute cholecystitis	14OCT2020 (59)		17OCT2020 (62)		4	3
2	CARD	Myocardial infarction	myocardial infarction	18NOV2020 (94)		20NOV2020 (96)		3	2
3	INFEC	Urinary tract infection	urinary tract infection	15OCT2020 (60)		17OCT2020 (62)		3	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN	Y	Resolved (17OCT2020)	NOT RELATED/OTHER: gallstones	2	36	Y
2	TC/TCN	Y	Resolved (20NOV2020)	NOT RELATED/OTHER: hypertension and hyperlipidemia	2	71	Y
3	TC	N	Resolved (17OCT2020)	NOT RELATED/OTHER: bacterial infection	2	37	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
fluzone quadrivalent	INFLUENZA VACCINE INACT SPLIT 4V	10OCT2020
shingrix	VARICELLA ZOSTER VACCINE RGE (CHO)	06NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
Completed	REPEAT SCREENING 1	09FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	74	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.5 cm	92.7 kg	29.4 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
kidney stones	Nephrolithiasis	1986	Past
hypertension	Hypertension	2000	Present
benign prostatic hypertrophy	Benign prostatic hyperplasia	2014	Present
coronary artery bypass graft	Coronary artery bypass	2014	Past
Coronary artery disease	Coronary artery disease	2014	Past
hyperlipidemia	Hyperlipidaemia	2014	Present
heart attack	Myocardial infarction	2014	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01SEP2020 (1)	16:03
2	BNT162b2	23SEP2020 (23)	13:46

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Atrial fibrillation	Atrial fibrillation	NOV2020 ()		09DEC2020 (100)			2
2	CARD	Atrial fibrillation	Atrial fibrillation	10DEC2020 (101)		14DEC2020 (105)		5	2
3	CARD	Atrial fibrillation	Atrial fibrillation	03JAN2021 (125)		04JAN2021 (126)		2	2
4	CARD	Atrial fibrillation	Atrial fibrillation	05JAN2021 (127)		ONGOING			2
5	NEOPL	Non-small cell lung cancer stage IV	stage IV non-small cell lung cancer	16NOV2020 (77)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	N	Resolved (09DEC2020)	NOT RELATED/OTHER: heart condition, HTN	2		N
2	TCN	Y	Resolved (14DEC2020)	NOT RELATED/OTHER: CAD, heart condition, HTN	2	79	Y
3	TCN	Y	Resolved (04JAN2021)	NOT RELATED/OTHER: heart condition	2	103	Y
4	TC	N	Yes	NOT RELATED/OTHER: heart condition, CAD	2	105	N
5	N	Y	Yes	NOT RELATED/OTHER: lung cancer	2	55	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
flulaval quadrivalent	INFLUENZA VACCINE INACT SPLIT 4V	26OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1980	40	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
181 cm	99.4 kg	30.3 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
stuttering	Dysphemia	1986	Present
chocolate food allergy	Food allergy	1996	Present
seasonal allergies	Seasonal allergy	1996	Present
vasectomy	Vasectomy	2019	Past
right ACL tear	Ligament rupture	AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	10:07
2	Placebo	25SEP2020 (24)	09:37
3	BNT162b2	10FEB2021 (162)	10:49
4	BNT162b2	02MAR2021 (182)	09:56

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	VASC	Accelerated hypertension	accelerated hypertension	23JAN2021 (144)	15:00	27JAN2021 (148)	17:00	5
2	MUSC	Arthralgia	pain on right knee	30OCT2020 (59)		28DEC2020 (118)		60
3	VASC	Hypertension	Hypertension	26JAN2021 (147)		27JAN2021 (148)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (27JAN2021)	NOT RELATED/OTHER: Idiopathic	2	121	Y
2	1	TC	N	Resolved (28DEC2020)	NOT RELATED/OTHER: ACL tear	2	36	N
3	2	TC	N	Resolved (27JAN2021)	NOT RELATED/OTHER: stress	2	124	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	27OCT2020	
Completed	REPEAT SCREENING 1	10FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	54	Native Hawaiian or Other Pacific Islander	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.6 cm	115.8 kg	33.6 kg/m2	18SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
nearsighted	Myopia	1983	Present
ibuprofen drug allergy	Drug hypersensitivity	2017	Present
gout	Gout	2018	Present
hypertension	Hypertension	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18SEP2020 (1)	09:20
2	Placebo	07OCT2020 (20)	08:48

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Guillain-Barre syndrome	Guillain barre syndrome	29DEC2020 (103)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Yes	NOT RELATED/OTHER: secondary to COVID-19	2	84	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
flu vaccine	INFLUENZA VACCINE	25OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18SEP2020	
Completed	VACCINATION	04NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	28	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	100.4 kg	38.3 kg/m2	27OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
nearsighted	Myopia	2002	Present
hypothyroidism	Hypothyroidism	2005	Present
depression	Depression	2013	Present
obese	Obesity	2015	Present
overweight	Overweight	2015	Present
gastric bypass surgery	Gastric bypass	2016	Present
gastric bypass	Gastric bypass	2016	Present
fibromyalgia	Fibromyalgia	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27OCT2020 (1)	13:16
2	Placebo	20NOV2020 (25)	10:43
3	BNT162b2	17FEB2021 (114)	11:44
4	BNT162b2	10MAR2021 (135)	10:11

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Pancreatitis acute	acute pancreatitis	21NOV2020 (26)		24NOV2020 (29)		4

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Resolved (24NOV2020)	NOT RELATED/OTHER: pending records	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27OCT2020	
Completed	VACCINATION	16DEC2020	
Completed	REPEAT SCREENING 1	17FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	70	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	94.45 kg	38 kg/m2	31JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Left knee injury	Joint injury	15JAN2008	Past
Hypercholesterolemia	Hypercholesterolaemia	30JUN2008	Present
Left knee replacement	Knee arthroplasty	12DEC2012	Past
Right shoulder injury	Limb injury	30JUN2014	Past
Right shoulder repair	Shoulder operation	15AUG2014	Past
Hypertension	Hypertension	30JUN2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31JUL2020 (1)	15:57
2	BNT162b2	19AUG2020 (20)	15:13

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Hormone receptor positive breast cancer	Malignant neoplasm of upper-outer quadrant of right breast in female, estrogen receptor positive	02FEB2021 (187)	12:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	N	Y	Yes	NOT RELATED/OTHER: Breast Cancer	2	168	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31JUL2020	
Completed	VACCINATION	22SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	64	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline
No Vital Signs - Baseline

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1974	Present
Hypertension	Hypertension	1979	Present
Hyperlipidemia	Hyperlipidaemia	2000	Present
Osteopenia	Osteopenia	2010	Present
Spontaneous Coronary artery dissection	Coronary artery dissection	07DEC2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29JUL2020 (1)	14:44
2	BNT162b2	17AUG2020 (20)	09:51

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Coronary artery dissection	Spontaneous coronary artery dissection	28AUG2020 (31)		28AUG2020 (31)		1	4	N	Y
2	CARD	Myocardial ischaemia	Myocardial Ischemia	28AUG2020 (31)		28AUG2020 (31)		1	1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (28AUG2020)	NOT RELATED/OTHER: History of coronary artery dissection	2	12	Y
2	Resolved (28AUG2020)	NOT RELATED/OTHER: Suffered some myocardial ischemia at the time of dissection	2	12	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29JUL2020	
Withdrawn	VACCINATION	17SEP2020	WITHDRAWAL BY SUBJECT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	17SEP2020	WITHDRAWAL BY SUBJECT

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	51	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166.19 cm	95.27 kg	34.4 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Raynauds	Raynaud's phenomenon	1996	Present
seasonal allergies	Seasonal allergy	1996	Present
lap band surgery	Gastric banding	2009	Past
Post Menopausal	Postmenopause	2017	Present
hyperlipidemia	Hyperlipidaemia	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03AUG2020 (1)	11:41
2	Placebo	25AUG2020 (23)	12:24
3	BNT162b2	15JAN2021 (166)	11:42
4	BNT162b2	05FEB2021 (187)	13:57

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	B-cell lymphoma	B-Cell Lymphoma	03DEC2020 (123)	08:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Yes	NOT RELATED/OTHER: Unrelated medical event	2	101	Y

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
R-CHOP Chemotherapy	CYCLOPHOSPHAMIDE;DOXORUBICIN HYDROCHLORIDE;PREDNISONE;RITUXIMAB;VINCRISTINE SULFATE	19FEB2021	ONGOING	INTRAVENOUS
Prednisone	PREDNISONE	19FEB2021	ONGOING	ORAL

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	22SEP2020	
Completed	REPEAT SCREENING 1	15JAN2021	
Completed	OPEN LABEL TREATMENT	12MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184.81 cm	127 kg	37.1 kg/m2	06AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hyperlipidemia	Hyperlipidaemia	01AUG2010	Present
erectile dysfunction	Erectile dysfunction	01OCT2016	Present
elevated (htn) blood pressure	Hypertension	01OCT2017	Present
insomnia (sleep disorder)	Insomnia	01OCT2017	Present
chronic fatigue	Fatigue	2018	Present
umbilical hernia repair	Umbilical hernia repair	01AUG2018	Past
lymphadenopathy	Lymphadenopathy	MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	06AUG2020 (1)	14:47
2	BNT162b2	25AUG2020 (20)	11:34

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	SURG	Radioactive iodine therapy	Radioactive Iodine Treatment	08FEB2021 (187)		08FEB2021 (187)		1	3
2	NEOPL	Thyroid cancer	Thyroid Cancer	18SEP2020 (44)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (08FEB2021)	NOT RELATED/OTHER: Thyroid Cancer Treatment	2	168	N
2	N	Y	Yes	NOT RELATED/OTHER: Malignant Mass	2	25	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	06AUG2020	
Completed	VACCINATION	23SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.8 cm	104.45 kg	34.9 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	01OCT1965	Past
lung cancer	Lung neoplasm malignant	01OCT2011	Past
cardiac catheterization	Catheterisation cardiac	07DEC2011	Present
hyperlipidemia	Hyperlipidaemia	07DEC2011	Present
R upper lung lobectomy	Lung lobectomy	11JAN2012	Past
diminished lung function due to lung surgery	Pulmonary function test decreased	01FEB2012	Present
Gallbladder Attacks	Gallbladder disorder	2013	Present
hypertension	Hypertension	01APR2018	Present
pre-diabetes	Glucose tolerance impaired	01APR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07AUG2020 (1)	12:20
2	Placebo	28AUG2020 (22)	10:20
3	BNT162b2	13JAN2021 (160)	09:59
4	BNT162b2	03FEB2021 (181)	10:29

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	HEPAT	Cholecystitis acute	Acute Cholecystitis	16SEP2020 (41)	08:00	30SEP2020 (55)		15	3	TC	Y
2	GASTR	Diarrhoea	Diarrhea	19AUG2020 (13)		31AUG2020 (25)		13	1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (30SEP2020)	NOT RELATED/OTHER: Subject with history of gallstones and associated gallbladder wall thickening	2	20	Y
2	Resolved (31AUG2020)	NOT RELATED/OTHER: Directly related to subject's acute cholecystitis	1	13	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	25SEP2020	
Completed	REPEAT SCREENING 1	13JAN2021	
Completed	OPEN LABEL TREATMENT	04MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	74	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.04 cm	106.36 kg	33.9 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypercholesterol	Blood cholesterol increased	2000	Present
Hypertension	Hypertension	2010	Present
Atherosclerotic Cardiovascular Artery Disease	Arteriosclerosis	2011	Present
Coronary Artery Bypass Graft	Coronary artery bypass	2011	Past
Pacemaker	Cardiac pacemaker insertion	2016	Present
Seasonal Allergy	Seasonal allergy	2017	Present
Gout	Gout	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	12:55
2	Placebo	09SEP2020 (22)	13:50
3	BNT162b2	08FEB2021 (174)	12:15
4	BNT162b2	01MAR2021 (195)	11:57

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Aortic valve incompetence	Aortic Valve Dysfunction	01OCT2020 (44)		ONGOING			2
2	GENRL	Injection site pain	pain at injection site	09FEB2021 (175)	09:00	10FEB2021 (176)	11:00	2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Yes	NOT RELATED/OTHER: pre-existing medical history	2	23	Y
2	N	N	Resolved (10FEB2021)	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	07OCT2020	
Completed	REPEAT SCREENING 1	08FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.83 cm	55.45 kg	20.6 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Dry mouth	Dry mouth	01JUN2015	Present
Right Knee replacement	Knee arthroplasty	01MAR2017	Past
Left knee replacement	Knee arthroplasty	01MAR2017	Past
Right cataract surgery	Cataract operation	01NOV2019	Past
left cataract surgery	Cataract operation	14NOV2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	13:15
2	Placebo	14SEP2020 (22)	14:52
3	BNT162b2	13JAN2021 (143)	12:34
4	BNT162b2	03FEB2021 (164)	12:52

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Brain neoplasm	Brain Tumor	07FEB2021 (168)		ONGOING	
2	GENRL	Feeling abnormal	Brain Fog	07FEB2021 (168)		ONGOING	
3	GENRL	Gait disturbance	Slowed Gait	07FEB2021 (168)		ONGOING	
4	NERV	Headache	Headache	07FEB2021 (168)		ONGOING	
5	MUSC	Mobility decreased	Decreased Left Hand Mobility	07FEB2021 (168)		ONGOING	
6	NERV	Speech disorder	Slowed Speech	07FEB2021 (168)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		4	N	Y	Yes	NOT RELATED/OTHER: Brain Tumor	4	5	Y
2		2	N	N	Yes	NOT RELATED/OTHER: Brain Tumor	4	5	N
3		2	N	N	Yes	NOT RELATED/OTHER: Brain Tumor	4	5	N
4		2	N	N	Yes	NOT RELATED/OTHER: Brain Tumor	4	5	N

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5		2	N	N	Yes	NOT RELATED/OTHER: Brain Tumor	4	5	N
6		2	N	N	Yes	NOT RELATED/OTHER: Brain Tumor	4	5	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	13JAN2021	
Completed	OPEN LABEL TREATMENT	04MAR2021	
	FOLLOW-UP		

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Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.66 cm	69.27 kg	26.8 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
intravenous pyelogram dye allergy	Contrast media allergy	1956	Present
hypertension	Hypertension	01SEP1995	Present
post-menopausal (19yrs)	Postmenopause	2001	Present
hyperlipidemia	Hyperlipidaemia	01SEP2005	Present
GI Cramping	Gastrointestinal pain	2012	Present
Cholecystectomy	Cholecystectomy	01SEP2012	Past
breast cancer bilateral	Breast cancer	24JUN2015	Past
breast lumpectomy	Breast conserving surgery	01AUG2015	Past
Macular degeneration	Macular degeneration	01DEC2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02SEP2020 (1)	13:45
2	BNT162b2	25SEP2020 (24)	10:37

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	RENAL	Bladder irritation	Bladder irritation	21JAN2021 (142)		07FEB2021 (159)		18	1	TC	N
2	GASTR	Gastrointestinal pain	Worsening GI Cramping	08SEP2020 (7)	08:00	20SEP2020 (19)		13	3	N	N
3	GASTR	Small intestinal obstruction	Small Bowel Obstruction	08SEP2020 (7)		20SEP2020 (19)		13	3	N	Y
4	INFEC	Urinary tract infection	Urinary Tract Infection	21JAN2021 (142)		07FEB2021 (159)		18	2	TC	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (07FEB2021)	NOT RELATED/OTHER: Due to urinary tract infection	2	119	N
2	Resolved (20SEP2020)	NOT RELATED/OTHER: Subject has history of intermittent GI issues	1	7	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
3	Resolved (20SEP2020)	NOT RELATED/OTHER: Pre-existing condition (GI cramping). See Med Hx	1	7	Y
4	Resolved (07FEB2021)	NOT RELATED/OTHER: She has a prior history of urinary tract infections	2	119	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu vaccine	INFLUENZA VACCINE	15NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	23OCT2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	35	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.77 cm	96 kg	31 kg/m2	13OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
MIGRAINES	Migraine	1985	Present
Motor Vehicle Accident	Road traffic accident	11NOV2016	Past
RECONSTRUCTIVE SURGERIES	Surgery	11NOV2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13OCT2020 (1)	15:57
2	Placebo	03NOV2020 (22)	12:27
3	BNT162b2	15JAN2021 (95)	12:05
4	BNT162b2	04FEB2021 (115)	14:54

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GASTR	Abdominal pain upper	Right Upper Quadrant Abdominal Pain	14FEB2021 (125)		17FEB2021 (128)		4	3	N	N
2	RESP	Asthma exercise induced	Exercise induced Asthma	NOV2020 ()		ONGOING			2	TC	N
3	VASC	Deep vein thrombosis	Deep Vein Thrombosis Left Leg	15FEB2021 (126)		ONGOING			4	N	Y
4	RESP	Pulmonary embolism	Bilateral Pulmonary Embolisms	15FEB2021 (126)		ONGOING			4	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (17FEB2021)	NOT RELATED/OTHER: Complication related to bilateral pulmonary embolism	4	11	N
2	Yes	NOT RELATED/OTHER: Exercise Induced			N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	Yes	NOT RELATED/OTHER: Recent surgery, unprovoked	4	12	Y
4	Yes	NOT RELATED/OTHER: Recent surgery, unprovoked	4	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13OCT2020	
Completed	VACCINATION	01DEC2020	
Completed	REPEAT SCREENING 1	15JAN2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	12MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	86 kg	34.9 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
nearsighted	Myopia	1975	Present
generalized pain	Pain	1980	Present
abdominal apron	Fat tissue increased	1999	Past
seasonal affective disorder	Seasonal affective disorder	1999	Present
insomnia	Insomnia	2000	Present
lower back pain (L5 Region)	Back pain	2007	Present
degenerative disk disease- back	Intervertebral disc degeneration	JAN2007	Past
Rods placed in back	Spinal operation	29MAR2007	Past
hypertension	Hypertension	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tummy tuck	Abdominoplasty	APR2017	Past
post menopausal	Postmenopause	2018	Present
right hip osteoarthritis	Osteoarthritis	APR2018	Past
right hip replacement	Hip arthroplasty	29MAY2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27AUG2020 (1)	15:09
2	BNT162b2	18SEP2020 (23)	10:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Breast cancer	Breast Cancer of Right Breast	04FEB2021 (162)		ONGOING			3
2	GENRL	Chills	Chills	19SEP2020 (24)	03:00	20SEP2020 (25)	08:00	2	1
3	GENRL	Fatigue	Fatigue	19SEP2020 (24)	09:00	20SEP2020 (25)	08:00	2	1
4	NERV	Headache	Headache	19SEP2020 (24)	03:00	20SEP2020 (25)	08:00	2	1
5	INJ&P	Procedural dizziness	Post Anesthesia Dizziness	03MAR2021 (189)		04MAR2021 (190)		2	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: neoplastic lesion	2	140	N
2	N	N	Resolved (20SEP2020)	Study Treatment	2	2	N
3	N	N	Resolved (20SEP2020)	Study Treatment	2	2	N
4	TC	N	Resolved (20SEP2020)	Study Treatment	2	2	N
5	N	Y	Resolved (04MAR2021)	NOT RELATED/OTHER: medication reaction	2	167	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	19OCT2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	41	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.1 cm	53.2 kg	19.8 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
spinal fusion	Spinal fusion surgery	1992	Past
spine surgery	Spinal operation	JUN1992	Past
chronic back pain	Back pain	2002	Present
scoliosis	Scoliosis	2002	Present
spondylolisthesis	Spondylolisthesis	2002	Present
spine surgery	Spinal operation	AUG2004	Past
spine surgery	Spinal operation	DEC2005	Past
spine surgery	Spinal operation	MAY2010	Past
migraines	Migraine	2012	Present

Medical History

Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
anxiety	Anxiety	2015	Present
depression	Depression	2015	Present
Failed back surgical syndrome	Post laminectomy syndrome	OCT2016	Present
spinal cord stimulator bilateral implantation	Spinal nerve stimulator implantation	OCT2016	Past
spinal neurostimulator lead bilateral insertion	Spinal nerve stimulator implantation	10FEB2017	Past
removal of spinal cord stimulator	Medical device removal	21JUN2019	Past

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	31AUG2020 (1)	13:15
2	Placebo	21SEP2020 (22)	11:36
3	BNT162b2	09FEB2021 (163)	15:01
4	BNT162b2	02MAR2021 (184)	12:32

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	NERV	Dizziness	Dizziness	14JAN2021 (137)		29JAN2021 (152)		16	2	N
2	NERV	Dizziness	Dizziness	15FEB2021 (169)		25FEB2021 (179)		11	3	N
3	NERV	Dizziness	Lightheadedness	02OCT2020 (33)	19:00	ONGOING			3	TC
4	NERV	Dizziness	Lightheadedness	14JAN2021 (137)		29JAN2021 (152)		16	2	N

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
5	GENRL	Fatigue	Fatigue	15FEB2021 (169)		25FEB2021 (179)		11	3	N
6	NERV	Headache	Headache	14JAN2021 (137)		29JAN2021 (152)		16	3	N
7	NERV	Headache	Headache	15FEB2021 (169)		25FEB2021 (179)		11	3	N
8	CARD	Junctional ectopic tachycardia	Junctional ectopic tachycardia	02OCT2020 (33)		06JAN2021 (129)		97	4	TC/TCN
9	NERV	Presyncope	Near symcopal episode	2021 ()		ONGOING			2	N
10	CARD	Tachycardia	Tachycardia	03OCT2020 (34)		ONGOING			3	TC
11	CARD	Tachycardia	Tachycardia	13JAN2021 (136)		ONGOING			2	TC

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Resolved (29JAN2021)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	116	N
2	N	Resolved (25FEB2021)	NOT RELATED/CONCOMITANT DRUG TREATMENT	3	7	N
3	N	Yes	NOT RELATED/OTHER: supraventricular tachycardia	2	12	N
4	N	Resolved (29JAN2021)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	116	N
5	N	Resolved (25FEB2021)	NOT RELATED/CONCOMITANT DRUG TREATMENT	3	7	N
6	N	Resolved (29JAN2021)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	116	N
7	N	Resolved (25FEB2021)	NOT RELATED/CONCOMITANT DRUG TREATMENT	3	7	N
8	Y	Resolved (06JAN2021)	NOT RELATED/OTHER: Aberrant cardiac ectopic rhythm locus	2	12	Y
9	N	Yes	NOT RELATED/OTHER: likely related to patient's tachycardia			N
10	N	Yes	NOT RELATED/OTHER: supraventricular tachycardia	2	13	N
11	N	Yes	NOT RELATED/OTHER: sinus tachycardia	2	115	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	19OCT2020	
Completed	REPEAT SCREENING 1	09FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	70	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	73.64 kg	23.9 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cerebral vascular accident	Cerebrovascular accident	25AUG2017	Past
Paroxysmal atrial fibrillation	Atrial fibrillation	19JAN2018	Present
Hiatal hernia	Hiatus hernia	09APR2018	Present
Hypertension	Hypertension	09APR2018	Present
Hypercholesterolemia	Hypercholesterolaemia	12JUL2018	Present
Migraines	Migraine	12JUL2018	Present
Benign prostatic hyperplasia	Benign prostatic hyperplasia	20MAY2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03AUG2020 (1)	13:58
2	Placebo	28AUG2020 (26)	11:48
3	BNT162b2	04JAN2021 (155)	14:38
4	BNT162b2	25JAN2021 (176)	13:17

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GENRL	Injection site pain	injection site pain	04JAN2021 (155)	21:00	06JAN2021 (157)		3	1	N	N
2	GENRL	Injection site pain	injection site pain	25JAN2021 (176)		26JAN2021 (177)		2	1	N	N
3	VASC	Orthostatic hypotension	Possible postural hypotension	31AUG2020 (29)	14:00	31AUG2020 (29)	16:00	1	3	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (06JAN2021)	Study Treatment	3	1	N

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	Resolved (26JAN2021)	Study Treatment	4	1	N
3	Resolved (31AUG2020)	NOT RELATED/OTHER: Neurology noted indicated likely postural hypoperfusion	2	4	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	25SEP2020	
Completed	REPEAT SCREENING 1	04JAN2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	25FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	70.59 kg	22.9 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to penicillin	Drug hypersensitivity	1947	Present
Hysterectomy	Hysterectomy	1973	Past
Hypertension	Hypertension	12JUL2007	Present
Atrial fibrillation	Atrial fibrillation	11APR2015	Present
Recurrent Blepharitis	Blepharitis	23AUG2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05AUG2020 (1)	10:22
2	BNT162b2	29AUG2020 (25)	09:46

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Colitis	Colitis	05SEP2020 (32)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	28SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1958	62	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
177.8 cm	89.86 kg	28.4 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
History of smoking	Tobacco user	1975	Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	11AUG2020 (1)	10:28
2	BNT162b2	01SEP2020 (22)	14:14

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	VASC	Aortic aneurysm	Ascending Aortic Aneurysm	04JAN2021 (147)		ONGOING	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		4	TCN	Y	Yes	NOT RELATED/OTHER: Unknown	2	126	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	82 kg	28.3 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Major Depressive Disorder	Major depression	2018	Present
Schizophrenia	Schizophrenia	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	13:41
2	Placebo	04SEP2020 (24)	15:20

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Craniocerebral injury	Closed head injury	19AUG2020 (8)		19AUG2020 (8)		1	3
2	PSYCH	Suicidal ideation	Suicidal Ideation	19AUG2020 (8)		21AUG2020 (10)		3	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (19AUG2020)	NOT RELATED/OTHER: Subject was in "an altercation"	1	8	N
2	TC	Y	Resolved (21AUG2020)	NOT RELATED/OTHER: History of Major Depressive Disorder	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Withdrawn	VACCINATION	04NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	04NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152.4 cm	105.64 kg	45.4 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
depression	Depression	1977	Present
cesarean section	Caesarean section	1982	Past
complete hysterectomy	Hysterectomy	2005	Past
ADHD	Attention deficit hyperactivity disorder	2010	Present
cervical fusion	Spinal fusion surgery	2017	Past
hypertension	Hypertension	2018	Present
Spondylosis	Spinal osteoarthritis	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10SEP2020 (1)	13:58
2	BNT162b2	02OCT2020 (23)	14:55

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Spondylolisthesis	Worsening of spondylolisthesis	01JAN2021 (114)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Yes	NOT RELATED/OTHER: History of spondylosis	2	92	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	30OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	43	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	114.55 kg	39.5 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic to penicillin	Drug hypersensitivity	1976	Present
Anemia	Anaemia	1990	Past
Gallbladder disease (inflammation)	Cholecystitis	JUL1994	Past
Surgery for gallbladder removal	Cholecystectomy	AUG1994	Past
Allergic to Monosodium glutamate (MSG)	Reaction to food additive	1996	Present
Migraines	Migraine	1997	Present
obesity	Obesity	1998	Present
Roux-en-y gastric bypass	Gastric bypass	OCT1998	Past
LEEP surgery	Loop electrosurgical excision procedure	NOV2002	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Stomach ulcers	Gastric ulcer	2007	Past
Dilation and curettage (D&C) procedure	Uterine dilation and curettage	2010	Past
Gestational diabetes	Gestational diabetes	2011	Past
Hospitalized for bronchitis	Bronchitis	MAY2011	Past
Pre-diabetic	Glucose tolerance impaired	2013	Past
Bypass surgery revision	Vascular graft	JAN2015	Past
Allergic to sulfur	Drug hypersensitivity	2018	Present
Seasonal Allergies	Seasonal allergy	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	12:27
2	Placebo	15SEP2020 (22)	10:37
3	BNT162b2	26JAN2021 (155)	11:00
4	BNT162b2	16FEB2021 (176)	10:21

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	GASTR	Ileus	Ileus	25DEC2020 (123)		28DEC2020 (126)		4	3	N	Y

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (28DEC2020)	NOT RELATED/OTHER: it is not related to vaccine, declared as ileus. Cause is idiopathic.	2	102	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	13OCT2020	
Completed	REPEAT SCREENING 1	26JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	74	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.75 cm	76.82 kg	30.4 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Eyelid surgery	Eyelid operation	1980	Past
Hypothyroidism, controlled	Hypothyroidism	1998	Present
Tear duct surgery	Lacrimal duct procedure	2000	Past
Liposuction	Liposuction	2000	Past
Exfoliation glaucoma, stable	Exfoliation glaucoma	2005	Present
High blood pressure, stable	Hypertension	2010	Present
Trabeculectomy	Trabeculectomy	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	11:50
2	Placebo	17SEP2020 (21)	13:07
3	BNT162b2	19JAN2021 (145)	13:06
4	BNT162b2	09FEB2021 (166)	12:57

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Atrial fibrillation	atrial fibrillation	12DEC2020 (107)		13DEC2020 (108)		2	3	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (13DEC2020)	NOT RELATED/OTHER: idiopathic, patient was advised to follow up with the cardiologist	2	87	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	20OCT2020	
Completed	REPEAT SCREENING 1	19JAN2021	
Completed	OPEN LABEL TREATMENT	09MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	68.18 kg	21.8 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Poison ivy allergy	Dermatitis contact	1973	Present
Bactrim allergy	Drug hypersensitivity	1985	Present
Depression, well-controlled	Depression	2010	Present
Right hip replacement	Hip arthroplasty	2015	Past
palpitation	Palpitations	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	12:32
2	Placebo	17SEP2020 (21)	10:35
3	BNT162b2	07JAN2021 (133)	11:32
4	BNT162b2	28JAN2021 (154)	10:21

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Pericardial effusion	small pericardial effusion	08OCT2020 (42)		ONGOING			2	N	N
2	CARD	Tachycardia	tachycardia	07OCT2020 (41)	10:00	08OCT2020 (42)	12:00	2	3	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: the volunteer has been having the tachycardia events in the past	2	22	N
2	Resolved (08OCT2020)	NOT RELATED/OTHER: patient has history of palpitation for the past 4 months	2	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	20OCT2020	
Completed	REPEAT SCREENING 1	07JAN2021	
Completed	OPEN LABEL TREATMENT	25FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	34	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	66.36 kg	22.2 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Wisdom teeth removal	Wisdom teeth removal	2003	Past
Depression, controlled	Depression	2016	Present
Hypothyroidism, controlled	Hypothyroidism	2017	Present
Seasonal allergies	Seasonal allergy	2017	Present
c-section delivery	Delivery	10JAN2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	14:52
2	Placebo	24NOV2020 (86)	09:59
3	BNT162b2	21JAN2021 (144)	10:42
4	BNT162b2	11FEB2021 (165)	13:41

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Dizziness	dizziness	24SEP2020 (25)		25SEP2020 (26)		2	2
2	MUSC	Intervertebral disc protrusion	disc herniation	14SEP2020 (15)		ONGOING			2
3	NERV	Paraesthesia	Paresthesias of Skin	21SEP2020 (22)		28SEP2020 (29)		8	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (25SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	25	N
2	TC	N	Yes	NOT RELATED/OTHER: Disc Herniation at L5-S1	1	15	N
3	TC	Y	Resolved (28SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	07JAN2021	
Completed	REPEAT SCREENING 1	21JAN2021	
Completed	OPEN LABEL TREATMENT	11MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	94.64 kg	30.7 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	03OCT1988	Present
GERD	Gastrooesophageal reflux disease	23JUN1997	Present
Hypercholesterolemia	Hypercholesterolaemia	23JUN1997	Present
Spinal Stenosis	Spinal stenosis	15JUN2009	Present
Stroke wit minimal residual	Cerebrovascular accident	15AUG2016	Present
Post herpetic neuralgia	Post herpetic neuralgia	19FEB2020	Present
Melanoma	Malignant melanoma	06APR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13AUG2020 (1)	13:30
2	Placebo	02SEP2020 (21)	11:00
3	BNT162b2	06JAN2021 (147)	11:39
4	BNT162b2	27JAN2021 (168)	11:18

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	MUSC	Pain in extremity	Arm Pain	27JAN2021 (168)		28JAN2021 (169)		2	1	N	N
2	NERV	Transient ischaemic attack	Transient Ischemic Attack	11JAN2021 (152)		12JAN2021 (153)		2	2	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (28JAN2021)	Study Treatment	4	1	N
2	Resolved (12JAN2021)	NOT RELATED/OTHER: The patient suffers of hypertension and hypercholesterolemia.	3	6	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	30SEP2020	
Completed	REPEAT SCREENING 1	06JAN2021	
Completed	OPEN LABEL TREATMENT	24FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	82.82 kg	24.7 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 2 Diabetes	Type 2 diabetes mellitus	1990	Present
Hypertension	Hypertension	2000	Present
Statin Allergy	Drug hypersensitivity	2005	Present
Peripheral Vascular Disease	Peripheral vascular disorder	2015	Present
Amputation of left and right great toe	Toe amputation	2015	Past
Coronary Stent Placement	Coronary arterial stent insertion	NOV2017	Past
Coronary Artery Blockage	Coronary artery occlusion	NOV2017	Past
Coronary Artery Disease	Coronary artery disease	2018	Present
High Cholesterol	Blood cholesterol increased	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	11:51
2	BNT162b2	15SEP2020 (22)	10:02

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INV	Blood glucose increased	Increase in baseline blood sugar	01SEP2020 (8)		ONGOING			2	TC	N
2	CARD	Coronary artery occlusion	Mid Left Anterior Descending Coronary Artery Occlusion	20JAN2021 (149)	00:00	20JAN2021 (149)	00:00	1	2	TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: History of type 2 diabetes. Over indulgence and not monitoring blood sugar	1	8	N
2	Resolved (20JAN2021)	NOT RELATED/CONCOMITANT NON-DRUG TREATMENT	2	128	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	65.64 kg	21.3 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Claudication	Intermittent claudication	JUN2005	Past
Bradycardia	Bradycardia	JUL2010	Past
Myocardial Infarction	Myocardial infarction	10JUL2010	Past
Lung Cancer	Lung neoplasm malignant	DEC2017	Past
Chronic cough (smokers cough)	Cough	DEC2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28AUG2020 (1)	13:05
2	BNT162b2	16SEP2020 (20)	12:00

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Chest injury	Bruised ribs	07OCT2020 (41)		21OCT2020 (55)		15
2	RESP	Chronic obstructive pulmonary disease	Chronic Obstructive Pulmonary Disease with acute exacerbation	06FEB2021 (163)		12FEB2021 (169)		7
3	INJ&P	Fall	Fall off ladder	07OCT2020 (41)		07OCT2020 (41)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (21OCT2020)	NOT RELATED/OTHER: accident	2	22	N
2	3	TC/TCN	Y	Resolved (12FEB2021)	NOT RELATED/OTHER: Pneumonia	2	144	Y
3	1	TCN	N	Resolved (07OCT2020)	NOT RELATED/OTHER: fall	2	22	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	14OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	99.55 kg	30.5 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Clot Right Leg	Thrombosis	1972	Past
Pulmonary Embolism	Pulmonary embolism	1978	Past
High Cholesterol	Blood cholesterol increased	2016	Present
DVT	Deep vein thrombosis	15DEC2018	Past
benign tumor of thymus	Benign neoplasm of thymus	JUL2019	Past
Thymectomy	Thymectomy	JUL2019	Past
cyst of the thymus gland	Thymic cyst	JUL2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	09:26
2	BNT162b2	21SEP2020 (22)	13:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Atelectasis	Bibasilar Atelectasis on chest xray	10SEP2020 (11)		10OCT2020 (41)		31	1
2	RESP	Interstitial lung disease	Interstitial Pneumonitis	09SEP2020 (10)		09SEP2020 (10)		1	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (10OCT2020)	NOT RELATED/OTHER: low inspiratory effort	1	11	N
2	N	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: ideopathic origin	1	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	26OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	105.45 kg	36.3 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2010	Present
Type 1 diabetes	Type 1 diabetes mellitus	2011	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	14:24

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	21SEP2020 (21)	13:39
3	BNT162b2	23FEB2021 (176)	13:16

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Cyst	Cyst-like mass on back of head	07SEP2020 (7)		10SEP2020 (10)		4	2
2	METAB	Hyperglycaemia	Hyperglycemia	11JAN2021 (133)		13JAN2021 (135)		3	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (10SEP2020)	NOT RELATED/OTHER: Unknown	1	7	N
2	N	Y	Resolved (13JAN2021)	NOT RELATED/OTHER: Type 1 Diabetes	2	113	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	19OCT2020	
Completed	REPEAT SCREENING 1	23FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	76	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	120.45 kg	50.1 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1970	Present
Hypertension	Hypertension	1990	Present
Post Menopausal	Postmenopause	1995	Past
Acid Reflux	Gastrooesophageal reflux disease	2000	Present
COPD	Chronic obstructive pulmonary disease	2014	Present
High Cholesterol	Blood cholesterol increased	2015	Present
Controlled Sleep Apnea	Sleep apnoea syndrome	2015	Present
Cardiac Arrhythmia	Arrhythmia	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	13:15
2	Placebo	23SEP2020 (22)	12:29
3	BNT162b2	25JAN2021 (146)	11:52
4	BNT162b2	15FEB2021 (167)	13:14

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Pneumonia	Pneumonia	17FEB2021 (169)		21FEB2021 (173)		5	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (21FEB2021)	NOT RELATED/OTHER: Pneumonia Hospitilization	4	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	21OCT2020	
Completed	REPEAT SCREENING 1	25JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	51	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	87.73 kg	28.5 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasovagal Syncope	Syncope	2000	Present
High Cholesterol	Blood cholesterol increased	2003	Present
Depression	Depression	2005	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03SEP2020 (1)	09:45
2	BNT162b2	25SEP2020 (23)	11:10

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Atrioventricular block first degree	1 Degree AV block	27SEP2020 (25)		27SEP2020 (25)		1	2
2	CARD	Bradycardia	Acute Bradycardia	27SEP2020 (25)		28SEP2020 (26)		2	3
3	NERV	Syncope	syncope	27SEP2020 (25)	10:00	29SEP2020 (27)	16:00	3	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (27SEP2020)	NOT RELATED/OTHER: Idiopathic origin	2	3	N
2	TC	Y	Resolved (28SEP2020)	NOT RELATED/OTHER: Vasovagal response	2	3	Y
3	N	Y	Resolved (29SEP2020)	NOT RELATED/OTHER: History of vasovagal syncope	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	28OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.99 cm	102.91 kg	33.9 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Post traumatic stress disorder	Post-traumatic stress disorder	2014	Present
Total left hip replacement	Hip arthroplasty	2015	Past
Hypertension	Hypertension	2016	Present
insomnia	Insomnia	2016	Present
Osteoarthritis	Osteoarthritis	2016	Present
Chronic pain syndrome	Pain	2016	Present
Surgical repair of the right bicep	Muscle operation	2017	Past
Tear of the right bicep	Muscle rupture	2017	Past
Depressive disorder	Depression	02SEP2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25SEP2020 (1)	13:21
2	BNT162b2	14OCT2020 (20)	12:37

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	RESP	Pulmonary embolism	Pulmonary Emboli	08NOV2020 (45)		15NOV2020 (52)		8	2	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (15NOV2020)	NOT RELATED/OTHER: Attributed PE to prior COVID infection-negative COVID in Hosp	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25SEP2020	
Completed	VACCINATION	14JAN2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	138.82 kg	41.4 kg/m2	21OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Morphine Allergy	Drug hypersensitivity	1999	Present
Type 2 diabetes mellitus	Type 2 diabetes mellitus	2010	Present
Post traumatic stress disorder	Post-traumatic stress disorder	2018	Present
High cholesterol	Blood cholesterol increased	2019	Present
Hypertension	Hypertension	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21OCT2020 (1)	12:07
2	Placebo	10NOV2020 (21)	11:35
3	BNT162b2	23FEB2021 (126)	12:00

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	COVID-19	COVID-19	14JAN2021 (86)		20JAN2021 (92)		7	2
3	GENRL	Injection site pain	Injection site pain, left arm	10NOV2020 (21)	21:00	11NOV2020 (22)	07:00	2	1
5	MUSC	Pain in extremity	Arm Pain	23FEB2021 (126)	16:00	24FEB2021 (127)		2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (20JAN2021)	NOT RELATED/OTHER: COVID + Hospitalization	2	66	Y
3	TC	N	Resolved (11NOV2020)	Study Treatment	2	1	N
5	N	N	Resolved (24FEB2021)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21OCT2020	
Completed	VACCINATION	09DEC2020	
Completed	REPEAT SCREENING 1	23FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	102.73 kg	38.8 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
cervical radiculopathy	Cervical radiculopathy	2000	Present
allergic to oxycodone	Drug hypersensitivity	2000	Present
allergic to hydrocodone	Drug hypersensitivity	2000	Present
Degenerative disc disease,lumbar	Intervertebral disc degeneration	2000	Present
menopausal	Menopause	2001	Present
chronic rhinitis	Rhinitis	2011	Present
factor V leiden disorder	Factor V Leiden mutation	2014	Present
intractable migraine without aura	Migraine without aura	2015	Present
GERD	Gastrooesophageal reflux disease	2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
right foot pain	Pain in extremity	2017	Present
allergic doxycycline	Drug hypersensitivity	2018	Present
hypertension	Hypertension	2018	Present
Mild coronary artery disease	Coronary artery disease	2019	Present
Insomnia	Insomnia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09SEP2020 (1)	13:39
2	Placebo	02OCT2020 (24)	09:44

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Acute respiratory failure	Acute hypoxemic respiratory failure	29JAN2021 (143)		06FEB2021 (151)		9	4
2	INFEC	COVID-19	COVID-19	29JAN2021 (143)		06FEB2021 (151)		9	4

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN	Y	Resolved (06FEB2021)	NOT RELATED/OTHER: COVID-19	2	120	Y
2	TC/TCN	Y	Resolved (06FEB2021)	NOT RELATED/OTHER: COVID-19 Illness	2	120	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	30OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	57.73 kg	21.8 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	14SEP2012	Present
seasonal allergies	Seasonal allergy	03DEC2012	Present
Anxiety	Anxiety	13SEP2018	Present
menopause	Menopause	2019	Present
mennorrhagia	Menorrhagia	18APR2019	Present
IRREGULAR MENSTRUAL CYCLE	Menstruation irregular	18APR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	12:46
2	Placebo	30SEP2020 (21)	11:57
3	BNT162b2	26FEB2021 (170)	11:57

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Abdominal pain lower	Left Lower Quadrant Pain	25SEP2020 (16)		ONGOING		
2	INV	Blood chloride decreased	Decreased Chloride (94)	24SEP2020 (15)		ONGOING		
3	INV	Blood sodium decreased	Decreased Sodium (131)	24SEP2020 (15)		ONGOING		
4	INV	High density lipoprotein increased	Increased HDL (95)	18SEP2020 (9)		ONGOING		
5	REPRO	Ovarian mass	Ovarian Mass	21SEP2020 (12)		ONGOING		
6	INV	Urine ketone body present	Trace Ketones (Urinalysis)	24SEP2020 (15)		ONGOING		
7	INV	White blood cells urine positive	Trace Leukocytes in Urinalysis	24SEP2020 (15)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TCN	N	Yes	NOT RELATED/OTHER: Not related to the study treatment	1	16	N
2	1	N	N	Yes	NOT RELATED/OTHER: Not related to study treatment	1	15	N
3	1	N	N	Yes	NOT RELATED/OTHER: Not related to the study	1	15	N

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	1	N	N	Yes	NOT RELATED/OTHER: Not related to the study treatment	1	9	N
5	2	TCN	Y	Yes	NOT RELATED/OTHER: Ovarian mass of unknown origin	1	12	Y
6	1	N	N	Yes	NOT RELATED/OTHER: Not related to study treatment	1	15	N
7	1	N	N	Yes	NOT RELATED/OTHER: Not related to the study treatment	1	15	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	28OCT2020	
Completed	REPEAT SCREENING 1	26FEB2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152 cm	72.8 kg	31.5 kg/m2	24SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
intermittent heart murmur	Cardiac murmur	1954	Present
lyrica allergy	Drug hypersensitivity	2012	Present
gabapentin allergy	Drug hypersensitivity	2012	Present
hernia	Hernia	2013	Present
lumbar degenerative disc disease	Intervertebral disc degeneration	2013	Present
partial denture - WEARER	Denture wearer	2016	Present
right knee osteoarthritis	Osteoarthritis	2018	Present
left thumb osteoarthritis	Osteoarthritis	2018	Present
type 2 diabetes	Type 2 diabetes mellitus	2019	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
femoral hernia	Femoral hernia	JAN2020	Past
hyperlipidemia	Hyperlipidaemia	JAN2020	Present
hypertension	Hypertension	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24SEP2020 (1)	13:20
2	Placebo	15OCT2020 (22)	12:31
3	BNT162b2	22JAN2021 (121)	13:55
4	BNT162b2	12FEB2021 (142)	11:47

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Cervicogenic headache	Cervicogenic headache	30OCT2020 (37)		03NOV2020 (41)		5
2	INJ&P	Fall	fall	OCT2020 ()		OCT2020 ()		
3	INJ&P	Fall	fall	OCT2020 ()		OCT2020 ()		
4	INJ&P	Fall	fall	OCT2020 ()		OCT2020 ()		
5	INJ&P	Head injury	Acute Trauma Head Injury	30OCT2020 (37)	08:00	03NOV2020 (41)		5

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	N	Y	Resolved (03NOV2020)	NOT RELATED/OTHER: Head Trauma	2	16	Y
2	1	N	N	Resolved (OCT2020)	NOT RELATED/OTHER: unknown			N
3	1	N	N	Resolved (OCT2020)	NOT RELATED/OTHER: unk			N
4	1	N	N	Resolved (OCT2020)	NOT RELATED/OTHER: unk			N
5	3	N	Y	Resolved (03NOV2020)	NOT RELATED/OTHER: 3 subsequent falls	2	16	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24SEP2020	
Completed	VACCINATION	10DEC2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	REPEAT SCREENING 1	22JAN2021	
Completed	OPEN LABEL TREATMENT	12MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	88.09 kg	28.6 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic Pancreatitis	Pancreatitis chronic	2014	Present
Sinusitus	Sinusitis	JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	14:07
2	BNT162b2	09SEP2020 (24)	09:08

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Myalgia	General Muscle Pain	17AUG2020 (1)	18:00	19AUG2020 (3)		3
2	GASTR	Pancreatitis	Worsening Pancreatitis	21AUG2020 (5)		23SEP2020 (38)		34

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (19AUG2020)	Study Treatment	1	1	N
2	3	N	Y	Resolved (23SEP2020)	NOT RELATED/OTHER: Pancreatitis	1	5	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	32	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	156.82 kg	45.5 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 2 Diabetes	Type 2 diabetes mellitus	31JUL2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	17:29
2	Placebo	08SEP2020 (21)	12:09

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
3	BNT162b2	19JAN2021 (154)	13:51
4	BNT162b2	08FEB2021 (174)	13:41

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Fatigue	Fatigue	19JAN2021 (154)	18:00	20JAN2021 (155)		2
2	GENRL	Fatigue	Fatigue	09FEB2021 (175)		12FEB2021 (178)		4
3	NERV	Headache	Headache	09FEB2021 (175)		12FEB2021 (178)		4
4	GENRL	Injection site pain	Pain at injection site	19JAN2021 (154)	18:00	20JAN2021 (155)		2
5	GENRL	Injection site pain	Pain at injection site	09FEB2021 (175)		10FEB2021 (176)		2
6	MUSC	Myalgia	Muscle Pain	19JAN2021 (154)	18:00	20JAN2021 (155)		2
7	RENAL	Nephrolithiasis	Kidney Stones	02DEC2020 (106)		08DEC2020 (112)		7

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	N	N	Resolved (20JAN2021)	Study Treatment	3	1	N
2	2	N	N	Resolved (12FEB2021)	Study Treatment	4	2	N
3	2	N	N	Resolved (12FEB2021)	Study Treatment	4	2	N
4	2	N	N	Resolved (20JAN2021)	Study Treatment	3	1	N
5	2	N	N	Resolved (10FEB2021)	Study Treatment	4	2	N

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
6	2	N	N	Resolved (20JAN2021)	Study Treatment	3	1	N
7	3	TC	Y	Resolved (08DEC2020)	NOT RELATED/OTHER: unknown	2	86	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	12OCT2020	
Completed	REPEAT SCREENING 1	19JAN2021	
Completed	OPEN LABEL TREATMENT	08MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2003	17	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.83 cm	51.18 kg	19 kg/m2	18NOV2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vitamin D Deficiency	Vitamin D deficiency	2017	Present
Anxiety Disorder	Anxiety disorder	OCT2017	Present
Major Depressive Disorder	Major depression	OCT2017	Present
Adjustment Disorder	Adjustment disorder	2018	Present
Dysthymic Disorder	Persistent depressive disorder	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18NOV2020 (1)	14:14
2	Placebo	11DEC2020 (24)	17:00
3	BNT162b2	24FEB2021 (99)	15:32

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PSYCH	Depression	Worsening Depression- no prior hospitalizations for depression	02MAR2021 (105)		ONGOING			4
2	GENRL	Injection site pain	Pain at injection site	24FEB2021 (99)	18:00	26FEB2021 (101)		3	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Yes	NOT RELATED/OTHER: Social and family issues	3	7	Y
2	N	N	Resolved (26FEB2021)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18NOV2020	
Completed	VACCINATION	08JAN2021	
Completed	REPEAT SCREENING 1	24FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.99 cm	82.45 kg	27.2 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
arthroscopic surgery left knee	Knee operation	1970	Past
osteoarthritis	Osteoarthritis	1971	Present
anxiety	Anxiety	1972	Present
Bipolar depression	Bipolar disorder	1972	Present
nervous breakdoen	Mental disorder	1972	Past
allergy to thorazine	Drug hypersensitivity	1983	Present
allergy to codeine	Drug hypersensitivity	1983	Present
arthroscopic surgery left knee	Knee operation	1985	Past
dyspepsia	Dyspepsia	1989	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypothyroid	Hypothyroidism	1990	Present
hyoid bone removed	Ostectomy	1990	Past
arthroscopic surgery left knee	Knee operation	1991	Past
seborrheic dermatitis	Seborrhoeic dermatitis	1995	Present
Type II diabetes	Type 2 diabetes mellitus	1995	Past
colitis	Colitis	2000	Past
irritable bowel	Irritable bowel syndrome	2000	Present
hypertension	Hypertension	2008	Present
insomnia	Insomnia	2010	Present
cervical disc disease	Intervertebral disc disorder	2010	Past
cervical disc surgery	Intervertebral disc operation	2010	Past
gastric bypass	Gastric bypass	2012	Past
thoracic spine disc disease	Intervertebral disc disorder	2013	Past
surgery T-3 disc	Intervertebral disc operation	2013	Past
anemia	Anaemia	2014	Past
arthroscopic surgery right knee	Knee operation	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	12:42
2	Placebo	10SEP2020 (23)	10:51
3	BNT162b2	04FEB2021 (170)	11:02
4	BNT162b2	26FEB2021 (192)	11:38

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PSYCH	Bipolar disorder	Worsening of Bipolar Disorder	13MAR2021 (207)		ONGOING			3
2	PSYCH	Bipolar disorder	worsening of bipolar disorder	29OCT2020 (72)		06NOV2020 (80)		9	3
3	GENRL	Chills	Chills	27FEB2021 (193)		27FEB2021 (193)		1	1
4	MUSC	Myalgia	Myalgia	27FEB2021 (193)		27FEB2021 (193)		1	1
5	RENAL	Pollakiuria	urinary frequency	06OCT2020 (49)		01NOV2020 (75)		27	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Yes	NOT RELATED/OTHER: Uncontrolled bipolar disorder	4	16	Y
2	TC	Y	Resolved (06NOV2020)	NOT RELATED/OTHER: historical condition with variability	2	50	Y
3	N	N	Resolved (27FEB2021)	Study Treatment	4	2	N
4	N	N	Resolved (27FEB2021)	Study Treatment	4	2	N
5	N	N	Resolved (01NOV2020)	NOT RELATED/OTHER: unknown	2	27	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	08OCT2020	
Completed	REPEAT SCREENING 1	04FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	174.55 kg	56.7 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
asthma	Asthma	DEC1952	Present
tonsillectomy	Tonsillectomy	1961	Past
morbid obesity	Obesity	1980	Present
hiatal hernia repair	Hernia hiatus repair	1988	Past
hiatal hernia	Hiatus hernia	1988	Past
hypertension	Hypertension	1997	Present
hypercholesterolemia	Hypercholesterolaemia	2006	Present
failed prostatectomy	Procedural failure	2007	Past
prostate cancer	Prostate cancer	2007	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
prostatism	Prostatism	2007	Present
low back pain	Back pain	2010	Present
diabetic neuropathy	Diabetic neuropathy	2018	Present
Type II diabetes	Type 2 diabetes mellitus	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	09:59
2	Placebo	21SEP2020 (22)	08:11
3	BNT162b2	22JAN2021 (145)	11:46
4	BNT162b2	12FEB2021 (166)	10:17

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Diarrhoea	Diarrhea	12FEB2021 (166)	14:30	12FEB2021 (166)	15:30	1
2	NEOPL	Malignant melanoma	malignant melanoma	04SEP2020 (5)		08OCT2020 (39)		35

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (12FEB2021)	Study Treatment	4	1	N
2	3	TC/TCN	Y	Resolved (08OCT2020)	NOT RELATED/OTHER: unknown	1	5	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	19OCT2020	
Completed	REPEAT SCREENING 1	22JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	129.82 kg	46.1 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin allergy	Drug hypersensitivity	1951	Present
tonsillectomy	Tonsillectomy	1954	Past
left shoulder injuries	Limb injury	1994	Past
left shoulder arthroplasty	Shoulder arthroplasty	1994	Past
Established Coronary Vascular Disease	Coronary artery disease	1997	Present
hemorrhoidectomy	Haemorrhoid operation	1997	Past
hemorrhoids	Haemorrhoids	1997	Past
colon polypectomy	Large intestinal polypectomy	1997	Past
colon polyps	Large intestine polyp	1997	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type II diabetes	Type 2 diabetes mellitus	1997	Present
morbid obesity	Obesity	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	09SEP2020 (1)	08:27
2	BNT162b2	29SEP2020 (21)	07:43

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Myocardial infarction	Myocardial Infarction	04FEB2021 (149)		ONGOING			4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Yes	NOT RELATED/OTHER: Established Coronary Vascular Disease	2	129	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	27OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.59 cm	60.59 kg	21.5 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Brazil Nut Allergy	Food allergy	1964	Present
Penicillin Allergy	Drug hypersensitivity	1965	Present
Dislocated Left Shoulder	Joint dislocation	1978	Past
Left Shoulder Surgery	Shoulder operation	25DEC1979	Past
Dislocated Right Shoulder	Joint dislocation	1996	Past
Right Shoulder Surgery	Shoulder operation	OCT2000	Past
Right Hip Osteoarthritis	Osteoarthritis	2008	Past
Right Hip Surgery	Hip surgery	AUG2016	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Correct Failed Right Shoulder Surgery	Shoulder operation	2017	Past
Right Shoulder Surgery	Shoulder operation	OCT2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	16:58
2	BNT162b2	08SEP2020 (21)	14:57

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	MUSC	Arthropathy	WIDENINNG OFACROMIOCLAVICULAR JOINT SPACE (GRADE 1)	06OCT2020 (49)		04MAR2021 (198)		150	2	TC	N
2	INJ&P	Facial bones fracture	FRACTURE OF ROOF OF RIGHT ORBITAL (GRADE 3)	06OCT2020 (49)		14DEC2020 (118)		70	3	TC	Y
3	INJ&P	Fall	FALL FROM BICYCLE	06OCT2020 (49)	08:20	06OCT2020 (49)	08:20	1	2	N	N
4	INJ&P	Muscle strain	PARTIAL TEAR OF THE RIGHT TRAPEZIUS MUSCLE (GRADE 1)	06OCT2020 (49)		04MAR2021 (198)		150	2	TC	N

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
5	RESP	Oropharyngeal pain	SORE THROAT	23AUG2020 (5)		30AUG2020 (12)		8	1	N	N
6	NERV	Subarachnoid haemorrhage	SUBARACHNOID HEMORRHAGE	06OCT2020 (49)	08:20	17OCT2020 (60)		12	4	TC	Y
7	INJ&P	Traumatic intracranial haemorrhage	TRAUMATIC INTRACRANIAL HEMORRHAGE	06OCT2020 (49)		04MAR2021 (198)		150	3	TC	Y

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (04MAR2021)	NOT RELATED/OTHER: BICYCLE ACCIDENT	2	29	N
2	Resolved (14DEC2020)	NOT RELATED/OTHER: BICYCLE ACCIDENT	2	29	Y
3	Resolved (06OCT2020)	NOT RELATED/OTHER: NO UNDERLYING CAUSE	2	29	N
4	Resolved (04MAR2021)	NOT RELATED/OTHER: BICYCLE ACCIDENT	2	29	N
5	Resolved (30AUG2020)	NOT RELATED/OTHER: UNRELATED NEW MEDICAL CONDITION	1	5	N
6	Resolved (17OCT2020)	NOT RELATED/OTHER: FALL FROM BICYCLE	2	29	Y
7	Resolved (04MAR2021)	NOT RELATED/OTHER: BICYCLE ACCIDENT	2	29	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
TETANUS-DIPHTHERIA VACCINE	DIPHTHERIA VACCINE;TETANUS VACCINE	06OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.2 cm	74 kg	26.5 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 1 Diabetes	Type 1 diabetes mellitus	AUG2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	11:44

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	VASC	Deep vein thrombosis	DEEP VEIN THROMBOSIS	31AUG2020 (12)		09SEP2020 (21)		10	3	TC
2	MUSC	Musculoskeletal stiffness	right shoulder stiffness	05SEP2020 (17)		07SEP2020 (19)		3	1	TCN
3	RESP	Pulmonary embolism	PULMONARY EMBOLISM	31AUG2020 (12)		02SEP2020 (14)		3	3	TC

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: MEDICAL HISTORY - TYPE 1 DIABETES	1	12	Y
2	N	Resolved (07SEP2020)	NOT RELATED/OTHER: unknown new medical condition	1	17	N
3	N	Resolved (02SEP2020)	NOT RELATED/OTHER: DEEP VEIN THROMBOSIS	1	12	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Withdrawn	VACCINATION	08SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	22	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.3 cm	83.6 kg	32.5 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
C-section	Caesarean section	16MAY2019	Past
Obesity	Obesity	06JUN2019	Present
Menorrhagia	Menorrhagia	03JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	15:26
2	Placebo	10SEP2020 (22)	16:04

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PREG	Abortion spontaneous incomplete	INCOMPLETE SPONTANEOUS ABORTION	04OCT2020 (46)		07OCT2020 (49)		4	3
2	RESP	Haemoptysis	HEMOPTYSIS	04OCT2020 (46)		04OCT2020 (46)		1	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	Y	Resolved (07OCT2020)	NOT RELATED/OTHER: UNKNOWN ETIOLOGY	2	25	Y
2	N	N	Resolved (04OCT2020)	NOT RELATED/OTHER: UNKNOWN ETIOLOGY	2	25	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	12OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.47 cm	64.09 kg	23.6 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteoarthritis Multiple Joints	Osteoarthritis	2004	Present
Post Menopause	Postmenopause	2010	Present
Depression	Depression	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02SEP2020 (1)	09:34
2	BNT162b2	24SEP2020 (23)	09:11

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Transient ischaemic attack	Suspected Transient Ischemic Attack	27OCT2020 (56)	05:30	28OCT2020 (57)	14:00	2	3
2	NERV	Tremor	Tremor	13OCT2020 (42)		ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (28OCT2020)	NOT RELATED/OTHER: Atherosclerotic vs Embolic disease	2	34	Y
2	N	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	20	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	05NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171 cm	69 kg	23.6 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Diabetes Type II	Type 2 diabetes mellitus	1999	Present
Hyperlipidemia	Hyperlipidaemia	2000	Present
Hypertension	Hypertension	2000	Present
Nearsighted	Myopia	2010	Present
smoking	Tobacco user	10AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10AUG2020 (1)	11:20
2	Placebo	02SEP2020 (24)	11:57

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INFEC	Pneumonia	pneumonia	03SEP2020 (25)		13SEP2020 (35)		11	3	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (13SEP2020)	NOT RELATED/OTHER: unblinded per tx physician physician request sponsor notify of unblinded	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10AUG2020	
Completed	VACCINATION	01OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	104.9 kg	35 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OBESITY	Obesity	2015	Present
Farsighted	Hypermetropia	2017	Present
HYPERTENSION	Hypertension	2018	Present
ADHD	Attention deficit hyperactivity disorder	MAR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03SEP2020 (1)	12:35
2	BNT162b2	25SEP2020 (23)	11:27

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Myocardial infarction	myocardial infarction	10NOV2020 (69)		12NOV2020 (71)		3	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (12NOV2020)	NOT RELATED/OTHER: coronary artery disease	2	47	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	26OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	39	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	118.64 kg	37.4 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	2000	Present
Anxiety	Anxiety	2010	Present
Hypothyroidism	Hypothyroidism	APR2011	Present
Allergic Rhinitis	Rhinitis allergic	07JUN2016	Present
S/p laparoscopic sleeve gastrectomy	Gastrectomy	10MAY2018	Past
Low Back Pain	Back pain	09JUL2018	Present
Panic Attacks	Panic attack	24JUL2019	Present
Hysterectomy	Hysterectomy	31JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	15:51
2	Placebo	09SEP2020 (24)	11:53
3	BNT162b2	16DEC2020 (122)	13:38
4	BNT162b2	04JAN2021 (141)	13:33

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	HEPAT	Cholecystitis acute	Acute Cholecystitis	21AUG2020 (5)		22AUG2020 (6)		2	3	TC/TCN	Y
2	HEPAT	Cholelithiasis	Cholelithiasis	21AUG2020 (5)		22AUG2020 (6)		2	2	TCN	N
3	HEPAT	Hepatitis acute	Acute hepatitis	25FEB2021 (193)		ONGOING			2	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (22AUG2020)	NOT RELATED/OTHER: Cholelithiasis and sudden weight loss due to baratric surgery 2018	1	5	Y

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	Resolved (22AUG2020)	NOT RELATED/OTHER: Sudden weight loss due to bariatric surgery	1	5	N
3	Yes	NOT RELATED/OTHER: suspected due to doxycycline and Zithromax	4	53	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Fluzone (Influenza vaccine)	INFLUENZA VACCINE	06OCT2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	REPEAT SCREENING 1	16DEC2020	
Completed	OPEN LABEL TREATMENT	01FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	77	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
181.61 cm	88.64 kg	26.8 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Peripheral Neuropathy	Neuropathy peripheral	11MAR2011	Present
Coronary Artery Disease	Coronary artery disease	28NOV2011	Present
Hyperlipidemia	Hyperlipidaemia	05DEC2012	Present
Allergic Rhinitis	Rhinitis allergic	24NOV2014	Present
Hypertension	Hypertension	13APR2015	Present
Benign localized hyperplasia of the prostate	Benign prostatic hyperplasia	29SEP2015	Present
Hyperuricemia	Hyperuricaemia	23FEB2017	Present
Atrial Flutter	Atrial flutter	07MAR2018	Present
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	29AUG2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obstructive Sleep Apnea	Sleep apnoea syndrome	29AUG2018	Present
Male Erectile Disorder	Erectile dysfunction	03DEC2018	Present
Retinal Detachmnet	Retinal detachment	14JAN2019	Past
Aneurysm of the Thoracic Aorta	Aortic aneurysm	15OCT2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	11:17
2	Placebo	14SEP2020 (20)	09:08
3	BNT162b2	05JAN2021 (133)	10:18
4	BNT162b2	26JAN2021 (154)	09:45

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CONG	Hypertrophic cardiomyopathy	Hypertrophic cardiomyopathy	08MAR2021 (195)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Yes	NOT RELATED/OTHER: Hypertension, Afib	4	42	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	13OCT2020	
Completed	REPEAT SCREENING 1	05JAN2021	
Completed	OPEN LABEL TREATMENT	25FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1945	74	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	76.36 kg	24.1 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
disc degeneration, lumbar	Intervertebral disc degeneration	1968	Present
allergic rhinitis	Rhinitis allergic	2005	Present
dyspepsia of stomach	Dyspepsia	2008	Present
arteriosclerotic cardiovascular disease	Arteriosclerosis	OCT2009	Present
diastolic congestive heart failure	Cardiac failure congestive	OCT2009	Present
benign essential hypertension	Essential hypertension	OCT2009	Present
benign hyperplasia of prostate	Benign prostatic hyperplasia	23MAY2014	Present
anxiety	Anxiety	12JAN2015	Present
sleep apnea	Sleep apnoea syndrome	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	09:48
2	Placebo	15SEP2020 (20)	08:30
3	BNT162b2	04JAN2021 (131)	14:27
4	BNT162b2	25JAN2021 (152)	08:09

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	Brain contusion	contusion of the frontal lobe	28NOV2020 (94)		23DEC2020 (119)		26	2	TC	Y
2	INJ&P	Fall	Fall	28NOV2020 (94)		28NOV2020 (94)		1	3	TC	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (23DEC2020)	NOT RELATED/OTHER: Fall tripped on a rock and did not lose consciousness	2	75	Y
2	Resolved (28NOV2020)	NOT RELATED/OTHER: Tripped on a rock and did not lose consciousness	2	75	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Fluzone High-Dose Quadrivalent	INFLUENZA VACCINE INACT SPLIT 4V	14OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	20OCT2020	
Completed	REPEAT SCREENING 1	04JAN2021	
Completed	OPEN LABEL TREATMENT	24FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
190.5 cm	135.45 kg	37.2 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Iron Deficiency anemia	Iron deficiency anaemia	26AUG1998	Present
Lumbar Radiculopathy	Lumbar radiculopathy	2010	Present
Acid Reflux disease	Gastrooesophageal reflux disease	08AUG2012	Present
Paroxysmal Atrial Fibrillation	Atrial fibrillation	24OCT2012	Present
Coronary arteriosclerosis	Arteriosclerosis coronary artery	13AUG2014	Present
Hematochezia	Haematochezia	08OCT2015	Past
Chronic Gout	Gout	30AUG2016	Present
Peripheral Neuropathy	Neuropathy peripheral	30AUG2016	Present
Type 2 Diabetes	Type 2 diabetes mellitus	09MAR2017	Present

Medical History

Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Hypertension	Hypertension	28AUG2017	Present
Macular degeneration	Macular degeneration	2018	Present
Benign Hyperplasia Prostate	Benign prostatic hyperplasia	10OCT2018	Present
Hyperlipidemia	Hyperlipidaemia	10OCT2018	Present
Hypothyroidism	Hypothyroidism	10OCT2018	Present
Mild Dementia	Dementia	28JAN2019	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	28AUG2020 (1)	09:24
2	Placebo	17SEP2020 (21)	08:30
3	BNT162b2	19JAN2021 (145)	09:10
4	BNT162b2	10FEB2021 (167)	08:34

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	CARD	Angina unstable	Unstable Angina Pectoris	20OCT2020 (54)		20OCT2020 (54)		1	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (20OCT2020)	NOT RELATED/OTHER: known Coronary artery disease	2	34	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	15OCT2020	
Completed	REPEAT SCREENING 1	19JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	55	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	88.64 kg	28 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis	Rhinitis allergic	1987	Present
smoker	Tobacco user	1990	Present
hyperlipidemia	Hyperlipidaemia	1998	Present
type 2 diabetes	Type 2 diabetes mellitus	1998	Present
type 2 diabetes neuropathy	Diabetic neuropathy	2014	Present
cervicalgia	Neck pain	18SEP2014	Present
attention deficit disorder	Attention deficit hyperactivity disorder	10MAR2017	Present
hypogonadism, testicular	Hypogonadism male	15NOV2019	Present
polycythemia	Polycythaemia	14MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10SEP2020 (1)	15:48
2	BNT162b2	29SEP2020 (20)	15:30

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	NERV	Cerebrovascular accident	Cerebrovascular accident	21OCT2020 (42)		ONGOING			3	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Yes	NOT RELATED/OTHER: underlying risk factors, smoker, Diabetes, polycythemia	2	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	27OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	71	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	121 kg	37.2 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hyperlipidemia	Hyperlipidaemia	2010	Present
Hypertension	Hypertension	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	12:10

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Other_AEI_SAE/profile Date of Generation: 07APR2021 (21:52)

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
2	Placebo	16SEP2020 (22)	10:27
3	BNT162b2	27JAN2021 (155)	15:00
4	BNT162b2	22FEB2021 (181)	14:39

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	GENRL	Asthenia	General Weakness	01OCT2020 (37)		31OCT2020 (67)		31	2	N	N
2	CARD	Coronary artery disease	Newly Diagnosed Coronary Artery Disease	01OCT2020 (37)		17DEC2020 (114)		78	3	TC/TCN	Y
3	NERV	Dizziness	Dizziness	01OCT2020 (37)		31OCT2020 (67)		31	2	N	N
4	RESP	Dyspnoea	Shortness of Breath	01OCT2020 (37)		17DEC2020 (114)		78	2	TCN	N
5	GENRL	Fatigue	Fatigue	23SEP2020 (29)		24SEP2020 (30)		2	1	N	N
6	GENRL	Injection site pain	Pain at injection site	28JAN2021 (156)		29JAN2021 (157)		2	1	N	N
7	GENRL	Malaise	Malaise	23SEP2020 (29)		24SEP2020 (30)		2	1	N	N
8	NERV	Syncope	Syncope	01OCT2020 (37)		01OCT2020 (37)		1	3	N	N
9	EYE	Vision blurred	Blurred Vision	01OCT2020 (37)		31OCT2020 (67)		31	2	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (31OCT2020)	NOT RELATED/OTHER: Subject instructed to seek out care from PCP to get accurate diagnosis.	2	16	N
2	Resolved (17DEC2020)	NOT RELATED/OTHER: Hyperlipidemia, Hypertension, and Obesity	2	16	Y
3	Resolved (31OCT2020)	NOT RELATED/OTHER: Subject instructed to seek out care from PCP to get accurate diagnosis.	2	16	N
4	Resolved (17DEC2020)	NOT RELATED/OTHER: Coronary Artery Disease	2	16	N
5	Resolved (24SEP2020)	Study Treatment	2	8	N
6	Resolved (29JAN2021)	Study Treatment	3	2	N
7	Resolved (24SEP2020)	Study Treatment	2	8	N
8	Resolved (01OCT2020)	NOT RELATED/OTHER: Subject was advised to seek care from PCP to get accurate diagnosis.	2	16	N
9	Resolved (31OCT2020)	NOT RELATED/OTHER: Subject instructed to seek out care from PCP to get accurate diagnosis.	2	16	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	27JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	Asian	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	84.6 kg	33 kg/m2	28AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	11:05
2	Placebo	18SEP2020 (22)	12:20

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	28DEC2020 (123)	10:38
4	BNT162b2	20JAN2021 (146)	11:02

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	Fall	Fall	22JAN2021 (148)		22JAN2021 (148)		1	2	N	N
2	NERV	Headache	Headache	18SEP2020 (22)		18SEP2020 (22)		1	1	N	N
3	NERV	Headache	Headache	21JAN2021 (147)		22JAN2021 (148)		2	1	N	N
4	GENRL	Injection site pain	Injection Site Pain	21JAN2021 (147)		22JAN2021 (148)		2	1	N	N
5	INJ&P	Lower limb fracture	Right Lower Extremity Fracture	22JAN2021 (148)		ONGOING			3	TCN	Y
6	MUSC	Myalgia	Myalgias	21JAN2021 (147)		22JAN2021 (148)		2	1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (22JAN2021)	NOT RELATED/OTHER: subject tripped over dog gate - mechanical fall	4	3	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	Resolved (18SEP2020)	Study Treatment	2	1	N
3	Resolved (22JAN2021)	Study Treatment	4	2	N
4	Resolved (22JAN2021)	Study Treatment	4	2	N
5	Yes	NOT RELATED/OTHER: Injury is from a fall	4	3	Y
6	Resolved (22JAN2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccine	INFLUENZA VACCINE	06OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	20OCT2020	
Completed	REPEAT SCREENING 1	28DEC2020	
Completed	OPEN LABEL TREATMENT	17FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	164.2 kg	49.1 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1963	Present
Chronic Deep Vein Thrombosis (DVT)	Deep vein thrombosis	1980	Present
Tobacco Use	Tobacco user	1995	Present
Hypertension	Hypertension	1998	Present
Type II Diabetes	Type 2 diabetes mellitus	1998	Present
Idiopathic Thrombocytopenic Purpura	Immune thrombocytopenia	2006	Present
Alcoholism	Alcoholism	2010	Present
Obstructive Sleep Apnea	Sleep apnoea syndrome	2010	Present
Obesity	Obesity	2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	11:05
2	Placebo	29SEP2020 (22)	10:06
3	BNT162b2	20JAN2021 (135)	08:30
4	BNT162b2	10FEB2021 (156)	08:30

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INFEC	Cellulitis	Cellulitis of left lower leg	01OCT2020 (24)		01NOV2020 (55)		32	3	TC/TCN	Y
2	INJ&P	Limb injury	Wound of left lower leg	12SEP2020 (5)		30SEP2020 (23)		19	3	TC	N
3	BLOOD	Neutropenia	Neutropenia	01OCT2020 (24)		01NOV2020 (55)		32	3	TC	Y
4	BLOOD	Thrombocytopenia	Thrombocytopenia	01OCT2020 (24)		01NOV2020 (55)		32	2	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (01NOV2020)	NOT RELATED/OTHER: underline comorbidities pt with a hx of Type II Diabetes and morbid obesity	2	3	Y
2	Resolved (30SEP2020)	NOT RELATED/OTHER: injury to leg.	1	5	N
3	Resolved (01NOV2020)	NOT RELATED/OTHER: underline comorbidities pt with a hx of Type II Diabetes and morbid obesity	2	3	Y
4	Resolved (01NOV2020)	NOT RELATED/OTHER: Cellulitis	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Pneumonia Vaccine	PNEUMOCOCCAL VACCINE	SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	27OCT2020	
Completed	REPEAT SCREENING 1	20JAN2021	
Completed	OPEN LABEL TREATMENT	10MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	74	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	62.27 kg	25.9 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hot Flashes	Hot flush	1986	Present
HYSTERECTOMY	Hysterectomy	1986	Past
Pulmonary Fibrosis	Pulmonary fibrosis	17AUG2000	Present
HYPERTENSION	Hypertension	2005	Present
Osteoarthritis	Osteoarthritis	2005	Present
GASTRIC SLEEVE	Gastrectomy	2010	Past
HIP REPLACEMENT (LEFT)	Hip arthroplasty	2010	Past
SHOULDER REPLACEMENT (LEFT)	Shoulder arthroplasty	2013	Past
CERVICAL SPINAL FUSION SURGERY	Spinal fusion surgery	2016	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ANKLE REPLACEMENT (RIGHT)	Ankle arthroplasty	2017	Past
Cough	Cough	2019	Present
GASTRIC BYPASS	Gastric bypass	OCT2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	15:47
2	Placebo	08SEP2020 (23)	13:50
3	BNT162b2	19JAN2021 (156)	11:52
4	BNT162b2	10FEB2021 (178)	14:03

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Intestinal ulcer perforation	Perforated Intestinal marginated Ulcer	31JAN2021 (168)	00:00	31JAN2021 (168)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	Y	Resolved (31JAN2021)	NOT RELATED/OTHER: N/A	3	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	06OCT2020	
Completed	REPEAT SCREENING 1	19JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline
No Vital Signs - Baseline

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Microdiscectomy Lumbar spine	Intervertebral disc operation	1980	Past
hypercholesterolaemia	Hypercholesterolaemia	2005	Present
hypertension	Hypertension	2005	Present
hypothyroidism	Hypothyroidism	2005	Present
Microdiscectomy Lumbar spine	Intervertebral disc operation	2005	Past
Herniated disc L4-L5	Intervertebral disc protrusion	2005	Past
nephrolithiasis	Nephrolithiasis	2008	Past
Hemorrhoid	Haemorrhoids	2015	Past
Lumbar radiculopathy	Lumbar radiculopathy	2019	Present
left inguinal Hernia repair	Inguinal hernia repair	AUG2019	Past
Hemorrhoidectomy	Haemorrhoid operation	JUL2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16SEP2020 (1)	08:53
2	BNT162b2	06OCT2020 (21)	09:57

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RENAL	Hydronephrosis	Hydronephrosis	02OCT2020 (17)		06OCT2020 (21)		5	2
2	RENAL	Nephrolithiasis	nephrolithiasis	02OCT2020 (17)		06OCT2020 (21)		5	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	N	Resolved (06OCT2020)	NOT RELATED/OTHER: Nephrolithiasis	1	17	N
2	TC/TCN	Y	Resolved (06OCT2020)	NOT RELATED/OTHER: Intercurrent illness	1	17	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	02SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	05NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	68	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	66 kg	23.1 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Inguinal Hernia	Inguinal hernia	1990	Past
Inguinal Hernia Repair	Inguinal hernia repair	1990	Past
Chronic Obstructive Pulmonary Disease	Chronic obstructive pulmonary disease	2015	Present
Joint Manipulation, Right Shoulder	Joint manipulation	2015	Present
Adhesive Capsulitis, Right Shoulder	Periarthritis	2015	Past
Adhesive Capsulitis, Right Shoulder	Periarthritis	2015	Past
Intolerance to Lisinopril	Drug intolerance	2017	Present
Intolerance to Benazepril	Drug intolerance	2017	Present
Dyslipidemia	Dyslipidaemia	2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2017	Present
Benign Prostatic Hyperplasia	Benign prostatic hyperplasia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	09:45
2	Placebo	21SEP2020 (22)	09:14
3	BNT162b2	04FEB2021 (158)	10:21
4	BNT162b2	25FEB2021 (179)	10:24

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Bladder cancer	Bladder Cancer	24OCT2020 (55)	13:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC/TCN	Y	Yes	NOT RELATED/OTHER: Neoplasia	2	34	Y

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Gemzar	GEMCITABINE HYDROCHLORIDE	15DEC2020	ONGOING	INTRAVENOUS
Cisplatin	CISPLATIN	22DEC2020	ONGOING	INTRAVENOUS

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	19OCT2020	
Completed	REPEAT SCREENING 1	04FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	35	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169.9 cm	88.6 kg	30.7 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ASTHMA	Asthma	1993	Present
SEPTOPLASTY	Nasal septal operation	2005	Past
DEVIATED SEPTUM	Nasal septum deviation	2005	Past
TONSILLECTOMY	Tonsillectomy	2005	Past
TONSILLITIS	Tonsillitis	2005	Past
CHOLECYSTECTOMY	Cholecystectomy	2007	Past
CHOLECYSTITIS	Cholecystitis	2007	Past
ALLERGY TO DOG DANDER	Allergy to animal	2010	Present
ALLERGY TO CAT DANDER	Allergy to animal	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
CESAREAN SECTION	Caesarean section	2013	Past
CHILDBIRTH	Delivery	2013	Past
CESAREAN SECTION	Caesarean section	2016	Past
CHILDBIRTH	Delivery	2016	Past
BUNIONS, BOTH FEET	Foot deformity	2018	Past
BUNIONECTOMY, RIGHT FOOT	Bunion operation	DEC2019	Past
BUNIONECTOMY, LEFT FOOT	Bunion operation	JUN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01SEP2020 (1)	08:18
2	BNT162b2	21SEP2020 (21)	08:22

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PREG	Abortion spontaneous	Abortion Spontaneous	23DEC2020 (114)	12:00	23DEC2020 (114)	12:00	1
2	NERV	Headache	HEADACHE	21SEP2020 (21)	18:00	23SEP2020 (23)	07:30	3
3	GASTR	Nausea	NAUSEA	21SEP2020 (21)	18:00	21SEP2020 (21)	21:00	1
4	GENRL	Pain	BODY ACHES	21SEP2020 (21)	18:00	23SEP2020 (23)	07:30	3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	Y	Resolved (23DEC2020)	NOT RELATED/OTHER: Conception	2	94	Y
2	2	N	N	Resolved (23SEP2020)	Study Treatment	2	1	N
3	1	N	N	Resolved (21SEP2020)	Study Treatment	2	1	N
4	3	TC	N	Resolved (23SEP2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	Asian	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.5 cm	79.4 kg	31.6 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic to bee venom	Allergy to arthropod sting	1970	Present
Allergic to tomatoes	Food allergy	1970	Present
Septoplasty	Nasal septal operation	1986	Past
Deviated septum	Nasal septum deviation	1986	Past
Depression	Depression	1990	Present
Hypothyroidism	Hypothyroidism	1990	Present
Allergic to latex	Rubber sensitivity	1990	Present
Sleep apnea	Sleep apnoea syndrome	1990	Present
Transient ischemic attack (mini stroke)	Transient ischaemic attack	1990	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Removal of vocal cord polyp	Laryngeal polypectomy	1997	Past
Vocal cord polyp	Vocal cord polyp	1997	Past
Carpal tunnel release, bilateral	Carpal tunnel decompression	2001	Past
Carpal tunnel syndrome, bilateral	Carpal tunnel syndrome	2001	Past
Barrett's esophagus	Barrett's oesophagus	2010	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2010	Present
Diabetes, Type II	Type 2 diabetes mellitus	2010	Present
Hypertension	Hypertension	2018	Present
Dyslipidemia	Dyslipidaemia	2019	Present
Broken wrist repair, left	Fracture treatment	27JUL2020	Past
Broken wrist, left	Wrist fracture	27JUL2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09SEP2020 (1)	08:48
2	Placebo	30SEP2020 (22)	08:12
3	BNT162b2	18JAN2021 (132)	07:56
4	BNT162b2	08FEB2021 (153)	07:22

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	NEOPL	Breast cancer stage I	Breast Cancer, Stage 1	30NOV2020 (83)	14:00	ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		2	TCN	Y	Yes	NOT RELATED/OTHER: Neoplasia	2	62	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Flu vaccine	INFLUENZA VACCINE	15OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	28OCT2020	
Completed	REPEAT SCREENING 1	18JAN2021	
Completed	OPEN LABEL TREATMENT	08MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	64	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	79.82 kg	25.9 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin allergy	Drug hypersensitivity	1968	Present
osteoarthritis	Osteoarthritis	JUL2007	Present
hypercholesterolemia	Hypercholesterolaemia	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	16:29
2	Placebo	14SEP2020 (22)	15:45
3	BNT162b2	20JAN2021 (150)	10:02
4	BNT162b2	09FEB2021 (170)	09:29

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	MUSC	Osteoarthritis	worsening of osteoarthritis, right hip	08SEP2020 (16)		24DEC2020 (123)		108	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	Y	Resolved (24DEC2020)	NOT RELATED/OTHER: osteoarthritis and aging	1	16	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	12OCT2020	
Completed	REPEAT SCREENING 1	20JAN2021	
Completed	OPEN LABEL TREATMENT	12MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	78.18 kg	25.4 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
depression	Depression	1996	Present
attention deficit disorder	Attention deficit hyperactivity disorder	2000	Present
hypertension	Hypertension	2008	Present
insomnia	Insomnia	2010	Present
neck pain	Neck pain	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	12:31
2	BNT162b2	15SEP2020 (22)	13:55

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Aortic dilatation	Ascending aorta ectasia	10OCT2020 (47)		ONGOING			1
2	GENRL	Injection site pain	injection site tenderness	25AUG2020 (1)	19:00	26AUG2020 (2)	12:00	2	1
3	CARD	Left ventricular dysfunction	Diastolic dysfunction of the left ventricle	11OCT2020 (48)		ONGOING			1
4	NERV	Transient global amnesia	transient global amnesia	10OCT2020 (47)		10OCT2020 (47)		1	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: Unknown, possibly hypertension	2	26	N
2	N	N	Resolved (26AUG2020)	Study Treatment	1	1	N
3	N	N	Yes	NOT RELATED/OTHER: Unknown, possibly hypertension	2	27	N
4	N	Y	Resolved (10OCT2020)	NOT RELATED/OTHER: unknown	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	13OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1940	79	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166.37 cm	86.82 kg	31.3 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
sulfa allergy	Drug hypersensitivity	1945	Present
Endometriosis	Endometriosis	1977	Past
tetracycline allergy	Drug hypersensitivity	1985	Present
codeine allergy	Drug hypersensitivity	1985	Present
hysterectomy	Hysterectomy	1987	Past
diverticulitis	Diverticulitis	1989	Past
Diabetes Type II	Type 2 diabetes mellitus	1990	Present
colon resection	Colectomy	1991	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
esophageal reflux	Gastrooesophageal reflux disease	2017	Present
hypercholesterolemia	Hypercholesterolaemia	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	14:35
2	BNT162b2	16SEP2020 (22)	13:27

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RENAL	Nephrolithiasis	Kidney stone, worsening	03OCT2020 (39)		16OCT2020 (52)		14	3
2	RENAL	Nephrolithiasis	kidney stones	19SEP2020 (25)	14:00	23SEP2020 (29)		5	3
3	INFEC	Pyelonephritis	Pyelonephritis	03OCT2020 (39)		30OCT2020 (66)		28	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (16OCT2020)	NOT RELATED/OTHER: Supersaturated urine	2	18	N

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	TC	Y	Resolved (23SEP2020)	NOT RELATED/OTHER: unknown	2	4	Y
3	TC	Y	Resolved (30OCT2020)	NOT RELATED/OTHER: Renal stone	2	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	14OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	104.55 kg	38.3 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
sulfa allergy	Drug hypersensitivity	1970	Present
penicillin allergy	Drug hypersensitivity	1970	Present
post menopausal	Postmenopause	2005	Present
bipolar disorder	Bipolar disorder	2010	Present
Depression	Depression	2011	Present
attention deficit disorder	Attention deficit hyperactivity disorder	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	11:01
2	Placebo	21SEP2020 (22)	10:41
3	BNT162b2	25JAN2021 (148)	13:25
4	BNT162b2	22FEB2021 (176)	10:46

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Post procedural infection	Post operative infection (sialolithiasis removal)	18NOV2020 (80)		29NOV2020 (91)		12
2	GASTR	Salivary gland calculus	Sialolithiasis	20SEP2020 (21)	18:00	12NOV2020 (74)		54

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (29NOV2020)	NOT RELATED/OTHER: microbes	2	59	Y
2	2	TC	Y	Resolved (12NOV2020)	NOT RELATED/OTHER: Salivary stone	1	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	19OCT2020	
Completed	REPEAT SCREENING 1	25JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179.07 cm	100.91 kg	31.4 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hiatal hernia	Hiatus hernia	1947	Present
hypertension	Hypertension	2000	Present
cardiomyopathy	Cardiomyopathy	2008	Present
left ventricular hypertrophy	Left ventricular hypertrophy	2008	Present
elevate prostate-specific antigen	Prostatic specific antigen increased	2018	Present
gout	Gout	FEB2018	Present
atrial fibrillation	Atrial fibrillation	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	16:26
2	Placebo	28SEP2020 (21)	14:03
3	BNT162b2	19JAN2021 (134)	14:40
4	BNT162b2	01MAR2021 (175)	14:08

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Atrial fibrillation	worsening of paroxysmal atrial fibrillation	14JAN2021 (129)		04FEB2021 (150)		22	2
2	NEOPL	Basal cell carcinoma	Basal Cell Carcinoma (face)	15OCT2020 (38)	09:00	29OCT2020 (52)		15	2
3	GASTR	Gastrooesophageal reflux disease	GERD	04FEB2021 (150)		ONGOING			1
4	GENRL	Injection site pain	tenderness at injection site	22JAN2021 (137)		29JAN2021 (144)	11:00	8	1
5	GASTR	Intestinal obstruction	intestinal obstruction	09FEB2021 (155)		19FEB2021 (165)		11	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	Y	Resolved (04FEB2021)	NOT RELATED/OTHER: hx of atrial fibrillation	2	109	Y
2	N	N	Resolved (29OCT2020)	NOT RELATED/OTHER: Mitosis	2	18	N
3	TC	N	Yes	NOT RELATED/OTHER: acid in wrong location	3	17	N

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
4	TC	N	Resolved (29JAN2021)	Study Treatment	3	4	N
5	N	Y	Resolved (19FEB2021)	NOT RELATED/OTHER: unknown	3	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	27OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	26OCT2020	
Completed	REPEAT SCREENING 1	19JAN2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	115.64 kg	38.7 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypertension	Hypertension	2015	Present
diabetes type II	Type 2 diabetes mellitus	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	10:55

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	29SEP2020 (20)	13:40
3	BNT162b2	27JAN2021 (140)	08:39
4	BNT162b2	22FEB2021 (166)	11:07

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	CARD	Coronary artery disease	vascular disease (coronary artery disease)	08OCT2020 (29)		ONGOING			3	TC
2	CARD	Myocardial infarction	Myocardial infarction	08OCT2020 (29)	18:00	19OCT2020 (40)		12	3	N
3	RENAL	Nocturia	nocturia	10SEP2020 (1)	22:00	12SEP2020 (3)		3	1	N
4	GENRL	Pain	body aches	23FEB2021 (167)	00:00	ONGOING			1	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Yes	NOT RELATED/OTHER: atherosclerosis	2	10	N
2	Y	Resolved (19OCT2020)	NOT RELATED/OTHER: vascular disease (coronary artery disease)	2	10	Y
3	N	Resolved (12SEP2020)	Study Treatment	1	1	N
4	N	Yes	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	27OCT2020	
Completed	REPEAT SCREENING 1	27JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	92.27 kg	30.9 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2010	Present
basal cell cancer, right eye lid	Basal cell carcinoma	MAR2020	Past
basal cell excision, right eye lid	Skin lesion removal	MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14SEP2020 (1)	13:47
2	BNT162b2	05OCT2020 (22)	12:40

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Cholecystitis	cholecystitis	09OCT2020 (26)		12OCT2020 (29)		4
2	HEPAT	Cholelithiasis	cholelithiasis (gallstones)	09OCT2020 (26)		11OCT2020 (28)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (12OCT2020)	NOT RELATED/OTHER: gallstones	2	5	Y
2	3	TC/TCN	N	Resolved (11OCT2020)	NOT RELATED/OTHER: Bile	2	5	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	20OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	02NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	57	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	97.73 kg	30 kg/m2	06OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypertension	Hypertension	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	06OCT2020 (1)	10:45
2	BNT162b2	27OCT2020 (22)	09:16

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Facial bones fracture	facial fracture	28FEB2021 (146)		04MAR2021 (150)		5
2	RENAL	Nephrolithiasis	Nephrolithiasis	28FEB2021 (146)		02MAR2021 (148)		3
3	INJ&P	Skin laceration	lacerations	28FEB2021 (146)		04MAR2021 (150)		5

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TCN	N	Resolved (04MAR2021)	NOT RELATED/OTHER: trauma	2	125	N
2	2	N	Y	Resolved (02MAR2021)	NOT RELATED/OTHER: unknown	2	125	Y
3	2	N	N	Resolved (04MAR2021)	NOT RELATED/OTHER: trauma	2	125	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06OCT2020	
Completed	VACCINATION	24NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	103.18 kg	32.6 kg/m2	07OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
herpes simplex I	Herpes simplex	1975	Present
esophageal reflux	Gastrooesophageal reflux disease	1980	Present
benign prostatic hypertrophy	Benign prostatic hyperplasia	1995	Present
left inguinal hernia	Inguinal hernia	2000	Past
left inguinal hernia repair	Inguinal hernia repair	2000	Past
hypothyroidism	Hypothyroidism	2002	Present
thyroidectomy	Thyroidectomy	2004	Past
hypercholesterolemia	Hypercholesterolaemia	2005	Present
degenerative joint disease	Osteoarthritis	2005	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
coronary artery disease	Coronary artery disease	2006	Present
Diverticulitis	Diverticulitis	2009	Past
ileectomy	Ileectomy	2009	Past
bilateral vision impairment	Visual impairment	2009	Past
bilateral Lasik surgery	Keratomileusis	2010	Past
hip replacement, right	Hip arthroplasty	2011	Past
cardiac stent placement, left descending artery	Coronary arterial stent insertion	2019	Past
hypertension	Hypertension	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07OCT2020 (1)	16:18
2	BNT162b2	28OCT2020 (22)	15:07

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	METAB	Gout	Gout (right great toe)	14NOV2020 (39)		20NOV2020 (45)		7
2	GENRL	Injection site pain	injection site soreness	07OCT2020 (1)	18:00	08OCT2020 (2)	16:00	2
3	GASTR	Small intestinal obstruction	small bowel obstruction	14DEC2020 (69)		17DEC2020 (72)		4

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC	N	Resolved (20NOV2020)	NOT RELATED/OTHER: uric acid sediment	2	18	N
2	1	N	N	Resolved (08OCT2020)	Study Treatment	1	1	N
3	3	N	Y	Resolved (17DEC2020)	NOT RELATED/OTHER: unknown	2	48	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07OCT2020	
Completed	VACCINATION	25NOV2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159 cm	76.6 kg	30.3 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hysterectomy	Hysterectomy	2001	Past
Autoimmune thyroiditis	Autoimmune thyroiditis	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15OCT2020 (1)	11:32

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	05NOV2020 (22)	10:55
3	BNT162b2	11FEB2021 (120)	12:42
4	BNT162b2	10MAR2021 (147)	10:02

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Headache	Headache	10MAR2021 (147)	13:30	12MAR2021 (149)	17:00	3	2
2	GASTR	Nausea	Nausea	11MAR2021 (148)	11:00	11MAR2021 (148)	15:00	1	1
3	MUSC	Spondylolisthesis	Spondylolisthasis L4/5	05FEB2021 (114)		09MAR2021 (146)		33	2
4	EAR	Vertigo	Vertigo	11MAR2021 (148)	11:00	12MAR2021 (149)	17:00	2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (12MAR2021)	Study Treatment	4	1	N
2	N	N	Resolved (11MAR2021)	Study Treatment	4	2	N
3	N	Y	Resolved (09MAR2021)	NOT RELATED/OTHER: due to Lumal spine syndrome	2	93	Y
4	N	N	Resolved (12MAR2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15OCT2020	
Completed	VACCINATION	07DEC2020	
Completed	REPEAT SCREENING 1	11FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	74	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	102.3 kg	34.6 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	1990	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15OCT2020 (1)	12:56
2	BNT162b2	03NOV2020 (20)	11:45

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	NEOPL	Adenocarcinoma pancreas	Adenocarcinoma Pancreas	11DEC2020 (58)		ONGOING			2	N
2	SKIN	Decubitus ulcer	Decubitus ulcer left heel	FEB2021 ()		ONGOING			2	TCN
3	INFEC	Escherichia sepsis	Escherichia coli sepsis	07JAN2021 (85)		09JAN2021 (87)		3	2	TC
4	HEPAT	Hepatic cyst	Liver cyst	05JAN2021 (83)		ONGOING			1	N
5	GENRL	Impaired healing	post operative wound healing disturbance	11FEB2021 (120)		16FEB2021 (125)		6	2	N
6	GENRL	Oedema peripheral	leg oedema	FEB2021 ()		08FEB2021 (117)			1	TC
7	CARD	Tachycardia	Tachycardia	21JAN2021 (99)		28JAN2021 (106)		8	1	TC

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Yes	NOT RELATED/OTHER: unknown	2	39	Y
2	N	Yes	NOT RELATED/OTHER: unknown	2		N
3	N	Resolved (09JAN2021)	NOT RELATED/OTHER: unknown	2	66	N
4	N	Yes	NOT RELATED/OTHER: unknown	2	64	N
5	Y	Resolved (16FEB2021)	NOT RELATED/OTHER: due to surgery pancreatic Adenocarcinoma	2	101	Y
6	N	Resolved (08FEB2021)	NOT RELATED/OTHER: unknown	2		N
7	N	Resolved (28JAN2021)	NOT RELATED/OTHER: unknown	2	80	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15OCT2020	
Completed	VACCINATION	01DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	70.2 kg	28.1 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Haemorrhoids	Haemorrhoids	1999	Present
Tubal ligation sterilisation	Female sterilisation	2005	Past
hypercholesterolemia	Hypercholesterolaemia	15APR2010	Present
arteriosclerotic Plaque	Arteriosclerosis	28APR2010	Present
struma diffusa	Goitre	24APR2012	Present
Diabetes mellitus II (stable and controlled)	Type 2 diabetes mellitus	03JAN2020	Present
depression (controlled)	Depression	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15OCT2020 (1)	13:18
2	Placebo	03NOV2020 (20)	08:43
3	BNT162b2	18JAN2021 (96)	11:29
4	BNT162b2	09FEB2021 (118)	09:25

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Abscess	Abscess	27FEB2021 (136)		27FEB2021 (136)		1	2
2	GASTR	Anal fistula	anal fistula	25FEB2021 (134)		25FEB2021 (134)		1	2
3	GASTR	Anal prolapse	anal prolapse	18FEB2021 (127)		27FEB2021 (136)		10	3
4	GENRL	Chills	Chills	10FEB2021 (119)	01:00	11FEB2021 (120)	08:00	2	2
5	MUSC	Pain in extremity	limb pain	10FEB2021 (119)	01:00	11FEB2021 (120)	08:00	2	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (27FEB2021)	NOT RELATED/OTHER: due to haemorrhoids	4	19	N
2	N	N	Resolved (25FEB2021)	Study Treatment	4	17	N
3	N	Y	Resolved (27FEB2021)	NOT RELATED/OTHER: Hemorrhoids	4	10	Y

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	N	N	Resolved (11FEB2021)	Study Treatment	4	2	N
5	N	N	Resolved (11FEB2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15OCT2020	
Completed	VACCINATION	02DEC2020	
Completed	REPEAT SCREENING 1	18JAN2021	
Completed	OPEN LABEL TREATMENT	10MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	62.1 kg	22.8 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arteriosclerosis	Arteriosclerosis	20JAN2014	Present
Hypercholesterinemia	Hypercholesterolaemia	29OCT2014	Present
Postmenopausal	Postmenopause	2015	Present
Mamma Carcinoma	Breast cancer	2017	Past
Spinacanalstenosis	Spinal stenosis	14MAY2018	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	15OCT2020 (1)	15:53
2	BNT162b2	05NOV2020 (22)	11:23

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	MUSC	Osteoarthritis	rhisarthrosis thumb right	17NOV2020 (34)		14FEB2021 (123)		90

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	N	Y	Resolved (14FEB2021)	NOT RELATED/OTHER: unknown	2	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15OCT2020	
Completed	VACCINATION	03DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	68.2 kg	24.2 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arteriosclerosis of the legs	Arteriosclerosis	07MAY2009	Present
Pollinosis	Seasonal allergy	2016	Present
Spondylolisthesis	Spondylolisthesis	29AUG2017	Present
Hysterectomy	Hysterectomy	2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15OCT2020 (1)	16:48
2	Placebo	03NOV2020 (20)	16:35
3	BNT162b2	09FEB2021 (118)	12:51
4	BNT162b2	02MAR2021 (139)	14:21

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	MUSC	Spondylolisthesis	worsening of Spondylolisthesis	19DEC2020 (66)		16JAN2021 (94)		29	3	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (16JAN2021)	NOT RELATED/OTHER: due to already existing Spondylolisthesis	2	47	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15OCT2020	
Completed	VACCINATION	01DEC2020	
Completed	REPEAT SCREENING 1	09FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186 cm	145.1 kg	41.9 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Pollinosis	Seasonal allergy	01JUL2000	Present
Osteochondrosis	Osteochondrosis	03APR2001	Present
Anxiety disorder	Anxiety disorder	MAY2001	Present
Splay-flat feet	Foot deformity	2002	Present
Depression	Depression	JAN2004	Present
irritable bowel	Irritable bowel syndrome	24AUG2010	Present
Lumbal spine syndrome	Spinal disorder	13OCT2014	Present
fatty liver	Hepatic steatosis	21NOV2014	Present
herniated disc cervical vertebra	Intervertebral disc protrusion	05OCT2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	08:17
2	Placebo	04NOV2020 (20)	08:05
3	BNT162b2	29JAN2021 (106)	08:31
4	BNT162b2	19FEB2021 (127)	08:22

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GASTR	Diarrhoea	Diarrhoea	20FEB2021 (128)	13:00	20FEB2021 (128)	22:00	1	2	N	N
2	GENRL	Injection site erythema	Redness injection site	21FEB2021 (129)	09:30	27FEB2021 (135)	08:00	7	2	N	N
3	GENRL	Injection site pain	Pain at injection site	20FEB2021 (128)	01:00	20FEB2021 (128)	17:00	1	2	N	N
4	MUSC	Intervertebral disc protrusion	herniated disc cervical vertebra	16NOV2020 (32)		20NOV2020 (36)		5	1	TC/TCN	Y
5	MUSC	Intervertebral disc protrusion	worsening herniated disc cervical vertebra	29JAN2021 (106)		ONGOING			3	N	N
6	GASTR	Vomiting	Vomiting	20FEB2021 (128)	13:00	20FEB2021 (128)	22:00	1	2	N	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (20FEB2021)	Study Treatment	4	2	N
2	Resolved (27FEB2021)	Study Treatment	4	3	N
3	Resolved (20FEB2021)	Study Treatment	4	2	N
4	Resolved (20NOV2020)	NOT RELATED/OTHER: surgery is necessary for diagnosed herniated disc on 05Oct2020	2	13	Y
5	Yes	NOT RELATED/OTHER: due to surgery at herniated cervical disc	3	1	N
6	Resolved (20FEB2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
Completed	VACCINATION	02DEC2020	
Completed	REPEAT SCREENING 1	29JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171 cm	95.4 kg	32.6 kg/m2	17OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Carpal Tunnel Syndrome	Carpal tunnel syndrome	25MAY2009	Present
Hypertension	Hypertension	07SEP2011	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17OCT2020 (1)	10:29

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	07NOV2020 (22)	10:54
3	BNT162b2	28JAN2021 (104)	09:31
4	BNT162b2	18FEB2021 (125)	09:10

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Arrhythmia	absolute arrhythmia	25FEB2021 (132)		ONGOING		
2	GENRL	Chills	Chills	28JAN2021 (104)	20:00	29JAN2021 (105)	06:00	2
3	GENRL	Chills	Chills	18FEB2021 (125)	16:30	19FEB2021 (126)	13:00	2
4	MUSC	Myalgia	Myalgia	28JAN2021 (104)	20:00	29JAN2021 (105)	06:00	2
5	MUSC	Myalgia	muscle pain	18FEB2021 (125)	16:30	19FEB2021 (126)	13:00	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	Y	Yes	NOT RELATED/OTHER: unknown	4	8	Y
2	1	N	N	Resolved (29JAN2021)	Study Treatment	3	1	N
3	1	TC	N	Resolved (19FEB2021)	Study Treatment	4	1	N
4	1	N	N	Resolved (29JAN2021)	Study Treatment	3	1	N
5	2	TC	N	Resolved (19FEB2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17OCT2020	
Completed	VACCINATION	05DEC2020	
Completed	REPEAT SCREENING 1	28JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159 cm	88.4 kg	35 kg/m2	19OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Psoriasis vulgaris	Psoriasis	01OCT1999	Present
pollinosis	Seasonal allergy	01OCT1999	Present
hypertension	Hypertension	01APR2000	Present
Postmenopausal	Postmenopause	2005	Present
reflux esophagitis	Gastrooesophageal reflux disease	12OCT2015	Present
retropatellar arthrosis	Osteoarthritis	11DEC2017	Present
scoliosis	Scoliosis	30AUG2018	Present
diabetes mellitus type 2	Type 2 diabetes mellitus	24OCT2019	Present
umbilical hernia	Umbilical hernia	30APR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19OCT2020 (1)	13:26
2	Placebo	07NOV2020 (20)	11:43
3	BNT162b2	26JAN2021 (100)	10:18
4	BNT162b2	16FEB2021 (121)	09:56

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Chills	Chills	16FEB2021 (121)	22:00	17FEB2021 (122)	17:00	2
2	NERV	Headache	Headache	26JAN2021 (100)	18:00	28JAN2021 (102)	12:00	3
3	NERV	Headache	Headache	17FEB2021 (122)	08:00	17FEB2021 (122)	18:00	1
4	GENRL	Injection site pain	Pain injection side	26JAN2021 (100)	14:30	27JAN2021 (101)	15:00	2
5	GASTR	Umbilical hernia	umbilical hernia	24NOV2020 (37)		03DEC2020 (46)		10

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (17FEB2021)	Study Treatment	4	1	N
2	2	TC	N	Resolved (28JAN2021)	Study Treatment	3	1	N
3	2	TC	N	Resolved (17FEB2021)	Study Treatment	4	2	N

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	1	N	N	Resolved (27JAN2021)	Study Treatment	3	1	N
5	1	N	Y	Resolved (03DEC2020)	NOT RELATED/OTHER: unknown	2	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19OCT2020	
Completed	VACCINATION	05DEC2020	
Completed	REPEAT SCREENING 1	26JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	72	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	56.3 kg	21.5 kg/m2	19OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
struma diffusa	Goitre	1997	Present
Postmenopausal	Postmenopause	2001	Present
hypertension	Hypertension	2003	Present
copd	Chronic obstructive pulmonary disease	2008	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	19OCT2020 (1)	13:30
2	BNT162b2	07NOV2020 (20)	11:40

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	NEOPL	Lymphoma	Lymphoma	30DEC2020 (73)		02MAR2021 (135)		63

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	N	Y	Resolved (02MAR2021)	NOT RELATED/OTHER: unknown	2	54	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19OCT2020	
Completed	VACCINATION	05DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	72	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	65.9 kg	22.8 kg/m2	19OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
diabetes mellitus type 2	Type 2 diabetes mellitus	1995	Present
hyperuricemia	Hyperuricaemia	08JAN1998	Present
arterial hypertension	Hypertension	10SEP2003	Present
renal insufficiency	Renal failure	26SEP2010	Present
anemia	Anaemia	09OCT2014	Present
Coxarthrosis left hip	Osteoarthritis	22MAR2017	Present
hypercholesterolemia	Hypercholesterolaemia	08JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19OCT2020 (1)	16:40
2	Placebo	07NOV2020 (20)	15:27
3	BNT162b2	13FEB2021 (118)	11:03
4	BNT162b2	05MAR2021 (138)	13:36

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Acute myocardial infarction	Acute Posterior Myocardial Infarction	03JAN2021 (77)	14:30	08JAN2021 (82)		6	4	TC/TCN	Y
2	GENRL	Peripheral swelling	Arm Swelling	13FEB2021 (118)	18:00	14FEB2021 (119)	16:00	2	1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (08JAN2021)	NOT RELATED/OTHER: arterial hypertension, hypercholesterolemia, diabetes mellitus type 2	2	58	Y
2	Resolved (14FEB2021)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
fluzone 0.7 ml i.m	INFLUENZA VACCINE	07DEC2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19OCT2020	
Completed	VACCINATION	05DEC2020	
Completed	REPEAT SCREENING 1	13FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1997	23	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176 cm	97.6 kg	31.5 kg/m2	20OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20OCT2020 (1)	12:10
2	Placebo	10NOV2020 (22)	09:36
3	BNT162b2	01MAR2021 (133)	10:41

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	NERV	Headache	headache	07NOV2020 (19)	16:00	07NOV2020 (19)	17:00	1
2	NERV	Headache	systemic vaccination reaction headache	01MAR2021 (133)	18:00	01MAR2021 (133)	20:00	1
3	GASTR	Inguinal hernia	inguinal hernia left	09NOV2020 (21)	16:00	19FEB2021 (123)	08:00	103

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC	N	Resolved (07NOV2020)	NOT RELATED/OTHER: stress induced	1	19	N
2	2	TC	N	Resolved (01MAR2021)	Study Treatment	3	1	N
3	2	TC/TCN	Y	Resolved (19FEB2021)	NOT RELATED/OTHER: unknown	1	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20OCT2020	
Completed	VACCINATION	08DEC2020	
Completed	REPEAT SCREENING 1	01MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171 cm	75 kg	25.6 kg/m2	10NOV2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10NOV2020 (1)	14:46
2	BNT162b2	01DEC2020 (22)	11:31

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Anal abscess	Anal Abscess	04JAN2021 (56)		06JAN2021 (58)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/TCN	Y	Resolved (06JAN2021)	NOT RELATED/OTHER: Anal Abscess	2	35	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10NOV2020	
Completed	VACCINATION	11JAN2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185 cm	107 kg	31.3 kg/m2	10NOV2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypertension	Hypertension	2016	Present
Subject had a shortness of breath complaints	Dyspnoea	JUL2020	Present
Subject had a lump on the neck	Neck mass	JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10NOV2020 (1)	15:20
2	BNT162b2	02DEC2020 (23)	11:18

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NEOPL	Lipoma	Encapsulated Lipoma	11JAN2021 (63)		20JAN2021 (72)		10	2	TC	Y
2	RESP	Nasal septum deviation	Nasal Septum Deviation	11JAN2021 (63)		20JAN2021 (72)		10	2	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (20JAN2021)	NOT RELATED/OTHER: Encapsulated lipoma excising operation was performed on 19Jan21.	2	41	Y
2	Resolved (20JAN2021)	NOT RELATED/OTHER: Deviated Septum Operation was performed on 19Jan21 due to Nasal Septum Deviation	2	41	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10NOV2020	
Completed	VACCINATION	06JAN2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	90 kg	29.4 kg/m2	03NOV2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03NOV2020 (1)	10:07
2	Placebo	24NOV2020 (22)	09:32
3	BNT162b2	26FEB2021 (116)	10:00

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	COVID-19	COVID-19 Illness	18DEC2020 (46)		23DEC2020 (51)		6	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (23DEC2020)	NOT RELATED/OTHER: Covid-19 pandemic	2	25	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
SKY Cellflu Quadrivalent	INFLUENZA VACCINE	16DEC2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03NOV2020	
Completed	VACCINATION	31DEC2020	
Completed	REPEAT SCREENING 1	26FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	46	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
183 cm	86 kg	25.7 kg/m2	30OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30OCT2020 (1)	10:50
2	Placebo	11DEC2020 (43)	10:20

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	20JAN2021 (83)	09:50
4	BNT162b2	12FEB2021 (106)	11:00

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Upper respiratory tract infection	Acute upper respiratory tract infections	07NOV2020 (9)		16NOV2020 (18)		10	1
2	INFEC	Upper respiratory tract infection	Acute upper respiratory tract infections	16NOV2020 (18)		07DEC2020 (39)		22	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (16NOV2020)	NOT RELATED/OTHER: suspected covid 19	1	9	N
2	TC	Y	Resolved (07DEC2020)	NOT RELATED/OTHER: Suspected COVID19	1	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30OCT2020	
Completed	VACCINATION	13JAN2021	
Completed	REPEAT SCREENING 1	20JAN2021	
Completed	OPEN LABEL TREATMENT	12MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176 cm	92 kg	29.7 kg/m2	06NOV2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2008	Present
Hyperlipidemia	Hyperlipidaemia	2019	Present
Type-2 Diabetes Mellitus	Type 2 diabetes mellitus	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	06NOV2020 (1)	11:40
2	BNT162b2	27NOV2020 (22)	11:07

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Hypertensive crisis	Hypertensive crisis	24NOV2020 (19)	21:30	25NOV2020 (20)	22:00	2	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (25NOV2020)	NOT RELATED/OTHER: Hypertensive urgency	1	19	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06NOV2020	
Completed	VACCINATION	25DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186 cm	88.2 kg	25.5 kg/m2	02NOV2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
vertebral disk herniation surgery	Intervertebral disc operation	2010	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02NOV2020 (1)	12:36
2	BNT162b2	23NOV2020 (22)	09:43

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	MUSC	Intervertebral disc protrusion	recurrence vertebral disc herniation	18NOV2020 (17)		02DEC2020 (31)		15	2
2	RESP	Pulmonary embolism	pulmonary embolism	05DEC2020 (34)		05DEC2020 (34)		1	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (02DEC2020)	NOT RELATED/OTHER: disk herniation	1	17	Y
2	TC	Y	Resolved (05DEC2020)	NOT RELATED/OTHER: immobility and surgery	2	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02NOV2020	
Completed	VACCINATION	21DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	32	American Indian or Alaska Native	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	124.09 kg	42.8 kg/m2	19OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
supraventricular tachycardia	Supraventricular tachycardia	24APR2003	Past
Morbid obesity	Obesity	17DEC2009	Present
chronic hip pain	Arthralgia	15AUG2014	Present
acid reflux	Gastrooesophageal reflux disease	15AUG2014	Past
hiatal hernia repair	Hernia hiatus repair	SEP2018	Past
pre-diabetes	Glucose tolerance impaired	31JUL2019	Present
Cholelithiasis	Cholelithiasis	09MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19OCT2020 (1)	15:44
2	BNT162b2	11NOV2020 (24)	11:00

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Abdominal pain	Abdominal pain	03NOV2020 (16)		06NOV2020 (19)		4
2	HEPAT	Cholecystitis acute	Acute cholecystitis	18JAN2021 (92)		21JAN2021 (95)		4
3	GASTR	Nausea	Nausea	04NOV2020 (17)		06NOV2020 (19)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (06NOV2020)	NOT RELATED/OTHER: Unknown	1	16	N
2	3	TC/TCN	Y	Resolved (21JAN2021)	NOT RELATED/OTHER: Cholelithiasis	2	69	Y
3	1	N	N	Resolved (06NOV2020)	NOT RELATED/OTHER: Unknown	1	17	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19OCT2020	
Completed	VACCINATION	14DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	26	American Indian or Alaska Native	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.8 cm	81.6 kg	27.6 kg/m2	02NOV2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Eczema	Eczema	1999	Present
Depression	Depression	2004	Present
ORIF Left Clavicle	Open reduction of fracture	07OCT2020	Past
Vancomycin Allergy	Drug hypersensitivity	14OCT2020	Present
Amoxicillin Allergy	Drug hypersensitivity	14OCT2020	Present
Incision and Drainage Left Clavicle	Incisional drainage	15OCT2020	Past
Incision and Drainage Left Clavicle	Incisional drainage	21OCT2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02NOV2020 (1)	12:29
2	Placebo	24NOV2020 (23)	11:24
3	BNT162b2	25FEB2021 (116)	10:52

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PSYCH	Alcohol abuse	Alcohol abuse	09JAN2021 (69)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TCN	Y	Yes	NOT RELATED/OTHER: Unhealthy use of alcohol	2	47	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02NOV2020	
Completed	VACCINATION	29DEC2020	
Completed	REPEAT SCREENING 1	25FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	American Indian or Alaska Native	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	68.5 kg	24.9 kg/m2	17NOV2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Iron Deficiency Anemia	Iron deficiency anaemia	20JUN2014	Present
Drug-Allergy: Methocarbamol	Drug hypersensitivity	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17NOV2020 (1)	16:26

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	07DEC2020 (21)	15:25
3	BNT162b2	11JAN2021 (56)	12:49
4	BNT162b2	02FEB2021 (78)	10:14

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	PSYCH	Alcohol withdrawal syndrome	Alcohol withdrawal	03MAR2021 (107)	02:00	04MAR2021 (108)		2	2	TC	Y
2	INJ&P	Thermal burn	Right forearm burn	01MAR2021 (105)		ONGOING			1	TCN	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (04MAR2021)	NOT RELATED/OTHER: Withdrawal from binge drinking of alcohol	4	30	Y
2	Yes	NOT RELATED/OTHER: Touching woodstove with forearm	4	28	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17NOV2020	
Completed	VACCINATION	06JAN2021	
Completed	REPEAT SCREENING 1	11JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	American Indian or Alaska Native	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.5 cm	119.9 kg	38.9 kg/m2	02DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Surgery: Right Knee	Knee operation	1988	Past
Obesity	Obesity	01MAY1992	Present
Surgery: Left Eye	Eye operation	2012	Past
Detached Retina	Retinal detachment	2012	Past
Glaucoma	Glaucoma	24APR2014	Present
Rhinitis	Rhinitis	01MAR2016	Present
Drug Allergy: Sulfa	Drug hypersensitivity	04FEB2018	Present
Diabetes	Diabetes mellitus	08JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02DEC2020 (1)	12:32
2	BNT162b2	28DEC2020 (27)	10:51

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	HEPAT	Cholecystitis acute	Acute Cholecystitis	20DEC2020 (19)	01:00	22DEC2020 (21)		3	2	TC	Y
2	NEOPL	Ovarian germ cell teratoma benign	Mature cystic teratoma left ovary	20DEC2020 (19)		22DEC2020 (21)		3	1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (22DEC2020)	NOT RELATED/OTHER: Acute cholecystitis	1	19	Y
2	Resolved (22DEC2020)	NOT RELATED/OTHER: Unknown-pelvic mass found incidentally on abdominal ultrasound	1	19	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02DEC2020	
Completed	VACCINATION	29JAN2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	American Indian or Alaska Native	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	125.1 kg	43.8 kg/m2	03DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
asthma	Asthma	1990	Present
Disease: Migraines	Migraine	1999	Present
Disease: high blood pressure	Hypertension	2002	Present
drug allergy: penicillin	Drug hypersensitivity	18APR2002	Present
arthritis	Arthritis	2015	Present
chronic bilateral knee pain	Arthralgia	DEC2015	Present
non-drug allergy: bee stings	Allergy to arthropod sting	2018	Present
bladder mesh insertion	Bladder operation	2018	Past
surgery: hysterectomy	Hysterectomy	JAN2018	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
anemia	Anaemia	2019	Present
Disease: high cholesterol	Blood cholesterol increased	2019	Present
heart murmur	Cardiac murmur	2019	Present
difficulty breathing/wheezing-intermittent	Wheezing	2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03DEC2020 (1)	16:31
2	BNT162b2	23DEC2020 (21)	10:18

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Asthma	Asthma exacerbation	16JAN2021 (45)		18JAN2021 (47)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	Y	Resolved (18JAN2021)	NOT RELATED/OTHER: Asthma	2	25	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Hepatitis B Adjuvant Vaccine	HEPATITIS B VACCINE	17JAN2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03DEC2020	
Completed	VACCINATION	21JAN2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	American Indian or Alaska Native	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.5 cm	128.2 kg	36.5 kg/m2	08DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	07MAR2009	Present
Seizures	Seizure	20NOV2014	Past
Alcoholic Hepatitis	Hepatitis alcoholic	MAY2020	Past
Alcoholic cirrhosis	Cirrhosis alcoholic	JUN2020	Present
Acute renal failure secondary to hepatorenal syndrome	Hepatorenal syndrome	16JUN2020	Past
Type 2 Diabetes	Type 2 diabetes mellitus	15OCT2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08DEC2020 (1)	13:16
3	BNT162b2	16FEB2021 (71)	11:02
4	BNT162b2	08MAR2021 (91)	09:49

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Injection site pain	Injection site pain	08DEC2020 (1)	13:16	09DEC2020 (2)	17:07	2	1
2	GASTR	Oesophageal varices haemorrhage	Esophageal varices hemorrhage	09JAN2021 (33)		09JAN2021 (33)		1	4
3	GASTR	Toothache	Toothache	01FEB2021 (56)		04FEB2021 (59)		4	1
4	GASTR	Vomiting	Vomiting	09DEC2020 (2)	08:00	09DEC2020 (2)	14:00	1	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (09DEC2020)	Study Treatment	1	1	N
2	TC/TCN	Y	Resolved (09JAN2021)	NOT RELATED/OTHER: Decompensated alcoholic cirrhosis	1	33	Y
3	TC/TCN	N	Resolved (04FEB2021)	NOT RELATED/OTHER: Dental caries	1	56	N
4	N	N	Resolved (09DEC2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08DEC2020	
Withdrawn	VACCINATION	22JAN2021	OTHER
Completed	REPEAT SCREENING 1	16FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	37	American Indian or Alaska Native	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	118.4 kg	36.5 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Uveitis	Uveitis	JAN2006	Present
Chronic intermittent back pain	Back pain	2012	Present
Seasonal allergies	Seasonal allergy	2012	Present
Syphilis	Syphilis	2013	Past
Foot fracture	Foot fracture	2014	Past
Surgical revision of scar tissue in foot	Scar excision	2014	Past
Anxiety	Anxiety	JUN2016	Past
Syphilis	Syphilis	MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	15:56
2	Placebo	07DEC2020 (53)	13:00
3	BNT162b2	17DEC2020 (63)	12:47
4	BNT162b2	08JAN2021 (85)	11:35

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Abscess jaw	Abscess in left jaw	31OCT2020 (16)		02DEC2020 (48)		33	3
2	INJ&P	Exposure to communicable disease	STD Exposure	06NOV2020 (22)		06NOV2020 (22)		1	1
3	INFEC	Meningitis bacterial	Meningitis Bacterial	10NOV2020 (26)		02DEC2020 (48)		23	3
4	INFEC	Otitis externa	Left Otitis Externa	06NOV2020 (22)		18NOV2020 (34)		13	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	N	Resolved (02DEC2020)	NOT RELATED/OTHER: Inflammation vs. infection	1	16	N
2	TC	N	Resolved (06NOV2020)	NOT RELATED/OTHER: Unprotected sex with a male	1	22	N
3	TC	Y	Resolved (02DEC2020)	NOT RELATED/OTHER: Bacterial infection	1	26	Y
4	TC	N	Resolved (18NOV2020)	NOT RELATED/OTHER: Ear infection	1	22	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
Withdrawn	VACCINATION	17DEC2020	OTHER
Completed	REPEAT SCREENING 1	17DEC2020	
Completed	OPEN LABEL TREATMENT	05FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	63	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	74.6 kg	27.4 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
depression	Depression	1980	Present
diabetes type II	Type 2 diabetes mellitus	2000	Present
hypercholesterolemia	Hypercholesterolaemia	APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	12:47
2	Placebo	23SEP2020 (23)	12:50
3	BNT162b2	02MAR2021 (183)	10:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Dyspnoea	Shortness of breath	03FEB2021 (156)	00:00	12FEB2021 (165)		10	2
2	GENRL	Fatigue	fatigue	03MAR2021 (184)	09:00	04MAR2021 (185)	09:00	2	2
3	GENRL	Injection site pain	injection site pain	02MAR2021 (183)	15:00	04MAR2021 (185)	09:00	3	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (12FEB2021)	NOT RELATED/OTHER: Unknown etiology	2	134	Y
2	N	N	Resolved (04MAR2021)	Study Treatment	3	2	N
3	N	N	Resolved (04MAR2021)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine	INFLUENZA VACCINE	12OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	22OCT2020	
Completed	REPEAT SCREENING 1	02MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	54	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177 cm	63 kg	20.1 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypercholesterolemia	Hypercholesterolaemia	2005	Present
Ileostomy	Ileostomy	2010	Past
Bowel perforation	Intestinal perforation	2010	Past
a-fibrullation	Atrial fibrillation	2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	09:37
2	Placebo	21SEP2020 (20)	10:52
3	BNT162b2	18DEC2020 (108)	11:54
4	BNT162b2	06JAN2021 (127)	12:35

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Chills	chills	06JAN2021 (127)	23:00	06JAN2021 (127)	23:30	1	1
2	GASTR	Gastrointestinal necrosis	Bowel necrosis	04FEB2021 (156)	00:00	ONGOING			4
3	NERV	Headache	intermittent headaches	07JAN2021 (128)	19:30	26JAN2021 (147)	08:00	20	1
4	MUSC	Myalgia	myalgia	06JAN2021 (127)	23:00	06JAN2021 (127)	23:30	1	1
5	INJ&P	Postoperative ileus	Postoperative ileus	11FEB2021 (163)		15FEB2021 (167)		5	3
6	GASTR	Small intestinal obstruction	Small Bowel Obstruction	16FEB2021 (168)		19FEB2021 (171)		4	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (06JAN2021)	Study Treatment	4	1	N
2	TC/TCN	Y	Yes	NOT RELATED/OTHER: History of Bowel perforation	4	30	Y
3	N	N	Resolved (26JAN2021)	Study Treatment	4	2	N
4	N	N	Resolved (06JAN2021)	Study Treatment	4	1	N

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
5	TC	Y	Resolved (15FEB2021)	NOT RELATED/OTHER: Postoperative complication	4	37	Y
6	TC	Y	Resolved (19FEB2021)	NOT RELATED/OTHER: Postoperative complication	4	42	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	09OCT2020
shingrix vaccine	VARICELLA ZOSTER VACCINE RGE (CHO)	09OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	19OCT2020	
Completed	REPEAT SCREENING 1	18DEC2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	03FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154 cm	50.3 kg	21.2 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteoarthritis	Osteoarthritis	1996	Present
Menopause	Menopause	1998	Present
GERD	Gastrooesophageal reflux disease	2002	Present
Melanoma	Malignant melanoma	2007	Past
Hypertension	Hypertension	2008	Present
Dyslipidemia	Dyslipidaemia	2014	Present
Hypothyroidism	Hypothyroidism	2014	Present
Eustachian Tube Dysfunction	Eustachian tube dysfunction	2017	Present
Cardiovascular prevention	Prophylaxis	2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Irritable bowl syndrome	Irritable bowel syndrome	2019	Present
Osteoporosis	Osteoporosis	2019	Present
Monoclonal Gammopathy of Unknown Significance	Hypergammaglobulinaemia benign monoclonal	17AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10SEP2020 (1)	15:26
2	BNT162b2	01OCT2020 (22)	15:36

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Adenocarcinoma pancreas	Pancreatic Adenocarcinoma	05NOV2020 (57)	11:21	ONGOING			3
2	GASTR	Enterocolitis	Enterocolitis	15JAN2021 (128)	00:00	ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Yes	NOT RELATED/OTHER: New development of pancreatic mass	2	36	Y
2	TC	Y	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	107	Y

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Flourouracil	FLUOROURACIL	07JAN2021	ONGOING	INTRAVENOUS
Irinotecan	IRINOTECAN	07JAN2021	ONGOING	INTRAVENOUS
Oxaliplatin	OXALIPLATIN	07JAN2021	ONGOING	INTRAVENOUS

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Withdrawn	VACCINATION	05NOV2020	OTHER
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	42	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	125.7 kg	38.8 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Diabetes Mellitus	Diabetes mellitus	2014	Present
Gout	Gout	2014	Present
hypertension	Hypertension	2015	Present
Cerebellar Stroke	Cerebellar stroke	2017	Past
Chronic Kidney Disease	Chronic kidney disease	2018	Present
Depression	Depression	2018	Present
Sleep Apnea	Sleep apnoea syndrome	2018	Present
glaucoma	Glaucoma	2019	Present
left frontal stroke	Cerebrovascular accident	JAN2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14SEP2020 (1)	12:56
2	BNT162b2	07OCT2020 (24)	15:22

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	METAB	Gout	exacerbation of gout in shoulder	04OCT2020 (21)	08:00	ONGOING			1
2	VASC	Hypertensive urgency	hypertensive urgency	28OCT2020 (45)	22:00	05NOV2020 (53)	03:40	9	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Yes	NOT RELATED/OTHER: food and medical history	1	21	N
2	TC	Y	Resolved (05NOV2020)	NOT RELATED/OTHER: hypertension	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	06NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1936	83	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	78.4 kg	27.5 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
dislocated shoulder	Joint dislocation	1966	Past
atrial fibrillation	Atrial fibrillation	1998	Present
gastroesophageal reflux	Gastrooesophageal reflux disease	2001	Present
Hypertension	Hypertension	2001	Present
sleep apnea	Sleep apnoea syndrome	2012	Present
barrett's Esophagitus	Barrett's oesophagus	2017	Present
Benign Prostatic Hypertrophy	Benign prostatic hyperplasia	2017	Present
diverticulitis	Diverticulitis	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16SEP2020 (1)	13:36
2	BNT162b2	09OCT2020 (24)	11:03

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INFEC	Abscess intestinal	Pericolonic Abscess	13OCT2020 (28)	19:00	ONGOING			4	TC/TCN
2	INFEC	Diverticulitis	progression of diverticulitis	29SEP2020 (14)	13:00	ONGOING			3	TC

Adverse Events					
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Yes	NOT RELATED/OTHER: related to an underlying condition reported in Medical History	2	5	Y
2	Y	Yes	NOT RELATED/OTHER: History of diverticulitis	1	14	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16SEP2020	
Completed	VACCINATION	06NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.8 cm	82.7 kg	26.8 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasectomy	Vasectomy	2010	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07AUG2020 (1)	10:47
2	BNT162b2	26AUG2020 (20)	11:18

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Herpes zoster oticus	Ramsay Hunt Syndrome	25JAN2021 (172)		14FEB2021 (192)		21	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (14FEB2021)	NOT RELATED/OTHER: herpes zoster virus infection	2	153	Y

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Prednisone	PREDNISONE	28JAN2021	01FEB2021	ORAL
Prednisone	PREDNISONE	05FEB2021	14FEB2021	ORAL
Prednisone	PREDNISONE	15FEB2021	19FEB2021	ORAL
Prednisone	PREDNISONE	20FEB2021	24FEB2021	ORAL
Prednisone	PREDNISONE	25FEB2021	01MAR2021	ORAL

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	23SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	35	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.2 cm	64.5 kg	23.9 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis	Rhinitis allergic	2002	Present
Renal lithiasis	Nephrolithiasis	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10AUG2020 (1)	12:00

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	01SEP2020 (23)	14:00
3	BNT162b2	22JAN2021 (166)	14:00
4	BNT162b2	11FEB2021 (186)	11:08

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GENRL	Injection site haematoma	Hematoma at injection site	23JAN2021 (167)		27JAN2021 (171)		5	1	N	N
2	GENRL	Injection site pain	PAIN AT INJECTION SITE	02SEP2020 (24)		02SEP2020 (24)		1	1	N	N
3	GENRL	Injection site pain	Pain at the injection site	12FEB2021 (187)		13FEB2021 (188)		2	2	TC	N
4	RENAL	Nephrolithiasis	Worsening of nephrolithiasis	09NOV2020 (92)	21:00	26NOV2020 (109)		18	3	TC	Y
5	GENRL	Pain	Body pain	12FEB2021 (187)		13FEB2021 (188)		2	2	TC	N
6	GENRL	Pyrexia	Fever 38.5	12FEB2021 (187)		13FEB2021 (188)		2	2	TC	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (27JAN2021)	Study Treatment	3	2	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	Resolved (02SEP2020)	Study Treatment	2	2	N
3	Resolved (13FEB2021)	Study Treatment	4	2	N
4	Resolved (26NOV2020)	NOT RELATED/OTHER: Renal lithiasis (previous renal calculus migration)	2	70	Y
5	Resolved (13FEB2021)	Study Treatment	4	2	N
6	Resolved (13FEB2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10AUG2020	
Completed	VACCINATION	30SEP2020	
Completed	REPEAT SCREENING 1	22JAN2021	
Completed	OPEN LABEL TREATMENT	11MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	30	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.6 cm	81 kg	32.2 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	SEP1995	Present
Allergy to dipyrone	Drug hypersensitivity	JUL2013	Present
Nephrolithiasis	Nephrolithiasis	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	13:48
2	Placebo	01SEP2020 (22)	14:15
3	BNT162b2	11MAR2021 (213)	10:10

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RENAL	Nephrolithiasis	Worsening of Nephrolithiasis	21DEC2020 (133)		22JAN2021 (165)		33	3
2	INFEC	Urinary tract infection	Urinary tract infection	29DEC2020 (141)		05JAN2021 (148)		8	2

Adverse Events						
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (22JAN2021)	NOT RELATED/OTHER: Nephrolithiasis	2	112	Y
2	TC	N	Resolved (05JAN2021)	NOT RELATED/OTHER: Worsening of nephrolithiasis	2	120	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	30SEP2020	
Completed	REPEAT SCREENING 1	11MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.5 cm	86 kg	28.9 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hemorrhoids	Haemorrhoids	FEB2001	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12AUG2020 (1)	12:18
2	BNT162b2	04SEP2020 (24)	12:49

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GASTR	Haemorrhoids	Hemorrhoid Worsening	26JAN2021 (168)		27JAN2021 (169)		2

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	TC/TCN	Y	Resolved (27JAN2021)	NOT RELATED/OTHER: Hemorrhoids	2	145	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	52	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.5 cm	97.3 kg	32.3 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	12:28
2	Placebo	03SEP2020 (23)	09:30

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Other_AEI_SAE/profile Date of Generation: 07APR2021 (21:52)

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	19FEB2021 (192)	14:30
4	BNT162b2	12MAR2021 (213)	09:40

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Fall	Bicycle fall	20SEP2020 (40)		20SEP2020 (40)		1
2	INJ&P	Forearm fracture	Right forearm fracture	20SEP2020 (40)	14:00	29SEP2020 (49)		10

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	N	Resolved (20SEP2020)	NOT RELATED/OTHER: accidental cause	2	18	N
2	3	TC/TCN	Y	Resolved (29SEP2020)	NOT RELATED/OTHER: fall bike	2	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	02OCT2020	
Completed	REPEAT SCREENING 1	19FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	92.3 kg	30.1 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
obesity	Obesity	2000	Present
Vasectomy	Vasectomy	2015	Past
renal lithiasis	Nephrolithiasis	APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	09:39
2	BNT162b2	11SEP2020 (23)	08:44

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Conjunctivitis	Conjunctivitis	01SEP2020 (13)		07SEP2020 (19)		7	1
2	RENAL	Renal colic	Renal colic	29AUG2020 (10)	05:00	30AUG2020 (11)	12:00	2	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (07SEP2020)	NOT RELATED/OTHER: possible cause: bacterial	1	13	N
2	TC/TCN	Y	Resolved (30AUG2020)	NOT RELATED/OTHER: Renal lithiasis	1	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	30	Asian	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152 cm	42.5 kg	18.4 kg/m2	21AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	10:30
2	BNT162b2	09SEP2020 (20)	12:01

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Chills	chills	10SEP2020 (21)		10SEP2020 (21)		1
2	INFEC	Gastroenteritis	Gastroenterocolitis	20NOV2020 (92)	22:00	29NOV2020 (101)		10
3	GENRL	Injection site pain	Pain at injection site	09SEP2020 (20)	18:00	10SEP2020 (21)		2
4	GENRL	Injection site pain	Pain at injecton site	22AUG2020 (2)		23AUG2020 (3)		2
5	GENRL	Pain	Body pain	22AUG2020 (2)		23AUG2020 (3)		2
6	GENRL	Pyrexia	Fever	22AUG2020 (2)		23AUG2020 (3)		2

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (10SEP2020)	Study Treatment	2	2	N
2	2	TC	Y	Resolved (29NOV2020)	NOT RELATED/OTHER: Food poisoning	2	73	Y
3	1	N	N	Resolved (10SEP2020)	Study Treatment	2	1	N
4	1	TC	N	Resolved (23AUG2020)	Study Treatment	1	2	N
5	1	TC	N	Resolved (23AUG2020)	Study Treatment	1	2	N
6	1	TC	N	Resolved (23AUG2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	68.8 kg	24.1 kg/m2	05SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05SEP2020 (1)	15:08
2	BNT162b2	25SEP2020 (21)	09:15

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Cervical vertebral fracture	Fracture of the fourth cervical vertebra	21OCT2020 (47)		30OCT2020 (56)		10
2	INJ&P	Contusion	Bruises in various regions of the body	21OCT2020 (47)		30OCT2020 (56)		10
3	INJ&P	Road traffic accident	hit by motorcycle	21OCT2020 (47)	18:00	21OCT2020 (47)		1
4	INJ&P	Skin abrasion	Excoriations in various regions of the body	21OCT2020 (47)		30OCT2020 (56)		10
5	INJ&P	Spinal cord injury cervical	Cervical spinal cord contusion	21OCT2020 (47)		30OCT2020 (56)		10
6	NERV	Subarachnoid haemorrhage	Subarachnoid hemorrhage	21OCT2020 (47)		30OCT2020 (56)		10
7	RENAL	Subcapsular renal haematoma	Peri-renal hematoma	21OCT2020 (47)		30OCT2020 (56)		10

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (30OCT2020)	NOT RELATED/OTHER: hit by motorcycle	2	27	Y
2	2	TC	N	Resolved (30OCT2020)	NOT RELATED/OTHER: hit by motorcycle	2	27	N
3	3	N	Y	Resolved (21OCT2020)	NOT RELATED/OTHER: accidental	2	27	Y
4	2	TC	N	Resolved (30OCT2020)	NOT RELATED/OTHER: hit by motorcycle	2	27	N
5	3	TC	Y	Resolved (30OCT2020)	NOT RELATED/OTHER: hit by motorcycle	2	27	Y
6	3	TC	Y	Resolved (30OCT2020)	NOT RELATED/OTHER: hit by motorcycle	2	27	Y
7	3	TC	Y	Resolved (30OCT2020)	NOT RELATED/OTHER: hit by motorcycle	2	27	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	05SEP2020	
Completed	VACCINATION	26NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.8 cm	97.1 kg	31.4 kg/m2	07SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Overweight	Overweight	2000	Present
Systemic arterial hypertension	Hypertension	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07SEP2020 (1)	10:26
2	BNT162b2	29SEP2020 (23)	10:26

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Injection site pain	Pain at the injection site	07SEP2020 (1)	16:00	08SEP2020 (2)		2
2	GENRL	Injection site pain	Pain at the injection site	30SEP2020 (24)		30SEP2020 (24)		1
3	RENAL	Ureterolithiasis	Left ureteral stone	13NOV2020 (68)	22:00	15NOV2020 (70)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (08SEP2020)	Study Treatment	1	1	N
2	1	N	N	Resolved (30SEP2020)	Study Treatment	2	2	N
3	2	TCN	Y	Resolved (15NOV2020)	NOT RELATED/OTHER: Unknown	2	46	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07SEP2020	
Completed	VACCINATION	27OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	34	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	61.3 kg	21.7 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis	Rhinitis allergic	1995	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16SEP2020 (1)	11:33
2	BNT162b2	06OCT2020 (21)	10:20

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	NEOPL	Leydig cell tumour of the testis	Leydig cell tumor in left testicle	23SEP2020 (8)		07OCT2020 (22)		15

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	N	Y	Resolved (07OCT2020)	NOT RELATED/OTHER: unknown cause	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16SEP2020	
Completed	VACCINATION	04NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	49	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
150.3 cm	83.3 kg	36.9 kg/m2	17SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Fibromyalgia	Fibromyalgia	2015	Present
low back pain	Back pain	2018	Present
Hysterectomy	Hysterectomy	FEB2019	Past
Perforation of the uterus by IUD	Uterine perforation	FEB2019	Past
Obesity	Obesity	MAR2019	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	17SEP2020 (1)	10:04
2	BNT162b2	07OCT2020 (21)	10:12

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	NERV	Idiopathic intracranial hypertension	idiopathic intracranial hypertension	22OCT2020 (36)		30OCT2020 (44)		9	3
2	GENRL	Injection site pruritus	Pruridus at the injection site	17SEP2020 (1)	18:15	20SEP2020 (4)		4	1
3	MUSC	Myalgia	Muscle pain	07OCT2020 (21)	12:00	09OCT2020 (23)		3	2
4	INFEC	Postoperative wound infection	surgical site infection (Flank)	03NOV2020 (48)		11DEC2020 (86)		39	3
5	GENRL	Pyrexia	Fever 38.2 C	07OCT2020 (21)	14:00	09OCT2020 (23)		3	2

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN	Y	Resolved (30OCT2020)	NOT RELATED/OTHER: idiopathic	2	16	Y
2	N	N	Resolved (20SEP2020)	Study Treatment	1	1	N
3	TC	N	Resolved (09OCT2020)	Study Treatment	2	1	N
4	TC	Y	Resolved (11DEC2020)	NOT RELATED/OTHER: peritoneal loin shunt	2	28	Y
5	TC	N	Resolved (09OCT2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17SEP2020	
Completed	VACCINATION	17DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1980	40	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.5 cm	74.2 kg	28.1 kg/m2	18SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18SEP2020 (1)	11:44
2	Placebo	09OCT2020 (22)	13:09

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	23JAN2021 (128)	14:37
4	BNT162b2	15FEB2021 (151)	14:00

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PSYCH	Anxiety	Anxiety	10NOV2020 (54)		ONGOING			2
2	GENRL	Fatigue	Fatigue	24JAN2021 (129)		25JAN2021 (130)		2	1
3	GASTR	Gastrooesophageal reflux disease	gastroesophageal reflux	NOV2020 ()		ONGOING			1
4	GENRL	Injection site pain	pain at the injection site	16FEB2021 (152)		18FEB2021 (154)		3	1
5	NERV	Loss of consciousness	Loss of consciousness	11FEB2021 (147)		11FEB2021 (147)		1	3
6	MUSC	Myalgia	Muscle pain	12FEB2021 (148)		13FEB2021 (149)		2	3
7	GENRL	Pyrexia	fever (37,8 C)	16FEB2021 (152)		18FEB2021 (154)		3	1
8	INJ&P	Road traffic accident	automobile accident (driver)	11FEB2021 (147)		11FEB2021 (147)		1	2
9	CARD	Supraventricular tachycardia	Supraventricular tachycardia	11FEB2021 (147)		11FEB2021 (147)		1	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Yes	NOT RELATED/OTHER: over-worrying about work	2	33	N
2	N	N	Resolved (25JAN2021)	Study Treatment	3	2	N
3	TC	N	Yes	NOT RELATED/OTHER: UNKNOWN	2		N

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	N	N	Resolved (18FEB2021)	Study Treatment	4	2	N
5	N	N	Resolved (11FEB2021)	NOT RELATED/OTHER: supraventricular tachycardia	3	20	N
6	TC	Y	Resolved (13FEB2021)	NOT RELATED/OTHER: Car accident	3	21	Y
7	N	N	Resolved (18FEB2021)	Study Treatment	4	2	N
8	N	N	Resolved (11FEB2021)	NOT RELATED/OTHER: supraventricular tachycardia	3	20	N
9	TC	N	Resolved (11FEB2021)	NOT RELATED/OTHER: unknown	3	20	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18SEP2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	11NOV2020	
Completed	REPEAT SCREENING 1	23JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.3 cm	88.5 kg	32.4 kg/m2	01OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
constipation	Constipation	2010	Present
obesity	Obesity	2010	Present
withdrawal of nasal basal cell cancer	Skin neoplasm excision	2011	Past
Hepatic steatosis	Hepatic steatosis	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01OCT2020 (1)	13:30
2	Placebo	22OCT2020 (22)	10:48

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Arrhythmia	Arrhythmia	19NOV2020 (50)		21NOV2020 (52)		3	1
2	INFEC	COVID-19	COVID-19	20DEC2020 (81)		14JAN2021 (106)		26	4
3	GENRL	Chest pain	Chest pain	19NOV2020 (50)		21NOV2020 (52)		3	1
4	RENAL	Dysuria	Dysuria	16FEB2021 (139)		ONGOING			1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (21NOV2020)	NOT RELATED/OTHER: Emotional stress	2	29	N
2	TC/TCN	Y	Resolved (14JAN2021)	NOT RELATED/OTHER: Unknown	2	60	Y
3	N	N	Resolved (21NOV2020)	NOT RELATED/OTHER: Emotional stress	2	29	N
4	TC	N	Yes	NOT RELATED/OTHER: urinary bacterial infection	2	118	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01OCT2020	
Completed	VACCINATION	23NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	72	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.3 cm	85 kg	29.3 kg/m2	01OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasectomy	Vasectomy	1985	Past
Hemorrhoids	Haemorrhoids	2001	Past
Dyslipidemia	Dyslipidaemia	2005	Present
Diabetes Mellitus type 2	Type 2 diabetes mellitus	2017	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	01OCT2020 (1)	14:16
2	BNT162b2	22OCT2020 (22)	11:52

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GENRL	Injection site pain	Pain at the injection site	01OCT2020 (1)	19:00	02OCT2020 (2)		2	1
2	GENRL	Injection site pain	Pain at the injection site	22OCT2020 (22)	20:00	24OCT2020 (24)		3	2
3	GENRL	Pyrexia	Fever (38 C)	02OCT2020 (2)		03OCT2020 (3)		2	1
4	GENRL	Pyrexia	Fever 38.5 C	22OCT2020 (22)	20:00	24OCT2020 (24)		3	2
5	GASTR	Rectal haemorrhage	Anorectal hemorrhage	20FEB2021 (143)		26FEB2021 (149)		7	4
6	INJ&P	Rectal injury	Anorectal laceration	20FEB2021 (143)		20FEB2021 (143)		1	3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (02OCT2020)	Study Treatment	1	1	N
2	TC	N	Resolved (24OCT2020)	Study Treatment	2	1	N
3	TC	N	Resolved (03OCT2020)	Study Treatment	1	2	N
4	TC	N	Resolved (24OCT2020)	Study Treatment	2	1	N
5	TC/TCN	Y	Resolved (26FEB2021)	NOT RELATED/OTHER: Hemorrhoidectomy complication	2	122	Y
6	TC/TCN	N	Resolved (20FEB2021)	NOT RELATED/OTHER: Hemorrhoidectomy complication	2	122	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01OCT2020	
Completed	VACCINATION	24NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	51	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159.3 cm	103 kg	40.6 kg/m2	03OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Pulmonary thromboembolism	Pulmonary embolism	1999	Past
Obesity	Obesity	2010	Present
Gastritis	Gastritis	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03OCT2020 (1)	12:05
2	Placebo	26OCT2020 (24)	11:49
3	BNT162b2	13FEB2021 (134)	13:00
4	BNT162b2	05MAR2021 (154)	11:25

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	VASC	Deep vein thrombosis	Deep vein thrombosis in right lower limb	05JAN2021 (95)		13JAN2021 (103)		9	2	TC/TCN
2	VASC	Venous thrombosis limb	Vein thrombosis in right lower limb	14JAN2021 (104)		22FEB2021 (143)		40	2	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (13JAN2021)	NOT RELATED/OTHER: reduced mobility (due to quarantine period)	2	72	Y
2	N	Resolved (22FEB2021)	NOT RELATED/OTHER: Unknown	2	81	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	03OCT2020	
Completed	VACCINATION	23NOV2020	
Completed	REPEAT SCREENING 1	13FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	Multiple	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161 cm	56 kg	21.6 kg/m2	06OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bilateral tubal ligation	Female sterilisation	2006	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	06OCT2020 (1)	11:40
2	BNT162b2	06NOV2020 (32)	10:16

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Chills	Chills	06NOV2020 (32)	21:00	06NOV2020 (32)		1
2	GENRL	Injection site pain	Pain at injection site	06NOV2020 (32)	21:00	07NOV2020 (33)		2
3	GENRL	Malaise	Malaise	06NOV2020 (32)	21:00	06NOV2020 (32)		1
4	MUSC	Myalgia	Muscle pain	06NOV2020 (32)	21:00	06NOV2020 (32)		1
5	GASTR	Nausea	Nausea	06NOV2020 (32)	21:00	06NOV2020 (32)		1
6	INFEC	Urinary tract infection	Urinary tract infection	18OCT2020 (13)	06:00	22OCT2020 (17)		5

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	TC	N	Resolved (06NOV2020)	Study Treatment	2	1	N
2	1	TC	N	Resolved (07NOV2020)	Study Treatment	2	1	N
3	1	TC	N	Resolved (06NOV2020)	Study Treatment	2	1	N
4	1	TC	N	Resolved (06NOV2020)	Study Treatment	2	1	N
5	1	TC	N	Resolved (06NOV2020)	Study Treatment	2	1	N
6	3	TC	Y	Resolved (22OCT2020)	NOT RELATED/OTHER: urinary infection	1	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	06OCT2020	
Completed	VACCINATION	10DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	42	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.8 cm	71 kg	25.2 kg/m2	09OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tubal ligations	Female sterilisation	2017	Past
bariatric surgery	Metabolic surgery	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09OCT2020 (1)	13:48

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	30OCT2020 (22)	10:01
3	BNT162b2	10FEB2021 (125)	11:40
4	BNT162b2	02MAR2021 (145)	11:00

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Injection site pain	Pain at the injection site	10FEB2021 (125)	18:00	11FEB2021 (126)	18:00	2	1
2	REPRO	Pelvic pain	Pelvic pain	13OCT2020 (5)		15OCT2020 (7)		3	2
3	NERV	Transient ischaemic attack	Transient Ischemic Attack	04DEC2020 (57)		08DEC2020 (61)		5	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (11FEB2021)	Study Treatment	3	1	N
2	TC	N	Resolved (15OCT2020)	NOT RELATED/OTHER: possible related to ovulation	1	5	N
3	TC	Y	Resolved (08DEC2020)	NOT RELATED/OTHER: Unknown	2	36	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09OCT2020	
Completed	VACCINATION	01DEC2020	
Completed	REPEAT SCREENING 1	10FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	76	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.8 cm	73.2 kg	26.6 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Menopause	Menopause	1993	Present
hypothyroidism	Hypothyroidism	OCT1999	Present
Diabetes mellitus type 2	Type 2 diabetes mellitus	OCT2000	Present
Systemic arterial hypertension	Hypertension	OCT2005	Present
Fracture of left femur	Femur fracture	NOV2019	Past
Osteoporosis	Osteoporosis	NOV2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	12:10
3	BNT162b2	05FEB2021 (113)	11:30
4	BNT162b2	26FEB2021 (134)	10:25

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	Fall	fall from own height	24OCT2020 (9)		24OCT2020 (9)		1	1	N	N
2	INJ&P	Femur fracture	Fracture of the right femur	24OCT2020 (9)		29OCT2020 (14)		6	3	TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (24OCT2020)	NOT RELATED/OTHER: was knocked down on the street by a dog	1	9	N
2	Resolved (29OCT2020)	NOT RELATED/OTHER: Accidental cause: patient fell after being knocked over by a dog	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	16OCT2020	
Withdrawn	VACCINATION	25NOV2020	PHYSICIAN DECISION
Completed	REPEAT SCREENING 1	05FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.7 cm	100.5 kg	33.3 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
vasectomy	Vasectomy	1985	Past
systemic arterial hypertension	Hypertension	2005	Present
pre-diabetes mellitus	Glucose tolerance impaired	2015	Present
obesity	Obesity	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	13:51
2	Placebo	04NOV2020 (20)	12:10
3	BNT162b2	05FEB2021 (113)	12:50
4	BNT162b2	26FEB2021 (134)	10:45

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Myalgia	myalgia	06FEB2021 (114)	14:00	07FEB2021 (115)		2
2	RENAL	Nephrolithiasis	Nephrolithiasis	01JAN2021 (78)		03JAN2021 (80)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (07FEB2021)	Study Treatment	3	2	N
2	4	TCN	Y	Resolved (03JAN2021)	NOT RELATED/OTHER: Idiopathic	2	59	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
Completed	VACCINATION	04DEC2020	
Completed	REPEAT SCREENING 1	05FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	74	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	76.4 kg	24.9 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillectomy	Tonsillectomy	1960	Past
Inguinal Hernia Repair	Inguinal hernia repair	1995	Past
Inguinal Hernia Repair	Inguinal hernia repair	2005	Past
Hypertension	Hypertension	2007	Present
Bilateral lens replacement	Intraocular lens implant	2010	Past
Gastric Carcinoma	Gastric cancer	OCT2014	Past
Laparotomy for tumour excision	Abdominal operation	27OCT2014	Past
Chemotherapy	Chemotherapy	FEB2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25SEP2020 (1)	10:47
2	BNT162b2	16OCT2020 (22)	12:02

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Penile neoplasm	Penile Intra Epithelial Neoplasia	06NOV2020 (43)	16:24	ONGOING	
2	NEOPL	Penile squamous cell carcinoma	PENILE INVASIVE MODERATELY DIFFERENTIAL KERATINIZING SQUAMOUS CELL CARCINOMA	06NOV2020 (43)	16:24	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	N	Y	Yes	NOT RELATED/OTHER: Neoplasia	2	22	Y
2		3	N	N	Yes	NOT RELATED/OTHER: CANCER	2	22	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25SEP2020	
Completed	VACCINATION	13NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
188 cm	101.4 kg	28.7 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic obstructive pulmonary disease. Subject does not take concomitant medicine.	Chronic obstructive pulmonary disease	01AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12AUG2020 (1)	11:38
2	BNT162b2	01SEP2020 (21)	11:03

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	INFEC	Arthritis bacterial	septic arthritis of the right knee.	13DEC2020 (124)	08:00	ONGOING			3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN	Y	Yes	NOT RELATED/OTHER: Staphylococcus sppisolated in joint fluid culture	2	104	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Gam-COVID-Vac (trade name Sputnik V)	AD26 COV2 S	26FEB2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	26FEB2021	PROTOCOL DEVIATION

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186 cm	126.7 kg	36.6 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Nephrolithiasis	Nephrolithiasis	2015	Present
Acute renal colic.	Renal colic	2015	Past
acute renal colic	Renal colic	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	13AUG2020 (1)	11:08
2	BNT162b2	04SEP2020 (23)	10:14

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RENAL	Nephrolithiasis	worsening of renal lithiasis	21NOV2020 (101)	17:00	27NOV2020 (107)	12:10	7

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (27NOV2020)	NOT RELATED/OTHER: Nephrolithiasis	2	79	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	08OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	43	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	70.4 kg	24.9 kg/m2	13AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	13AUG2020 (1)	12:36
2	BNT162b2	02SEP2020 (21)	09:55

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	NERV	Peripheral nerve lesion	Right index finger collateral nerve lesion	08OCT2020 (57)	10:00	09DEC2020 (119)	10:00	63	3	TC/TCN

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (09DEC2020)	NOT RELATED/OTHER: trauma to the right index finger with a gate	2	37	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	01OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179 cm	100 kg	31.2 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	10AUG2005	Present
obstructive sleep apneas	Sleep apnoea syndrome	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14AUG2020 (1)	11:40
2	BNT162b2	04SEP2020 (22)	09:39

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Ischaemic stroke	Ischemic Stroke	07DEC2020 (116)	10:00	10JAN2021 (150)		35	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (10JAN2021)	NOT RELATED/OTHER: history of arterial hypertension	2	95	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1991	29	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154 cm	54.5 kg	23 kg/m2	14AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	12:55
2	Placebo	03SEP2020 (21)	09:23
3	BNT162b2	26FEB2021 (197)	14:26

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Ulna fracture	Left arm olecranon fracture	17SEP2020 (35)	20:00	12FEB2021 (183)	11:00	149

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC/TCN	Y	Resolved (12FEB2021)	NOT RELATED/OTHER: Car crash	2	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	30OCT2020	
Completed	REPEAT SCREENING 1	26FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	52	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154 cm	102 kg	43 kg/m2	15AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hysterectomy	Hysterectomy	2013	Past
Arterial hypertension	Hypertension	01JAN2013	Present
Benign uterine tumor	Benign uterine neoplasm	01APR2013	Past
Allergic Bronchial Ashtma	Asthma	01JAN2017	Present
Gallstones	Cholelithiasis	29MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15AUG2020 (1)	10:55
2	BNT162b2	07SEP2020 (24)	10:00

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Bone fissure	Fissure of left elbow bone	23OCT2020 (70)	20:00	28NOV2020 (106)	12:00	37
2	HEPAT	Cholecystitis acute	Acute cholecystitis	12DEC2020 (120)	20:00	13JAN2021 (152)		33
3	INJ&P	Joint dislocation	Dislocation of the left elbow	23OCT2020 (70)	20:00	28NOV2020 (106)	12:00	37
4	INFEC	Pyelonephritis	pyelonephritis	12SEP2020 (29)	09:00	20SEP2020 (37)	20:00	9

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC/TCN	N	Resolved (28NOV2020)	NOT RELATED/OTHER: limb trauma	2	47	N
2	3	TC/TCN	Y	Resolved (13JAN2021)	NOT RELATED/OTHER: gallstones	2	97	Y
3	1	TC/TCN	N	Resolved (28NOV2020)	NOT RELATED/OTHER: Limb Trauma	2	47	N
4	3	TC	N	Resolved (20SEP2020)	NOT RELATED/OTHER: unknown	2	6	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15AUG2020	
Completed	VACCINATION	05OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	70.8 kg	25.1 kg/m2	15AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15AUG2020 (1)	12:47
2	BNT162b2	03SEP2020 (20)	10:42

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	BLOOD	Anaemia	anemia	25SEP2020 (42)	08:00	06OCT2020 (53)	08:00	12	2	TC	N
2	NEOPL	Malignant melanoma	Pigmented ephitelioid melanoma of the vagina	25SEP2020 (42)		ONGOING			2	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (06OCT2020)	NOT RELATED/OTHER: probable relationship with vaginal tumor under study	2	23	N
2	Yes	NOT RELATED/OTHER: unknown	2	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161 cm	86.25 kg	33.3 kg/m2	15AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic gastritis	Chronic gastritis	2003	Present
Obesity	Obesity	2003	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15AUG2020 (1)	14:55

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Other_AEI_SAE/profile Date of Generation: 07APR2021 (21:52)

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	04SEP2020 (21)	16:20
3	BNT162b2	10MAR2021 (208)	12:10

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Influenza like illness	Flu like syndrome	20AUG2020 (6)	20:00	28AUG2020 (14)		9
2	INFEC	Urinary tract infection	high urinary infection	20AUG2020 (6)	10:00	29OCT2020 (76)	08:00	71
3	GASTR	Vomiting	Vomiting	29AUG2020 (15)	08:30	01SEP2020 (18)	23:00	4

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Resolved (28AUG2020)	NOT RELATED/OTHER: unknown	1	6	Y
2	2	TC	N	Resolved (29OCT2020)	NOT RELATED/OTHER: unknown	1	6	N
3	1	N	N	Resolved (01SEP2020)	NOT RELATED/OTHER: unknown	1	15	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15AUG2020	
Completed	VACCINATION	02OCT2020	
Completed	REPEAT SCREENING 1	10MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	72	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	91.6 kg	30.3 kg/m2	15AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
arterial hypertension	Hypertension	01JAN2005	Present
PSA elevation	Prostatic specific antigen increased	12AUG2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15AUG2020 (1)	15:35
2	BNT162b2	07SEP2020 (24)	18:40

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Prostate cancer	Prostate adenocarcinoma.	20NOV2020 (98)	12:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	TC/TCN	Y	Yes	NOT RELATED/OTHER: unknown	2	75	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Gam-COVID-Vac (trade name Sputnik V).	AD26 COV2 S	18FEB2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	24FEB2021	PROTOCOL DEVIATION

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
189 cm	83 kg	23.2 kg/m2	16AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Nephrolithiasis	Nephrolithiasis	06JUL2011	Present
Dyslipidemia	Dyslipidaemia	06JUL2014	Present
Hypertension	Hypertension	06JUL2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16AUG2020 (1)	11:24
2	BNT162b2	07SEP2020 (23)	10:10

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Carcinoid tumour of the stomach	Well-differentiated multifocal neuroendocrine tumor of the stomach	02JAN2021 (140)	10:00	ONGOING	
2	HEPAT	Portosplenomesenteric venous thrombosis	Portosplenomesenteric venous thrombosis	03MAR2021 (200)	10:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC/TCN	Y	Yes	NOT RELATED/OTHER: unknown	2	118	Y
2		3	TC	Y	Yes	NOT RELATED/OTHER: unknown	2	178	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16AUG2020	
Completed	VACCINATION	06OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187 cm	133 kg	38 kg/m2	16AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
smoking	Tobacco user	MAR1990	Past
Polytrauma	Multiple injuries	MAY2003	Past
Benign skin tumor	Benign neoplasm of skin	MAR2008	Past
benign skin tumor resection	Skin neoplasm excision	APR2008	Past
type 2 diabetes	Type 2 diabetes mellitus	29JAN2016	Present
Diabetic retinopathy	Diabetic retinopathy	JAN2017	Present
cataracts surgery right eye	Cataract operation	MAR2017	Past
cataract surgery left eye	Cataract operation	MAY2017	Past
Right Hallux Necrosis	Extremity necrosis	19APR2018	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
amputation of the right hallux	Toe amputation	19APR2018	Past
ulcer in the trans metatarsal region	Skin ulcer	15JUN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16AUG2020 (1)	12:43
2	BNT162b2	07SEP2020 (23)	20:20

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INFEC	Gangrene	Rightfoot transmetatarsallimited gangrene	03DEC2020 (110)	12:00	17FEB2021 (186)	18:00	77	3	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (17FEB2021)	NOT RELATED/OTHER: Ulcer in the transmetatarsal region of the right foot in a diabetic patient.	2	88	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16AUG2020	
Completed	VACCINATION	05OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	24	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
188 cm	91.8 kg	26 kg/m2	16AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16AUG2020 (1)	13:23
2	Placebo	07SEP2020 (23)	10:40
3	BNT162b2	26FEB2021 (195)	10:44

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GENRL	Asthenia	Asthenia	23SEP2020 (39)	08:00	23SEP2020 (39)	23:00	1	1
2	INJ&P	Ligament rupture	Rupture of the anterior cruciate ligament of the left knee	21NOV2020 (98)	16:00	03FEB2021 (172)	17:00	75	2
3	INJ&P	Meniscus injury	Rupture of the external meniscus of the left knee	21NOV2020 (98)	16:00	03FEB2021 (172)	17:00	75	2

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (23SEP2020)	NOT RELATED/OTHER: unknown	2	17	N
2	TCN	Y	Resolved (03FEB2021)	NOT RELATED/OTHER: soccer injury	2	76	Y
3	TC/TCN	Y	Resolved (03FEB2021)	NOT RELATED/OTHER: sports injury (soccer)	2	76	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16AUG2020	
Completed	VACCINATION	09OCT2020	
Completed	REPEAT SCREENING 1	26FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	68.6 kg	24.6 kg/m2	16AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16AUG2020 (1)	14:36
2	BNT162b2	07SEP2020 (23)	13:47

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GASTR	Gastritis	Acute gastritis	17OCT2020 (63)	10:00	03NOV2020 (80)	10:00	18
2	INJ&P	Hand fracture	closed fracture first phalanx right little finger	14SEP2020 (30)	19:30	15OCT2020 (61)	11:57	32

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC/TCN	Y	Resolved (03NOV2020)	NOT RELATED/OTHER: unknown	2	41	Y
2	1	TC/TCN	N	Resolved (15OCT2020)	NOT RELATED/OTHER: hit with a clay pot	2	8	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16AUG2020	
Completed	VACCINATION	05OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	52	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	63.5 kg	23.6 kg/m2	17AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	11:10
2	Placebo	07SEP2020 (22)	12:45
3	BNT162b2	23FEB2021 (191)	16:04

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INFEC	Urosepsis	Urosepsis	15SEP2020 (30)	16:00	22SEP2020 (37)	17:00	8

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC	Y	Resolved (22SEP2020)	NOT RELATED/OTHER: unknown	2	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	06OCT2020	
Completed	REPEAT SCREENING 1	23FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	66.6 kg	26.7 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
gastric bypass	Gastric bypass	22JAN2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	11:59
2	BNT162b2	07SEP2020 (22)	10:50

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Invasive ductal breast carcinoma	Right breast invasive ductal carcinoma	15NOV2020 (91)	10:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	N	Y	Yes	NOT RELATED/OTHER: unknown	2	70	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	06OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	99.5 kg	40.4 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
laparoscopic cholecystectomy	Cholecystectomy	APR2011	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	13:39
2	BNT162b2	07SEP2020 (22)	16:35

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	HEPAT	Biliary colic	biliary colic	30OCT2020 (75)	19:00	03NOV2020 (79)	11:00	5

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC	Y	Resolved (03NOV2020)	NOT RELATED/OTHER: unknown	2	54	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	05OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	78.85 kg	26.3 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Colon Cancer	Colon cancer	03APR2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	17:46

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	07SEP2020 (22)	14:15
3	BNT162b2	25FEB2021 (193)	17:22

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Foot fracture	Hallux fracture and second toe of the right foot	16SEP2020 (31)	08:00	20OCT2020 (65)	19:00	35

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (20OCT2020)	NOT RELATED/OTHER: work accident	2	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	09OCT2020	
Completed	REPEAT SCREENING 1	25FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	27	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	70 kg	24.2 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypothyroidism	Hypothyroidism	01JUL2000	Present
Diabetes type 1	Type 1 diabetes mellitus	01JUL2011	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	18:10

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Other_AEI_SAE/profile Date of Generation: 07APR2021 (21:52)

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	07SEP2020 (22)	14:13
3	BNT162b2	01MAR2021 (197)	13:00

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	METAB	Hypoglycaemia	severe hipoglycemia	16OCT2020 (61)	15:30	16OCT2020 (61)	15:35	1
2	NERV	Seizure	seizure	16OCT2020 (61)	15:30	16OCT2020 (61)	15:35	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Resolved (16OCT2020)	NOT RELATED/OTHER: Diabetes type 1	2	40	Y
2	3	N	N	Resolved (16OCT2020)	NOT RELATED/OTHER: hypoglycemia	2	40	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	05OCT2020	
Completed	REPEAT SCREENING 1	01MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	30	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171 cm	61 kg	20.9 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bicuspid aortic valve	Bicuspid aortic valve	01JUN2004	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	18:36
2	Placebo	09SEP2020 (24)	16:16

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	VASC	Aortic stenosis	Severe aortic stenosis	13OCT2020 (58)	08:00	ONGOING			3
2	RESP	Pulmonary mass	pulmonary nodules	04JAN2021 (141)	10:00	23FEB2021 (191)	20:46	51	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	Y	Yes	NOT RELATED/OTHER: history of bicuspid aortic valve	2	35	Y
2	N	N	Resolved (23FEB2021)	NOT RELATED/OTHER: unknown	2	118	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	13OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	42	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	77 kg	29.3 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Post traumatic stress	Post-traumatic stress disorder	01OCT2016	Past
insomnia	Insomnia	15JUN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	10:41
2	Placebo	08SEP2020 (22)	09:55

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Cholecystitis chronic	chronic lithiasic cholecystitis	27OCT2020 (71)	14:00	09MAR2021 (204)	16:00	134
2	NERV	Headache	headache	04OCT2020 (48)	23:00	05OCT2020 (49)	20:00	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/TCN	Y	Resolved (09MAR2021)	NOT RELATED/OTHER: unknown	2	50	Y
2	2	TC	N	Resolved (05OCT2020)	NOT RELATED/OTHER: unknown	2	27	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	06OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	68 kg	24.1 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
arterial hypertension	Hypertension	02JUL2002	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	12:19
2	Placebo	08SEP2020 (22)	14:55

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	19JAN2021 (155)	13:25
4	BNT162b2	09FEB2021 (176)	11:05

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Headache	headache	09SEP2020 (23)	19:00	17SEP2020 (31)		9
2	NERV	Syncope	Syncope	11SEP2020 (25)	10:00	12SEP2020 (26)	15:00	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (17SEP2020)	Study Treatment	2	2	N
2	3	TC	Y	Resolved (12SEP2020)	NOT RELATED/OTHER: unknown	2	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	07OCT2020	
Completed	REPEAT SCREENING 1	19JAN2021	
Completed	OPEN LABEL TREATMENT	09MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	75.3 kg	26.1 kg/m2	18AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18AUG2020 (1)	18:10
2	BNT162b2	09SEP2020 (23)	09:25

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	SURG	Finger amputation	Right index finger partial distal phalanx amputation	05DEC2020 (110)	16:00	17FEB2021 (184)	18:00	75	3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN	Y	Resolved (17FEB2021)	NOT RELATED/OTHER: trauma with a ship's anchor	2	88	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
149 cm	60.85 kg	27.4 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypercholesterolemia	Hypercholesterolaemia	13AUG2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	21:15
2	Placebo	07SEP2020 (21)	19:32

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	19FEB2021 (186)	13:08
4	BNT162b2	11MAR2021 (206)	14:15

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	GENRL	Axillary pain	Nonspecific left axillary pain	10SEP2020 (24)	09:00	30SEP2020 (44)	09:00	21	1	N
2	INJ&P	Fall	FALL FROM 50 CM HIGH	26SEP2020 (40)	12:30	26SEP2020 (40)	12:30	1	2	N
3	INJ&P	Humerus fracture	Right humerus fracture	26SEP2020 (40)	12:30	14JAN2021 (150)	19:00	111	3	TC/TCN

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Resolved (30SEP2020)	Study Treatment	2	4	N
2	N	Resolved (26SEP2020)	NOT RELATED/OTHER: Accidental stumble, climb on a chair	2	20	N
3	Y	Resolved (14JAN2021)	NOT RELATED/OTHER: fallen from a chair	2	20	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	07OCT2020	
Completed	REPEAT SCREENING 1	19FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	46	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161 cm	58.65 kg	22.6 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 1 Diabetes	Type 1 diabetes mellitus	19AUG1976	Present
Dyslipidemia	Dyslipidaemia	19AUG2017	Present
Arterial hypertension	Hypertension	19AUG2017	Present
Heart attack	Myocardial infarction	26AUG2017	Past
Left leg amputation	Leg amputation	20DEC2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	17:20
2	BNT162b2	08SEP2020 (21)	16:43

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	METAB	Hypoglycaemia	Severe hypoglycemia	16DEC2020 (120)	23:00	23DEC2020 (127)	15:00	8	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (23DEC2020)	NOT RELATED/OTHER: poorly controlled type 1 diabetes	2	100	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	25	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	110 kg	38.1 kg/m2	19AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	17:56
2	BNT162b2	09SEP2020 (22)	10:55

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	MUSC	Osteochondritis	Osteochondritis	05SEP2020 (18)	12:00	06SEP2020 (19)	13:31	2

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	N	Y	Resolved (06SEP2020)	NOT RELATED/OTHER: unknown	1	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	40	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	130.9 kg	44.2 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
gallstones	Cholelithiasis	01JAN2000	Present
Obesity	Obesity	FEB2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	10:20
2	BNT162b2	10SEP2020 (22)	10:22

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Bile duct stone	Choledochal lithiasis	23JAN2021 (157)	09:00	ONGOING		
2	HEPAT	Biliary colic	Biliary colic	25FEB2021 (190)	12:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Yes	NOT RELATED/OTHER: History of gallstones	2	136	Y
2	3	TC	Y	Yes	NOT RELATED/OTHER: History of gallbladder lithiasis	2	169	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	08OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	24	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	59.5 kg	23.2 kg/m2	20AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	14:05
2	Placebo	09SEP2020 (21)	14:05

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	27JAN2021 (161)	13:11
4	BNT162b2	18FEB2021 (183)	12:19

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	HEPAT	Cholelithiasis	Gallstones	06NOV2020 (79)	08:00	08NOV2020 (81)	13:30	3	1
2	RENAL	Hydronephrosis	Right hydronephrosis	05NOV2020 (78)	20:30	ONGOING			2
3	GENRL	Injection site erythema	erythema at the injection site	18FEB2021 (183)	12:19	19FEB2021 (184)	09:00	2	1
4	RENAL	Nephrolithiasis	nephrolithiasis	05NOV2020 (78)	20:30	21DEC2020 (124)	13:00	47	3
5	RENAL	Renal colic	Renal colic	20OCT2020 (62)	10:00	20OCT2020 (62)	12:00	1	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (08NOV2020)	NOT RELATED/OTHER: Unknown	2	59	N
2	TC	N	Yes	NOT RELATED/OTHER: Renal colic	2	58	N
3	N	N	Resolved (19FEB2021)	Study Treatment	4	1	N
4	TC/TCN	Y	Resolved (21DEC2020)	NOT RELATED/OTHER: Renal colic in october 2020.	2	58	Y
5	TC	N	Resolved (20OCT2020)	NOT RELATED/OTHER: Unknown	2	42	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	07OCT2020	
Completed	REPEAT SCREENING 1	27JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184 cm	119.45 kg	35.3 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OBESITY	Obesity	09APR2002	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	15:15
2	BNT162b2	11SEP2020 (23)	18:25

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	CARD	Acute coronary syndrome	Acute coronary syndrome without ST-T segment elevation	16SEP2020 (28)	09:15	19SEP2020 (31)	14:00	4	2
2	CARD	Bundle branch block right	right bundle branch block	16SEP2020 (28)	15:20	19SEP2020 (31)	14:00	4	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	Y	Resolved (19SEP2020)	NOT RELATED/OTHER: unknown	2	6	Y
2	N	N	Resolved (19SEP2020)	NOT RELATED/OTHER: Acute coronary syndrome	2	6	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179 cm	79 kg	24.7 kg/m2	20AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	18:40
2	Placebo	10SEP2020 (22)	16:11
3	BNT162b2	04MAR2021 (197)	10:30

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	CARD	Acute coronary syndrome	acute coronary syndrome	22NOV2020 (95)	22:00	08JAN2021 (142)	16:00	48

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC/TCN	Y	Resolved (08JAN2021)	NOT RELATED/OTHER: atherosclerosis	2	74	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	14NOV2020	
Completed	REPEAT SCREENING 1	04MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	74.9 kg	25.9 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Smoking	Tobacco user	1980	Present
caries in left lower third molar	Dental caries	JAN2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	19:20

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Other_AEI_SAE/profile Date of Generation: 07APR2021 (21:52)

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	08SEP2020 (20)	18:30
3	BNT162b2	19FEB2021 (184)	10:44
4	BNT162b2	12MAR2021 (205)	11:00

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Acute myocardial infarction	acute myocardial infarction with ST elevation	25NOV2020 (98)	18:15	30NOV2020 (103)		6	4	TC/TCN	Y
2	NERV	Headache	headache	01OCT2020 (43)	09:00	03OCT2020 (45)	18:00	3	1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (30NOV2020)	NOT RELATED/OTHER: unknown	2	79	Y
2	Resolved (03OCT2020)	NOT RELATED/OTHER: caries in left lower third molar previously diagnosed in January 2018	2	24	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	06OCT2020	
Completed	REPEAT SCREENING 1	19FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	89 kg	29.4 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Dyslipidemia	Dyslipidaemia	05APR2017	Present
Hyperuricemia	Hyperuricaemia	04DEC2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	10:07
2	BNT162b2	13SEP2020 (24)	12:00

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	Burns first degree	First-degree burn	10OCT2020 (51)	14:00	23OCT2020 (64)	09:00	14	2	TC/TCN	N
2	INJ&P	Burns second degree	Second-degree burn	10OCT2020 (51)	14:00	23OCT2020 (64)	09:00	14	2	TC/TCN	N
3	INJ&P	Fall	bicycle fall	20JAN2021 (153)	11:00	20JAN2021 (153)	11:01	1	2	TC/TCN	N
4	INJ&P	Humerus fracture	Right humerus fracture	20JAN2021 (153)	11:00	26FEB2021 (190)	09:00	38	2	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (23OCT2020)	NOT RELATED/OTHER: Burn A AB from boiling water, domestic accident	2	28	N
2	Resolved (23OCT2020)	NOT RELATED/OTHER: Domestic accident	2	28	N

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	Resolved (20JAN2021)	NOT RELATED/OTHER: Terrain irregularity	2	130	N
4	Resolved (26FEB2021)	NOT RELATED/OTHER: bike fall	2	130	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	14OCT2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	149 kg	50.4 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sleep apnea	Sleep apnoea syndrome	01JAN2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	13:20
2	BNT162b2	11SEP2020 (22)	10:50

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	CARD	Arrhythmia supraventricular	Arrhythmia supraventricular	17SEP2020 (28)	11:00	19SEP2020 (30)	10:00	3	4	TC/TCN	Y

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (19SEP2020)	NOT RELATED/OTHER: unknown, but probably corresponds to an accessory intraventricular line	2	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	70.8 kg	27 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depressive disorder	Depression	15MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	13:40

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	08OCT2020 (49)	11:26
3	BNT162b2	13MAR2021 (205)	18:35

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	Craniocerebral injury	minor cranioencephalic trauma	08OCT2020 (49)	12:18	08OCT2020 (49)	12:18	1	1	N	N
2	NERV	Syncope	syncope	08OCT2020 (49)	12:18	08OCT2020 (49)	14:06	1	3	TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (08OCT2020)	NOT RELATED/OTHER: Head trauma due to fall from own height after syncope	2	1	N
2	Resolved (08OCT2020)	NOT RELATED/OTHER: syncope of probable vasogenic cause	2	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	11NOV2020	
Completed	REPEAT SCREENING 1	13MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	57	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	75.6 kg	28.1 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	01AUG2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	14:40
2	BNT162b2	11SEP2020 (22)	12:25

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	Road traffic accident	Vehicle collision (subject was riding a bicycle)	02FEB2021 (166)	21:00	02FEB2021 (166)	21:05	1	3	TC/TCN	N
2	INJ&P	Wrist fracture	Right wrist fracture	02FEB2021 (166)	21:00	27FEB2021 (191)	15:00	26	2	TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (02FEB2021)	NOT RELATED/OTHER: unknown	2	145	N
2	Resolved (27FEB2021)	NOT RELATED/OTHER: Vehicle collision (subject was riding a bicycle)	2	145	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	14OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	76	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	91.05 kg	28.1 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	06JUN2003	Present
Polyglobulia	Polycythaemia	01MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	14:55
2	Placebo	11SEP2020 (22)	12:34

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Polycythaemia vera	Polycythemia vera	15DEC2020 (117)	17:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	TC	Y	Yes	NOT RELATED/OTHER: unknown	2	96	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182 cm	83.5 kg	25.2 kg/m2	21AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	18:50
2	BNT162b2	09SEP2020 (20)	14:00

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	PSYCH	Anxiety	severe anxiety	23SEP2020 (34)	23:00	14OCT2020 (55)	15:30	22
2	GENRL	Injection site pain	mild pain at the injection site	23AUG2020 (3)	11:17	25AUG2020 (5)	14:47	3
3	INFEC	Suspected COVID-19	Suspected COVID-19 Illness	09SEP2020 (20)	21:00	14SEP2020 (25)	11:00	6

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	N	N	Resolved (14OCT2020)	NOT RELATED/OTHER: constitutive features	2	15	N
2	1	N	N	Resolved (25AUG2020)	Study Treatment	1	3	N
3	3	TC	Y	Resolved (14SEP2020)	NOT RELATED/OTHER: unknown	2	1	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Withdrawn	VACCINATION	23SEP2020	WITHDRAWAL BY SUBJECT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	23SEP2020	WITHDRAWAL BY SUBJECT

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	21	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	46 kg	18 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
asthma	Asthma	23AUG2004	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	18:51
2	Placebo	10SEP2020 (21)	12:23

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	19FEB2021 (183)	19:22
4	BNT162b2	11MAR2021 (203)	11:44

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Asthmatic crisis	SEVERE ASTHMATIC CRYSIS	21OCT2020 (62)	12:00	29OCT2020 (70)	18:00	9

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (29OCT2020)	NOT RELATED/OTHER: Chronic Asthma	2	42	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	12OCT2020	
Completed	REPEAT SCREENING 1	19FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
151 cm	49 kg	21.5 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Migraines	Migraine	01JAN2003	Present
Hypotiroidism	Hypothyroidism	04JUL2015	Present
Familial hypercholesterolemia	Type IIa hyperlipidaemia	04JUL2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	20:00
2	BNT162b2	11SEP2020 (22)	14:27

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GENRL	Injection site erythema	Erythema at the injection site	12SEP2020 (23)	17:56	15SEP2020 (26)	17:56	4	1	N	N
2	GENRL	Injection site lymphadenopathy	Axillary and cervical lymphadenopathy ipsilateral to the injection site	12SEP2020 (23)	18:01	17SEP2020 (28)	18:01	6	1	N	N
3	GENRL	Injection site warmth	slight increase in temperature at injection site	12SEP2020 (23)	17:56	15SEP2020 (26)	17:56	4	1	TC	N
4	REPRO	Metrorrhagia	Metrorrhagia	13SEP2020 (24)	18:03	19SEP2020 (30)	18:04	7	1	N	N
5	NERV	Migraine	Migraine	22AUG2020 (2)	02:00	22AUG2020 (2)	04:00	1	2	TC	N
6	NERV	Optic neuritis	Optic Neuritis	01DEC2020 (103)	21:00	ONGOING			3	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (15SEP2020)	Study Treatment	2	2	N
2	Resolved (17SEP2020)	Study Treatment	2	2	N
3	Resolved (15SEP2020)	Study Treatment	2	2	N
4	Resolved (19SEP2020)	NOT RELATED/OTHER: unknown	2	3	N
5	Resolved (22AUG2020)	NOT RELATED/OTHER: associated with visual aura, photophobia, photopsies, which are usually unilater	1	2	N
6	Yes	NOT RELATED/OTHER: unknown	2	82	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	08OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	42	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159 cm	75.44 kg	29.8 kg/m2	22AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22AUG2020 (1)	12:35
2	Placebo	14SEP2020 (24)	17:55

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	NEOPL	Papillary thyroid cancer	Suspected papillary thyroid carcinoma	28JAN2021 (160)	10:00	ONGOING	
2	ENDO	Thyroid mass	Thyroid nodules	30OCT2020 (70)	12:00	ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		3	TCN	Y	Yes	NOT RELATED/OTHER: Thyroid nodules	2	137	Y
2		1	N	N	Yes	NOT RELATED/OTHER: Unknown	2	47	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22AUG2020	
Completed	VACCINATION	15OCT2020	
Withdrawn	REPEAT SCREENING 1	25FEB2021	NO LONGER MEETS ELIGIBILITY CRITERIA
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	48	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
183 cm	82.5 kg	24.6 kg/m2	22AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cholecystectomy	Cholecystectomy	01JAN2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	22AUG2020 (1)	14:35
2	BNT162b2	10SEP2020 (20)	17:20

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	NERV	Carpal tunnel syndrome	right carpal tunnel syndrome	15OCT2020 (55)	20:00	19FEB2021 (182)	12:00	128

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TCN	Y	Resolved (19FEB2021)	NOT RELATED/OTHER: unknown	2	36	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22AUG2020	
Completed	VACCINATION	14OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	52.05 kg	18.7 kg/m2	22AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
intermittent gross hematuria	Haematuria	14JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22AUG2020 (1)	14:40
2	Placebo	10SEP2020 (20)	15:35

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_BLA_Narrative_Other_AEI_SAE/profile Date of Generation: 07APR2021 (21:52)

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	03FEB2021 (166)	14:57
4	BNT162b2	24FEB2021 (187)	16:25

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RENAL	Haematuria	haematuria	25AUG2020 (4)	14:00	22SEP2020 (32)	08:00	29
2	RENAL	Urinary bladder polyp	Bladder polyp	18SEP2020 (28)	08:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (22SEP2020)	NOT RELATED/OTHER: Bladder polyp	1	4	N
2	1	TCN	Y	Yes	NOT RELATED/OTHER: Unknow.	2	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	22AUG2020	
Completed	VACCINATION	09OCT2020	
Completed	REPEAT SCREENING 1	03FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	54	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186 cm	105.2 kg	30.4 kg/m2	23AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
lumbar disc herniation	Intervertebral disc protrusion	2005	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23AUG2020 (1)	09:40

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	11SEP2020 (20)	12:34
3	BNT162b2	12MAR2021 (202)	11:13

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Back pain	low back pain	25SEP2020 (34)	08:00	02OCT2020 (41)	08:00	8
2	NEOPL	Clear cell renal cell carcinoma	Clear cell renal cell carcinoma	12OCT2020 (51)	18:00	ONGOING		
3	MUSC	Neck pain	cervicalgia	12OCT2020 (51)	08:00	11NOV2020 (81)	11:00	31
4	EAR	Tinnitus	bilateral tinnitus	13OCT2020 (52)	08:00	25NOV2020 (95)	18:00	44

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (02OCT2020)	NOT RELATED/OTHER: medical history	2	15	N
2	3	TCN	Y	Yes	NOT RELATED/OTHER: unknown	2	32	Y
3	2	TC/TCN	N	Resolved (11NOV2020)	NOT RELATED/OTHER: unknown	2	32	N
4	2	N	N	Resolved (25NOV2020)	NOT RELATED/OTHER: unknown	2	33	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	23AUG2020	
Completed	VACCINATION	09OCT2020	
Completed	REPEAT SCREENING 1	12MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	36	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	58.3 kg	22.8 kg/m2	23AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23AUG2020 (1)	13:00
2	Placebo	13SEP2020 (22)	14:25

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	SKIN	Pityriasis rosea	Pityriasis rosea	29SEP2020 (38)	20:00	28OCT2020 (67)	12:00	30
2	INFEC	Renal abscess	Right kidney abscess	07DEC2020 (107)	18:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Resolved (28OCT2020)	NOT RELATED/OTHER: Unknown cause	2	17	N
2	2	TC/TCN	Y	Yes	NOT RELATED/OTHER: unknown	2	86	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23AUG2020	
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177 cm	93 kg	29.7 kg/m2	23AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23AUG2020 (1)	16:01
2	Placebo	13SEP2020 (22)	11:39
3	BNT162b2	25FEB2021 (187)	16:51

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	HEPAT	Cholelithiasis	cholelithiasis	24DEC2020 (124)	18:00	05JAN2021 (136)	17:00	13

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC/TCN	Y	Resolved (05JAN2021)	NOT RELATED/OTHER: unknown	2	103	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23AUG2020	
Completed	VACCINATION	12OCT2020	
Completed	REPEAT SCREENING 1	25FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	73	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176 cm	94 kg	30.3 kg/m2	23AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Atrial fibrillation	Atrial fibrillation	04APR2012	Present
Arterial hypertension	Hypertension	04APR2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	23AUG2020 (1)	19:10
2	BNT162b2	11SEP2020 (20)	18:16

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Atrial flutter	Atrial Flutter	19FEB2021 (181)	16:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Yes	NOT RELATED/OTHER: Atrial fibrillation	2	162	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	65	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	63 kg	23.7 kg/m2	24AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	16:09
2	Placebo	15SEP2020 (23)	15:17

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	RESP	Pulmonary mass	Right pulmonary nodule	24SEP2020 (32)	17:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TCN	Y	Yes	NOT RELATED/OTHER: unknown	2	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Withdrawn	VACCINATION	26OCT2020	WITHDRAWAL BY SUBJECT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	26OCT2020	WITHDRAWAL BY SUBJECT

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152 cm	71.5 kg	30.9 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bronchial asthma	Asthma	1967	Present
Hypothyroidism	Hypothyroidism	01JUN1995	Present
low back pain	Back pain	2005	Present
bilteral pleural effusion	Pleural effusion	15APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	17:00
2	Placebo	13SEP2020 (21)	18:40
3	BNT162b2	25FEB2021 (186)	15:51

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Ischaemic stroke	Ischemic Stroke	06NOV2020 (75)	23:00	22JAN2021 (152)	18:00	78

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (22JAN2021)	NOT RELATED/OTHER: unknown	2	55	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	13OCT2020	
Completed	REPEAT SCREENING 1	25FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	48	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	78.8 kg	24.3 kg/m2	24AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	18:15
2	Placebo	13SEP2020 (21)	13:40

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	20FEB2021 (181)	14:45
4	BNT162b2	11MAR2021 (200)	15:40

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Cholecystitis	Cholecystitis	25DEC2020 (124)	23:00	28JAN2021 (158)	18:00	35

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/TCN	Y	Resolved (28JAN2021)	NOT RELATED/OTHER: unknown	2	104	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	20FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	82.55 kg	31.5 kg/m2	24AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	18:57
2	BNT162b2	13SEP2020 (21)	18:03

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	Ankle fracture	Right Ankle Fracture	02JAN2021 (132)	10:00	01MAR2021 (190)	19:00	59	3	TC/TCN	Y
2	INJ&P	Fall	Fall from own height.	02JAN2021 (132)	10:00	02JAN2021 (132)	10:00	1	3	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (01MAR2021)	NOT RELATED/OTHER: trauma to the right ankle from falling from his own height	2	112	Y
2	Resolved (02JAN2021)	NOT RELATED/OTHER: unknown	2	112	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	13OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
195 cm	124.5 kg	32.7 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 2 diabetes	Type 2 diabetes mellitus	01AUG2008	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	19:30

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	16SEP2020 (24)	09:58
3	BNT162b2	05MAR2021 (194)	14:19

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Extradural abscess	Epidural abscess	01DEC2020 (100)	10:00	20JAN2021 (150)	12:00	51	2
2	MUSC	Intervertebral disc protrusion	Herniated disc L3 -L4	05DEC2020 (104)	14:00	20JAN2021 (150)	12:00	47	2
3	MUSC	Spinal osteoarthritis	L2 to L4 spinal osteoarthritis	05DEC2020 (104)	14:00	20JAN2021 (150)	12:00	47	2
4	INFEC	Staphylococcal sepsis	Oxacillin sensitive Staphylococcus aureus sepsis	01DEC2020 (100)	10:00	20JAN2021 (150)	12:00	51	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (20JAN2021)	NOT RELATED/OTHER: unknown	2	77	Y
2	N	N	Resolved (20JAN2021)	NOT RELATED/OTHER: unknown	2	81	N
3	N	N	Resolved (20JAN2021)	NOT RELATED/OTHER: unknown	2	81	N
4	TC/TCN	Y	Resolved (20JAN2021)	NOT RELATED/OTHER: epidural abscess	2	77	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	20OCT2020	
Completed	REPEAT SCREENING 1	05MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	91 kg	29.7 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	08AUG2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	20:05
2	Placebo	13SEP2020 (21)	17:52

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	19FEB2021 (180)	13:18
4	BNT162b2	12MAR2021 (201)	12:21

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	CARD	Atrial fibrillation	Atrial fibrillation	25FEB2021 (186)	10:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	TC	Y	Yes	NOT RELATED/OTHER: Unknown	3	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	19FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	88 kg	29.1 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Kidney stones	Nephrolithiasis	01JAN1961	Present
Irritable colon	Irritable bowel syndrome	01JAN2005	Present
Arterial hypertension	Hypertension	2012	Present
L4-L5 disc herniation	Intervertebral disc protrusion	DEC2013	Present
Surgical placement of interspinous spacer at L4-L5	Spinal operation	06DEC2013	Past
Hypercholesterolemia	Hypercholesterolaemia	15JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	20:55
2	BNT162b2	14SEP2020 (22)	20:05

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	MUSC	Intervertebral disc protrusion	Worsening lumbar disc herniation	10SEP2020 (18)	10:00	12NOV2020 (81)	15:00	64	3	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (12NOV2020)	NOT RELATED/OTHER: Unresolved chronic lumbar disc herniation. spinal surgery performed in 2013	1	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	12OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	62	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	72 kg	25.5 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	08AUG1995	Present
Benign prostatic hypertrophy	Benign prostatic hyperplasia	08AUG2010	Present
Dyslipidemia	Dyslipidaemia	01AUG2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	12:45
2	Placebo	15SEP2020 (22)	09:15
3	BNT162b2	20JAN2021 (149)	15:05
4	BNT162b2	11FEB2021 (171)	14:45

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	RENAL	Bladder neck obstruction	bladder neck obstruction	09FEB2021 (169)	10:00	ONGOING			2	N	N
2	CONG	Congenital bladder neck obstruction	primary bladder neck obstruction	15OCT2020 (52)	08:00	11MAR2021 (199)	18:00	148	2	TC/TCN	Y
3	NERV	Headache	headache	12FEB2021 (172)	19:00	13FEB2021 (173)	02:00	2	1	N	N
4	INJ&P	Muscle rupture	Right hamstring muscle tear	16OCT2020 (53)	20:00	06NOV2020 (74)	18:00	22	1	N	N
5	MUSC	Myalgia	myalgia	12FEB2021 (172)	19:00	13FEB2021 (173)	02:00	2	1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: functional cause of bladder detrusor muscle disorder	3	21	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	Resolved (11MAR2021)	NOT RELATED/OTHER: functional alteration of the detrusor muscle.	2	31	Y
3	Resolved (13FEB2021)	Study Treatment	4	2	N
4	Resolved (06NOV2020)	NOT RELATED/OTHER: Physical activity	2	32	N
5	Resolved (13FEB2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	23OCT2020	
Completed	REPEAT SCREENING 1	20JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	72 kg	27.1 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	25AUG2010	Present
bilateral oophorectomy	Oophorectomy bilateral	OCT2014	Past
Bilateral adnexal cysts	Adnexa uteri cyst	07OCT2014	Past
Bilateral adnexectomy	Salpingo-oophorectomy bilateral	21OCT2014	Past
allergic rhinitis	Rhinitis allergic	2015	Present
asthma	Asthma	01APR2019	Present
hospitalization for asthmatic crisis	Asthmatic crisis	01JUL2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	17:05
2	BNT162b2	15SEP2020 (22)	18:38

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Angina unstable	Unstable angina	08NOV2020 (76)	17:00	12NOV2020 (80)	15:00	5

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (12NOV2020)	NOT RELATED/OTHER: unknown	2	55	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	Not Reported	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	79.15 kg	28.7 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Heavy Smoking	Tobacco user	1975	Past
Gastroduodenal Bleeding Ulcer	Gastrointestinal ulcer haemorrhage	1998	Past
Diverticulitis	Diverticulitis	01APR2018	Past
Colon Resection	Colectomy	15APR2018	Past
Dyslipemia	Dyslipidaemia	SEP2018	Present
Acute myocardial infarction	Acute myocardial infarction	21SEP2018	Past
angioplasty with stent placement	Vascular stent insertion	21SEP2018	Past
Arterial Hypertension	Hypertension	23SEP2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	18:45
2	BNT162b2	14SEP2020 (21)	16:25

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Angina pectoris	Angina Pectoris	20SEP2020 (27)	17:00	24SEP2020 (31)	08:30	5
2	PSYCH	Anxiety	Anxiety Crysis	29SEP2020 (36)	12:00	29SEP2020 (36)	18:30	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (24SEP2020)	NOT RELATED/OTHER: coronary disease	2	7	Y
2	2	N	N	Resolved (29SEP2020)	NOT RELATED/OTHER: Angina Pectoris	2	16	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171 cm	94.5 kg	32.3 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	01JUL2013	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	18:30
2	BNT162b2	13SEP2020 (20)	18:15

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	EYE	Retinal tear	Right eye retinal tear	03MAR2021 (191)	11:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	TC/TCN	Y	Yes	NOT RELATED/OTHER: unknown	2	172	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	12OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	26	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	76.45 kg	25.8 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
CHRONIC LOW BACK PAIN	Back pain	01JUN2019	Present
HERNIATED DISC L3 L4 AND L5	Intervertebral disc protrusion	01JUN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	09:10
2	BNT162b2	17SEP2020 (23)	11:04

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	MUSC	Back pain	LOW BACK PAIN WORSENING	30AUG2020 (5)	09:00	22SEP2020 (28)	20:00	24	2
2	HEPAT	Cholelithiasis obstructive	Cholestatic syndrome secondary to lithiasis	05MAR2021 (192)	09:00	10MAR2021 (197)	12:00	6	2
3	RENAL	Pollakiuria	NOCTURNE POLLAKIURIA	28AUG2020 (3)	09:00	28OCT2020 (64)	17:00	62	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (22SEP2020)	NOT RELATED/OTHER: underlying disc pathology	1	5	N
2	TC	Y	Resolved (10MAR2021)	NOT RELATED/OTHER: lithiasis	2	170	Y
3	N	N	Resolved (28OCT2020)	NOT RELATED/OTHER: unknown	1	3	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	77	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	89 kg	31.2 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
arterial hypertension	Hypertension	25AUG2018	Present
prostatic hyperplasia	Benign prostatic hyperplasia	31AUG2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	13:38
2	Placebo	14SEP2020 (20)	09:00

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Osteoarthritis	Worsening of left hip osteoarthritis	23JAN2021 (151)	08:00	ONGOING		
2	MUSC	Osteoarthritis	hip osteoarthritis	11NOV2020 (78)	20:30	26NOV2020 (93)	17:47	16

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Yes	NOT RELATED/OTHER: unknown	2	132	Y
2	1	TC	N	Resolved (26NOV2020)	NOT RELATED/OTHER: Unknown	2	59	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	16OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182 cm	91 kg	27.5 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Non-hodking lymphoma	Non-Hodgkin's lymphoma	19MAR2013	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	15:07
2	Placebo	14SEP2020 (20)	12:15

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	NEOPL	Non-Hodgkin's lymphoma recurrent	Recurrence of Non-Hodgkin Lymphoma	20NOV2020 (87)	12:00	ONGOING	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		2	N	Y	Yes	NOT RELATED/OTHER: unknown	2	68	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	14OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	26	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	64 kg	23.5 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Dengue	Dengue fever	15APR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	11:05
2	Placebo	16SEP2020 (21)	14:20

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	21JAN2021 (148)	10:25
4	BNT162b2	11FEB2021 (169)	16:07

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Epistaxis	Epistaxis	20SEP2020 (25)	19:30	19OCT2020 (54)	22:00	30	2
2	INJ&P	Multiple injuries	Polytrauma	20SEP2020 (25)	19:30	21DEC2020 (117)	19:00	93	3
3	VASC	Subgaleal haematoma	subgaleal hematoma	20SEP2020 (25)	19:30	09NOV2020 (75)	09:30	51	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	N	Resolved (19OCT2020)	NOT RELATED/OTHER: sphenoid fracture	2	5	N
2	TC/TCN	Y	Resolved (21DEC2020)	NOT RELATED/OTHER: Hit by a vehicle	2	5	Y
3	TCN	N	Resolved (09NOV2020)	NOT RELATED/OTHER: road accident	2	5	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	12NOV2020	
Completed	REPEAT SCREENING 1	21JAN2021	
Completed	OPEN LABEL TREATMENT	11MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177 cm	96 kg	30.6 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 2 diabetes	Type 2 diabetes mellitus	01JAN2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27AUG2020 (1)	10:32
2	BNT162b2	15SEP2020 (20)	09:44

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	CARD	Coronary artery disease	Coronary Cardiopathy	04DEC2020 (100)	10:00	29JAN2021 (156)	18:00	57

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC/TCN	Y	Resolved (29JAN2021)	NOT RELATED/OTHER: unknown	2	81	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	63	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	83 kg	25.6 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	19AUG1992	Present
Type 2 diabetes	Type 2 diabetes mellitus	31AUG2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	11:20

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	17SEP2020 (22)	17:18
3	BNT162b2	29JAN2021 (156)	13:04
4	BNT162b2	18FEB2021 (176)	11:16

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Pneumonia	Community-acquired pneumonia	12NOV2020 (78)	09:00	17NOV2020 (83)	10:00	6

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (17NOV2020)	NOT RELATED/OTHER: unknown	2	57	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	21OCT2020	
Completed	REPEAT SCREENING 1	29JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	65	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176 cm	74.4 kg	24 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 2 diabetes	Type 2 diabetes mellitus	01APR2014	Present
Prostate cancer	Prostate cancer	01OCT2018	Past
Radical Prostatectomy	Radical prostatectomy	01DEC2018	Past
Erectile dysfunction	Erectile dysfunction	01AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27AUG2020 (1)	12:51
2	BNT162b2	15SEP2020 (20)	14:25

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Penile infection	Penile infection	22JAN2021 (149)	10:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Yes	NOT RELATED/OTHER: Erectile dysfunction surgery	2	130	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	31	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	59 kg	23 kg/m2	27AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27AUG2020 (1)	14:00
2	BNT162b2	16SEP2020 (21)	14:10

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Food poisoning	Food poisoning	03FEB2021 (161)	10:00	07FEB2021 (165)	08:00	5

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (07FEB2021)	NOT RELATED/OTHER: unknown	2	141	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1999	20	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
153 cm	52 kg	22.2 kg/m2	27AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	17:10
2	Placebo	15SEP2020 (20)	18:00
3	BNT162b2	13MAR2021 (199)	16:17

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GASTR	Abdominal pain upper	Epigastralgia	15OCT2020 (50)	06:30	19OCT2020 (54)	17:00	5
2	GASTR	Pancreatitis acute	acute pancreatitis	30NOV2020 (96)	22:00	14DEC2020 (110)	18:00	15

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (19OCT2020)	NOT RELATED/OTHER: unknown	2	31	N
2	2	TC	Y	Resolved (14DEC2020)	NOT RELATED/OTHER: unknown	2	77	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	19OCT2020	
Completed	REPEAT SCREENING 1	13MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	60 kg	21 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Gastro esophageal Reflux	Gastrooesophageal reflux disease	15JUL2015	Present
Dyslipidemia	Dyslipidaemia	01JAN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28AUG2020 (1)	10:15
2	BNT162b2	16SEP2020 (20)	12:21

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Gastric cancer	Signetringcellgastriccarcinoma(SRCGC)	29JAN2021 (155)	16:30	ONGOING			3
2	GASTR	Gastrooesophageal reflux disease	exacerbation of gastroesophageal reflux	01OCT2020 (35)	08:00	29OCT2020 (63)	16:00	29	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Yes	NOT RELATED/OTHER: unknown	2	136	Y
2	TC	N	Resolved (29OCT2020)	NOT RELATED/OTHER: chronic antral ulcer	2	16	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	100.9 kg	36.6 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Smoking	Tobacco user	1972	Past
Type 2 Diabetes Mellitus	Type 2 diabetes mellitus	01NOV2017	Present
Muscle cramps in calves	Muscle spasms	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	12:12
2	Placebo	16SEP2020 (20)	11:24

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Amyotrophic lateral sclerosis	potential amyotrophic lateral sclerosis	10OCT2020 (44)	09:00	ONGOING		
2	RESP	Pulmonary mass	Pulmonary micronodules	04NOV2020 (69)	09:00	29NOV2020 (94)		26

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/TCN	Y	Yes	NOT RELATED/OTHER: unknown	2	25	Y
2	1	N	N	Resolved (29NOV2020)	NOT RELATED/OTHER: unknown	2	50	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178 cm	68 kg	21.5 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
S1 disc extrusion and L4-L5 bulging	Intervertebral disc protrusion	01OCT2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	13:40
2	Placebo	17SEP2020 (21)	14:20

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	28JAN2021 (154)	15:10
4	BNT162b2	17FEB2021 (174)	14:03

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	MUSC	Back pain	Low back pain	21SEP2020 (25)	09:00	12OCT2020 (46)	09:00	22	2	TC/TCN
2	MUSC	Intervertebral disc protrusion	Worsening of herniated disc	21SEP2020 (25)	09:00	05JAN2021 (131)	17:00	107	3	TC/TCN

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Resolved (12OCT2020)	NOT RELATED/OTHER: disc extrusion at S1 and bulge at L4-L5	2	5	N
2	Y	Resolved (05JAN2021)	NOT RELATED/OTHER: history of herniated disc	2	5	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	11NOV2020	
Completed	REPEAT SCREENING 1	28JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	56	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	98 kg	32 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
intermittent asthma	Asthma	(b) (6) 1963	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	17:50

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	16SEP2020 (20)	11:30
3	BNT162b2	09MAR2021 (194)	14:13

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Pneumonia	community acquired pneumonia	03OCT2020 (37)	21:00	15OCT2020 (49)	21:03	13

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/TCN	Y	Resolved (15OCT2020)	NOT RELATED/OTHER: unknown	2	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	20OCT2020	
Completed	REPEAT SCREENING 1	09MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	90.9 kg	30 kg/m2	28AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28AUG2020 (1)	18:00
2	BNT162b2	16SEP2020 (20)	14:33

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	INJ&P	Burns second degree	Second degree burn of the right arm and forearm.	27JAN2021 (153)	22:00	ONGOING	
2	INJ&P	Burns third degree	Third degree burn on the right hand	27JAN2021 (153)	22:00	ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		3	TC/TCN	Y	Yes	NOT RELATED/OTHER: accident	2	134	Y
2		3	TC/TCN	Y	Yes	NOT RELATED/OTHER: Accident	2	134	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	62	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	87 kg	28.4 kg/m2	29AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	29AUG2020 (1)	10:12
2	Placebo	17SEP2020 (20)	09:26

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	19JAN2021 (144)	11:35
4	BNT162b2	09FEB2021 (165)	10:38

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Dental caries	Cavities in left inferior third molar	28NOV2020 (92)	08:00	03DEC2020 (97)	08:00	6
2	INFEC	Pyelonephritis	left pyelonephritis	04DEC2020 (98)	08:00	22DEC2020 (116)	20:00	19

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/TCN	N	Resolved (03DEC2020)	NOT RELATED/OTHER: Unknown	2	73	N
2	2	TC	Y	Resolved (22DEC2020)	NOT RELATED/OTHER: E. Coli infection.	2	79	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	21OCT2020	
Completed	REPEAT SCREENING 1	19JAN2021	
Completed	OPEN LABEL TREATMENT	09MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	59 kg	23.6 kg/m2	29AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Congenital degenerative myopia	Congenital myopia	(b) (6) 1952	Present
Smoking	Tobacco user	01JAN1970	Present
Irritable colon	Irritable bowel syndrome	01JAN2000	Present
Skin carcinoma	Skin cancer	01JAN2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29AUG2020 (1)	11:25
2	BNT162b2	17SEP2020 (20)	17:32

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NEOPL	Squamous cell carcinoma	In situ squamous cell carcinoma	15JAN2021 (140)	08:00	ONGOING			2	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: Risk factors (previous history of skin cancer, smoking, sun exposure)	2	121	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152 cm	63 kg	27.3 kg/m2	29AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Erosive gastritis	Gastritis erosive	SEP2016	Present
Post-traumatic stress	Post-traumatic stress disorder	01JUL2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29AUG2020 (1)	12:12
2	BNT162b2	17SEP2020 (20)	18:35

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	GASTR	Abdominal pain	abdominal pain	18SEP2020 (21)	04:00	19SEP2020 (22)	23:00	2	3	TC
2	NEOPL	Adenocarcinoma pancreas	pancreatic ductal adenocarcinoma	17FEB2021 (173)	08:00	ONGOING			3	TC/TCN
3	METAB	Dyslipidaemia	dyslipidemia	01DEC2020 (95)	08:00	ONGOING			1	N
4	GASTR	Gastritis erosive	worsening of antral erosive gastritis	24SEP2020 (27)	08:00	21OCT2020 (54)	14:30	28	1	TC/TCN
5	MUSC	Myalgia	abdominal myalgia	18SEP2020 (21)	10:00	19SEP2020 (22)	23:00	2	3	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Resolved (19SEP2020)	NOT RELATED/OTHER: unknown	2	2	N
2	Y	Yes	NOT RELATED/OTHER: unknown	2	154	Y
3	N	Yes	NOT RELATED/OTHER: unknown	2	76	N
4	N	Resolved (21OCT2020)	NOT RELATED/OTHER: Associated with diet	2	8	N
5	N	Resolved (19SEP2020)	NOT RELATED/OTHER: related to a medical history of the patient.	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Conjugate vaccine against meningococcal serogroups A, C, W-135 and Y	MENINGOCOCCAL VACCINE A/C/Y/W	25JAN2021
Pneumococcal polysaccharide conjugate vaccine 0.5 ml intramuscular solution for injection	PNEUMOCOCCAL VACCINE POLYSACCH	25JAN2021
Haemophilus influenzae B vaccine, conjugated purified antigen	HIB VACCINE CONJ	26JAN2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	86 kg	30.5 kg/m2	29AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cardiac ByPass	Coronary artery bypass	01JAN1998	Past
Sleep disorder	Sleep disorder	01JAN2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	29AUG2020 (1)	12:50

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	17SEP2020 (20)	10:35
3	BNT162b2	28JAN2021 (153)	14:35
4	BNT162b2	17FEB2021 (173)	17:26

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Arteriosclerosis coronary artery	Worsening of Coronary atherosclerosis	02DEC2020 (96)	10:00	13JAN2021 (138)	14:00	43

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TCN	Y	Resolved (13JAN2021)	NOT RELATED/OTHER: unknown	2	77	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	21OCT2020	
Completed	REPEAT SCREENING 1	28JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	61.2 kg	22.8 kg/m2	29AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Amblyopia of the right eye	Amblyopia	(b) (6) 1968	Present
Left hemicrania migraine	Migraine	01JUN1977	Present
allergic to penicillin	Drug hypersensitivity	26AUG1977	Present
Myopia of the left eye	Myopia	01JAN1986	Present
Depression and anxiety	Depression	01JUN2005	Past
Herpes zoster	Herpes zoster	28DEC2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29AUG2020 (1)	16:31
2	BNT162b2	17SEP2020 (20)	16:05

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	EYE	Choroidal neovascularisation	Myopic choroidal neovascular membrane of the left eye	06SEP2020 (9)	17:00	27NOV2020 (91)		83	1	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (27NOV2020)	NOT RELATED/OTHER: Complication of high myopia presented by the voluntary as antecedent	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178 cm	114 kg	36 kg/m2	29AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
type 2 diabetes	Type 2 diabetes mellitus	01JAN2008	Present
pancreatic cysts	Pancreatic cyst	2017	Present
Insomnia	Insomnia	01MAR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	29AUG2020 (1)	16:43
2	Placebo	17SEP2020 (20)	12:26
3	BNT162b2	28JAN2021 (153)	13:20
4	BNT162b2	17FEB2021 (173)	16:47

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	GASTR	Anal fistula	perianal fistula	02FEB2021 (158)	12:30	03FEB2021 (159)	20:34	2	1	TCN
2	METAB	Hyperglycaemia	Hyperglycemia	27NOV2020 (91)	09:00	05DEC2020 (99)	11:00	9	2	TC/TCN

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Resolved (03FEB2021)	NOT RELATED/OTHER: unknown	3	6	N
2	Y	Resolved (05DEC2020)	NOT RELATED/OTHER: mismanagement of your type 2 diabetes	2	72	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	21OCT2020	
Completed	REPEAT SCREENING 1	28JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1941	79	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
151 cm	82 kg	36 kg/m2	30AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
partial thyroidectomy	Thyroidectomy	1975	Past
depressive syndrome	Depression	2002	Present
Obesity	Obesity	2010	Present
Arterial Hypertension	Hypertension	01AUG2015	Present
Arrhytmia. Origin unknown	Arrhythmia	01DEC2019	Present
hematuria	Haematuria	02JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30AUG2020 (1)	10:34
2	BNT162b2	08OCT2020 (40)	18:09

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RENAL	Haematuria	Exacerbation of gross hematuria	11OCT2020 (43)	08:00	29DEC2020 (122)	17:59	80
2	NEOPL	Transitional cell carcinoma	High grade infiltrating urothelial carcinoma	29DEC2020 (122)	18:00	ONGOING		
3	INFEC	Urinary tract infection	Uncomplicated urinary infection	31AUG2020 (2)	14:50	02OCT2020 (34)	08:00	33

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (29DEC2020)	NOT RELATED/OTHER: Unknow	2	4	N
2	3	TC	Y	Yes	NOT RELATED/OTHER: unknown	2	83	Y
3	1	TC	N	Resolved (02OCT2020)	NOT RELATED/OTHER: Urinary infection	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30AUG2020	
Completed	VACCINATION	11NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	125 kg	41.3 kg/m2	30AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Congenital ocular toxoplasmosis	Congenital toxoplasmosis	(b) (6) 1970	Past
Heavy Smoking	Tobacco user	03MAR1986	Past
Obesity	Obesity	1992	Present
ANGIOPLASTY	Angioplasty	JAN2015	Past
STENT PLACEMENT	Stent placement	JAN2015	Past
Myocardial infarction	Myocardial infarction	18JAN2015	Past
Arterial hypertension	Hypertension	19AUG2015	Present
Dyslipidemia	Dyslipidaemia	20AUG2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30AUG2020 (1)	12:25
2	BNT162b2	19SEP2020 (21)	09:56

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Angina unstable	Unstable Angina Pectoris	14OCT2020 (46)	18:00	16OCT2020 (48)	11:00	3	3	TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (16OCT2020)	NOT RELATED/OTHER: Unknown cause, history of acute myocardial infarction	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30AUG2020	
Completed	VACCINATION	22OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	55	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177 cm	95 kg	30.3 kg/m2	30AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30AUG2020 (1)	12:52
2	Placebo	19SEP2020 (21)	11:56

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	26JAN2021 (150)	11:22
4	BNT162b2	17FEB2021 (172)	11:25

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RENAL	Nephrolithiasis	Nephrolithiasis	05DEC2020 (98)	22:00	21JAN2021 (145)		48

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (21JAN2021)	NOT RELATED/OTHER: unknown	2	78	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30AUG2020	
Completed	VACCINATION	22OCT2020	
Completed	REPEAT SCREENING 1	26JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	68	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	80 kg	32 kg/m2	30AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	01JAN1998	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30AUG2020 (1)	13:25
2	BNT162b2	19SEP2020 (21)	18:30

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	INV	Body temperature increased	Body temperature increased	06SEP2020 (8)	22:00	09SEP2020 (11)	10:00	4	1
2	VASC	Hypertension	Arterial hypertension	18NOV2020 (81)	19:00	06DEC2020 (99)	08:00	19	1
3	EYE	Macular oedema	macular edema of the right eye	05NOV2020 (68)	10:00	ONGOING			3
4	EYE	Ophthalmic vein thrombosis	Venous thrombosis of the right eye	05NOV2020 (68)	10:00	ONGOING			3

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (09SEP2020)	NOT RELATED/OTHER: unknown	1	8	N
2	TC/TCN	N	Resolved (06DEC2020)	NOT RELATED/OTHER: Unknown	2	61	N
3	TC	N	Yes	NOT RELATED/OTHER: Venous thrombosis of the right eye	2	48	N
4	TC	Y	Yes	NOT RELATED/OTHER: unknown	2	48	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30AUG2020	
Completed	VACCINATION	23OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1942	78	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176 cm	80 kg	25.8 kg/m2	31AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	12:10
2	BNT162b2	19SEP2020 (20)	10:44

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	INJ&P	Fall	fall from his own height	30JAN2021 (153)	12:00	30JAN2021 (153)	12:04	1	2	TCN
2	INJ&P	Patella fracture	Left Patella fracture	30JAN2021 (153)	12:00	ONGOING			3	TC/TCN

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Resolved (30JAN2021)	NOT RELATED/OTHER: the volunteer slipped due to the wet floor	2	134	N
2	Y	Yes	NOT RELATED/OTHER: left knee trauma	2	134	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	22OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	24	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182 cm	71 kg	21.4 kg/m2	31AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	16:04
2	Placebo	19SEP2020 (20)	10:25

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	20FEB2021 (174)	16:04
4	BNT162b2	11MAR2021 (193)	11:20

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Gastroenteritis	gastroenterocolitis	09JAN2021 (132)	09:00	11JAN2021 (134)	17:00	3
2	GENRL	Injection site pain	Pain at injection site.	21FEB2021 (175)	08:00	21FEB2021 (175)	22:00	1
3	GASTR	Vomiting	Vomiting	21FEB2021 (175)	08:00	21FEB2021 (175)	10:00	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/TCN	Y	Resolved (11JAN2021)	NOT RELATED/OTHER: unknown	2	113	Y
2	1	TC	N	Resolved (21FEB2021)	Study Treatment	3	2	N
3	1	N	N	Resolved (21FEB2021)	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	22OCT2020	
Completed	REPEAT SCREENING 1	20FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	78.5 kg	25.9 kg/m2	31AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	16:26
2	BNT162b2	19SEP2020 (20)	14:50

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GASTR	Gastrooesophageal reflux disease	Gastroesophageal reflux disease	30OCT2020 (61)	08:00	11DEC2020 (103)	18:39	43
2	CARD	Pericarditis	Pericarditis	17OCT2020 (48)	09:00	ONGOING		

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC	N	Resolved (11DEC2020)	NOT RELATED/OTHER: Unknown	2	42	N
2	2	TC/TCN	Y	Yes	NOT RELATED/OTHER: unknown	2	29	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	29DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	60	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179 cm	128 kg	39.9 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
RIGHT DEAF	Deafness unilateral	01JUL1960	Present
arterial hypertension	Hypertension	01JAN2005	Present
OBESITY	Obesity	01JUL2005	Present
Glaucoma in both eyes	Glaucoma	01JUL2017	Present
ISOLATED HEMATOCHESIS	Haematochezia	15AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	17:10
2	Placebo	19SEP2020 (20)	15:55
3	BNT162b2	03FEB2021 (157)	14:57
4	BNT162b2	24FEB2021 (178)	17:28

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Ischaemic stroke	Ischemic stroke	12OCT2020 (43)	17:00	16OCT2020 (47)	17:30	5

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Resolved (16OCT2020)	NOT RELATED/OTHER: unknown	2	24	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	14NOV2020	
Completed	REPEAT SCREENING 1	03FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	74	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	79 kg	28 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Atheromatosis	Arteriosclerosis	01FEB1994	Present
Acute myocardial infarction	Acute myocardial infarction	24MAR1994	Past
Coronary stent placement	Coronary arterial stent insertion	16SEP2013	Past
bladder polypectomy	Bladder polypectomy	2015	Past
bladder polypectomy	Bladder polypectomy	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	18:31
2	BNT162b2	19SEP2020 (20)	11:40

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Diverticulum intestinal	Diverticulosis in the sigmoid colon	27JAN2021 (150)	09:00	27JAN2021 (150)	09:01	1
2	RENAL	Renal cyst	Cortical cyst in right kidney	27JAN2021 (150)	09:00	27JAN2021 (150)	09:01	1
3	NEOPL	Transitional cell carcinoma	High-grade urothelial carcinoma	11NOV2020 (73)	09:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (27JAN2021)	NOT RELATED/OTHER: Unknown	2	131	N
2	1	N	N	Resolved (27JAN2021)	NOT RELATED/OTHER: Unknown	2	131	N
3	3	TC/TCN	Y	Yes	NOT RELATED/OTHER: unknown	2	54	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	22OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	41	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	122.2 kg	39.9 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Systemic arterial hypertension	Hypertension	2012	Present
headache	Headache	11AUG2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	11:05

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	02SEP2020 (22)	11:15
3	BNT162b2	25JAN2021 (167)	13:01
4	BNT162b2	15FEB2021 (188)	11:12

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Dyspepsia	Dyspepsia	31JAN2021 (173)		12FEB2021 (185)		13	3
2	GASTR	Gastrooesophageal reflux disease	Non-erosive reflux esophagitis	31JAN2021 (173)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (12FEB2021)	NOT RELATED/OTHER: Unknown	3	7	N
2	TC/TCN	Y	Yes	NOT RELATED/OTHER: Non-erosive reflux	3	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	01OCT2020	
Completed	REPEAT SCREENING 1	25JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1942	77	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	71 kg	27.7 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cholecystectomy	Cholecystectomy	1990	Past
Systemic arterial hypertension	Hypertension	1995	Present
Hypothyroidism	Hypothyroidism	1995	Present
Menopause	Menopause	1995	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	16:27
2	Placebo	02SEP2020 (22)	11:37
3	BNT162b2	24FEB2021 (197)	11:48

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Chronic gastritis	Chronic pangastritis	02MAR2021 (203)		ONGOING			1
2	GASTR	Colitis	Inflammatory colitis	16DEC2020 (127)		ONGOING			2
3	GASTR	Diverticulum intestinal	Diverticular disease of the colon	16DEC2020 (127)		ONGOING			4
4	IMMUN	Drug hypersensitivity	Dipyrone allergy	30JAN2021 (172)		30JAN2021 (172)		1	1
5	GASTR	Intestinal mass	Mass in sigmoid	08FEB2021 (181)		09FEB2021 (182)		2	4
6	INFEC	Urinary tract infection	Urinary tract infection	16DEC2020 (127)		22DEC2020 (133)		7	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: Helicobacter pylori	3	7	N
2	TC	N	Yes	NOT RELATED/OTHER: Abnominal pain	2	106	N
3	TC/TCN	Y	Yes	NOT RELATED/OTHER: Unknown	2	106	Y
4	N	N	Resolved (30JAN2021)	NOT RELATED/OTHER: Allergy	2	151	N
5	TCN	Y	Resolved (09FEB2021)	NOT RELATED/OTHER: Diverticular disease	2	160	Y
6	TC	N	Resolved (22DEC2020)	NOT RELATED/OTHER: Bacterial infection	2	106	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	02OCT2020	
Completed	REPEAT SCREENING 1	24FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152.5 cm	55.5 kg	23.9 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Breast lump	Breast mass	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18AUG2020 (1)	09:26
2	BNT162b2	09SEP2020 (23)	10:33

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	REPRO	Breast hyperplasia	Atypical intraductal hyperplasia in left breast	29SEP2020 (43)		30SEP2020 (44)		2

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC	Y	Resolved (30SEP2020)	NOT RELATED/OTHER: Breast nodule	2	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	07OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	42	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	128.2 kg	42.8 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasectomy	Vasectomy	2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	10:59
2	Placebo	09SEP2020 (22)	10:42

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	28JAN2021 (163)	11:15
4	BNT162b2	18FEB2021 (184)	10:32

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Fall	Fall from own height	06MAR2021 (200)		06MAR2021 (200)		1
2	MUSC	Myalgia	Myalgia	19FEB2021 (185)		19FEB2021 (185)		1
3	INJ&P	Scapula fracture	Fracture of the anterior border of the right glenoid	06MAR2021 (200)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Resolved (06MAR2021)	NOT RELATED/OTHER: unknown	4	17	Y
2	1	TC	N	Resolved (19FEB2021)	Study Treatment	4	2	N
3	3	TCN	Y	Yes	NOT RELATED/OTHER: Fall	4	17	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	08OCT2020	
Completed	REPEAT SCREENING 1	28JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
155.5 cm	67.9 kg	28.1 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Carpal tunnel syndrome	Carpal tunnel syndrome	2013	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	18:32
2	BNT162b2	24SEP2020 (21)	09:34

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	HEPAT	Cholecystitis acute	Acute cholecystitis	24OCT2020 (51)		28OCT2020 (55)		5
2	HEPAT	Cholelithiasis	Cholelithiasis	24OCT2020 (51)		28OCT2020 (55)		5

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC	Y	Resolved (28OCT2020)	NOT RELATED/OTHER: gallstone	2	31	Y
2	3	TC	Y	Resolved (28OCT2020)	NOT RELATED/OTHER: Gallstone	2	31	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	22OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	Multiple	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	81.3 kg	28.5 kg/m2	17SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Systemic arterial hypertension	Hypertension	DEC2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17SEP2020 (1)	15:31
2	BNT162b2	08OCT2020 (22)	16:14

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	BLOOD	Hypochromic anaemia	HYPOCHROMIC ANEMIA / MICROCYTIC	04NOV2020 (49)		23NOV2020 (68)		20	1	N	N
2	INFEC	Pyelonephritis acute	ACUTE PYELONEPHRITIS	02NOV2020 (47)		16NOV2020 (61)		15	2	TC	Y

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (23NOV2020)	NOT RELATED/OTHER: ANEMIA TO BE CLARIFIED	2	28	N
2	Resolved (16NOV2020)	NOT RELATED/OTHER: POSSIBLE BACTERIA URINARY TRACT INFECTION	2	26	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17SEP2020	
Completed	VACCINATION	09NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	24	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161 cm	84 kg	32.4 kg/m2	18SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18SEP2020 (1)	11:08
2	Placebo	09OCT2020 (22)	09:45

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	10FEB2021 (146)	08:56
4	BNT162b2	02MAR2021 (166)	08:36

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Injection site pain	Injection site pain	10FEB2021 (146)	18:00	11FEB2021 (147)		2
2	NEOPL	Teratoma	High grade immature teratoma	18JAN2021 (123)		27JAN2021 (132)		10

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (11FEB2021)	Study Treatment	3	1	N
2	3	N	Y	Resolved (27JAN2021)	NOT RELATED/OTHER: Unknown	2	102	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18SEP2020	
Completed	VACCINATION	11NOV2020	
Completed	REPEAT SCREENING 1	10FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	Multiple	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	74.1 kg	24.2 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic rhinitis	Rhinitis allergic	1977	Past
Adverse reaction to corticosteroids	Adverse drug reaction	2013	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21SEP2020 (1)	11:03
2	BNT162b2	13OCT2020 (23)	10:34

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Cellulitis	Cellulitis on the right foot	27DEC2020 (98)		ONGOING		
2	NERV	Headache	Headache	22SEP2020 (2)		23SEP2020 (3)		2
3	GENRL	Injection site pain	Injection site pain	21SEP2020 (1)		24SEP2020 (4)		4
4	MUSC	Myalgia	Myakgia	22SEP2020 (2)		23SEP2020 (3)		2
5	MUSC	Myalgia	Myalgia	13OCT2020 (23)	19:00	15OCT2020 (25)		3
6	GENRL	Pyrexia	Fever	13OCT2020 (23)	19:00	15OCT2020 (25)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Yes	NOT RELATED/OTHER: Bacterial infection	2	76	Y
2	1	N	N	Resolved (23SEP2020)	Study Treatment	1	2	N
3	1	N	N	Resolved (24SEP2020)	Study Treatment	1	1	N
4	1	N	N	Resolved (23SEP2020)	Study Treatment	1	2	N
5	1	TC	N	Resolved (15OCT2020)	Study Treatment	2	1	N
6	1	TC	N	Resolved (15OCT2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
DT vaccine	DIPHTHERIA VACCINE TOXOID;TETANUS VACCINE TOXOID	10FEB2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Completed	VACCINATION	10NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	49	Multiple	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185 cm	100.4 kg	29.3 kg/m2	30SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Systemic arterial hypertension	Hypertension	2018	Present
Pre diabetes	Glucose tolerance impaired	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30SEP2020 (1)	15:57
2	BNT162b2	21OCT2020 (22)	09:09

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	Clavicle fracture	Fracture of right clavicle	31JAN2021 (124)		03FEB2021 (127)		4	3	TC/TCN	Y
2	SKIN	Rash	Skin rash in arms	12NOV2020 (44)		13NOV2020 (45)		2	1	N	N
3	INJ&P	Rib fracture	Fracture of ribs	31JAN2021 (124)		03FEB2021 (127)		4	3	TC/TCN	Y
4	INJ&P	Road traffic accident	Motor Vehicle Accident	31JAN2021 (124)		31JAN2021 (124)		1	3	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (03FEB2021)	NOT RELATED/OTHER: Motor Vehicle Accident.Subject was the driver and there is no medical causality	2	103	Y
2	Resolved (13NOV2020)	NOT RELATED/OTHER: Contact dermatitis	2	23	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
3	Resolved (03FEB2021)	NOT RELATED/OTHER: Motor Vehicle Accident	2	103	Y
4	Resolved (31JAN2021)	NOT RELATED/OTHER: Subject was the driver. There is no medical suspected cause for the accident.	2	103	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30SEP2020	
Completed	VACCINATION	18NOV2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	78.5 kg	28.8 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic tension headache	Tension headache	1970	Present
Hemorrhoidal disease	Haemorrhoids	1980	Present
gastroesophageal reflux disease	Gastrooesophageal reflux disease	2000	Present
Systemic arterial hypertension	Hypertension	2005	Present
Allergic rhinitis	Rhinitis allergic	2005	Present
carotid atherosclerotic disease	Carotid arteriosclerosis	2015	Present
dyslipidemia	Dyslipidaemia	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15OCT2020 (1)	08:54
2	BNT162b2	06NOV2020 (23)	09:22

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Amnesia	Transitional global amnesia	09NOV2020 (26)		11NOV2020 (28)		3
2	PSYCH	Disorientation	Disorientation to clarify	09NOV2020 (26)		12NOV2020 (29)		4
3	NERV	Dizziness	Dizziness	09NOV2020 (26)		10NOV2020 (27)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	N	Resolved (11NOV2020)	NOT RELATED/OTHER: Unknown	2	4	N
2	3	TC	Y	Resolved (12NOV2020)	NOT RELATED/OTHER: to clarify	2	4	Y
3	3	TC	N	Resolved (10NOV2020)	NOT RELATED/OTHER: Unknown	2	4	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15OCT2020	
Completed	VACCINATION	04DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
155 cm	76 kg	31.6 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hysterectomy	Hysterectomy	1998	Past
Uterine fibroids	Uterine leiomyoma	1998	Past
Allergic rhinitis	Rhinitis allergic	2000	Present
Osteoporosis	Osteoporosis	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16OCT2020 (1)	13:32
2	BNT162b2	05NOV2020 (21)	12:00

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Respiratory tract infection viral	Respiratory Tract Viral infection	10DEC2020 (56)		18DEC2020 (64)		9

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Resolved (18DEC2020)	NOT RELATED/OTHER: Viral infection	2	36	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
Completed	VACCINATION	03DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	87.05 kg	32.4 kg/m2	29SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy sulfas	Drug hypersensitivity	1964	Present
Allergy Penicillin	Drug hypersensitivity	1964	Present
Hypertension	Hypertension	2008	Present
Vasectomy	Vasectomy	2012	Past
Intermittent headache	Headache	MAY2016	Present
Vision impairment	Visual impairment	MAY2017	Present
Hypercholesterolemia	Hypercholesterolaemia	DEC2018	Present
Depression-stable	Depression	AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29SEP2020 (1)	10:40
2	BNT162b2	20OCT2020 (22)	13:11

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GASTR	Gastrooesophageal reflux disease	Reflux esophagitis	12NOV2020 (45)		ONGOING			2	TC	N
2	GASTR	Hiatus hernia	Hiatus hernia	12NOV2020 (45)		ONGOING			2	TC/TCN	N
3	GENRL	Non-cardiac chest pain	REFERRED NON-CARDIAC CHEST PAIN	10NOV2020 (43)		12NOV2020 (45)		3	3	TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: Hiatus hernia	2	24	N
2	Yes	NOT RELATED/OTHER: Unknown	2	24	N
3	Resolved (12NOV2020)	NOT RELATED/OTHER: Non Cardiac chest pain related to gastro-esophageal reflux pathology	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29SEP2020	
Completed	VACCINATION	17NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	22	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	113 kg	38.2 kg/m2	03OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	2014	Present
Obese	Obesity	2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03OCT2020 (1)	10:20
2	BNT162b2	24OCT2020 (22)	08:20

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	PSYCH	Depression	Worsening of depression	25DEC2020 (84)		15JAN2021 (105)		22	3	TC/TCN	Y
2	INFEC	Urinary tract infection	Urine tract Infection-pathogen unknown	15NOV2020 (44)		18NOV2020 (47)		4	2	TC	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (15JAN2021)	NOT RELATED/OTHER: Medical history Depression- stopped conmeds	2	63	Y
2	Resolved (18NOV2020)	NOT RELATED/OTHER: unknown	2	23	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03OCT2020	
Completed	VACCINATION	21NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171 cm	79.8 kg	27.3 kg/m2	10OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Endometriosis uterus	Endometriosis	2017	Past
Endometriosis left ovary	Endometriosis	2017	Past
Hysterectomy	Hysterectomy	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10OCT2020 (1)	08:50
2	Placebo	31OCT2020 (22)	08:24
3	BNT162b2	27FEB2021 (141)	08:30

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	REPRO	Endometriosis	Worsening of Endometriosis left ovary	06JAN2021 (89)		20JAN2021 (103)	10:31	15
2	MUSC	Pain in extremity	Painful Left Arm	27FEB2021 (141)		28FEB2021 (142)		2

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC/TCN	Y	Resolved (20JAN2021)	NOT RELATED/OTHER: Unknown	2	68	Y
2	1	TC	N	Resolved (28FEB2021)	Study Treatment	3	1	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10OCT2020	
Completed	VACCINATION	28NOV2020	
Completed	REPEAT SCREENING 1	27FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2001	19	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
183 cm	88 kg	26.3 kg/m2	30SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30SEP2020 (1)	11:24
2	Placebo	21OCT2020 (22)	10:17

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INJ&P	Flail chest	Flail Chest	30OCT2020 (31)		ONGOING			3	TC/TCN
2	INJ&P	Road traffic accident	Motorcyle accident	30OCT2020 (31)		30OCT2020 (31)		1	2	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Yes	NOT RELATED/OTHER: Flail chest secondary to motorcycle accident	2	10	Y
2	N	Resolved (30OCT2020)	NOT RELATED/OTHER: Motorcycle accident	2	10	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30SEP2020	
Withdrawn	VACCINATION	30OCT2020	WITHDRAWAL BY SUBJECT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	30OCT2020	WITHDRAWAL BY SUBJECT

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	92 kg	30 kg/m2	30SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2010	Present
post menopausal	Postmenopause	2018	Present
Chronic back pain	Back pain	2019	Present
Slip disc LS with chronic pain	Intervertebral disc protrusion	2019	Present
Hypercholesterolemia	Hypercholesterolaemia	JUN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30SEP2020 (1)	14:35
2	BNT162b2	21OCT2020 (22)	11:39

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	MUSC	Back pain	Worsening back pain	09NOV2020 (41)		15NOV2020 (47)		7	2
2	MUSC	Intervertebral disc protrusion	Worsening pain related to L5/S1 and L4/L5 disc protrusion	09NOV2020 (41)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	N	Resolved (15NOV2020)	NOT RELATED/OTHER: Back pain (Etiology unknown)	2	20	N
2	TC/TCN	Y	Yes	NOT RELATED/OTHER: Back pain	2	20	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30SEP2020	
Completed	VACCINATION	18NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1980	40	Multiple	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	45.1 kg	15.6 kg/m2	08OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Achalasia	Oesophageal achalasia	2005	Present
Major depressive disorder	Major depression	APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08OCT2020 (1)	10:56
2	Placebo	30OCT2020 (23)	17:42

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PSYCH	Depression	Severe depressive episode	04FEB2021 (120)		08FEB2021 (124)		5	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (08FEB2021)	NOT RELATED/OTHER: Etiology to be confirmed	2	98	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08OCT2020	
Completed	VACCINATION	04DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1945	74	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	119.3 kg	36.8 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Penicillin/Sulfa Hives	Urticaria	2010	Present
Stroke	Cerebrovascular accident	2014	Present
Arthritis	Arthritis	2015	Present
Hypertension	Hypertension	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	15:41
2	Placebo	21OCT2020 (41)	13:13
3	BNT162b2	15JAN2021 (127)	12:02
4	BNT162b2	05FEB2021 (148)	13:01

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Cardiac failure acute	Acute Heart Failure	23SEP2020 (13)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Yes	NOT RELATED/OTHER: Atherosclerotic cardiovascular disease	1	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	18NOV2020	
Completed	REPEAT SCREENING 1	15JAN2021	
Completed	OPEN LABEL TREATMENT	05MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	74	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.5 cm	56.2 kg	22.4 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
High Cholesterol	Blood cholesterol increased	2015	Present
Seasonal Allergy	Seasonal allergy	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14SEP2020 (1)	16:38

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	05OCT2020 (22)	14:47
3	BNT162b2	09JAN2021 (118)	13:36
4	BNT162b2	28JAN2021 (137)	12:05

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Brain abscess	Brain abscess	10OCT2020 (27)		ONGOING			4
2	NERV	Headache	Headache (R sided headache around R eye)	03OCT2020 (20)		05OCT2020 (22)		3	1
3	INFEC	Sinusitis	Sinusitis	10OCT2020 (27)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	Y	Yes	NOT RELATED/OTHER: Sinusitis / blocked sinuses	2	6	Y
2	TC	N	Resolved (05OCT2020)	NOT RELATED/OTHER: Headache	1	20	N
3	TCN	N	Yes	NOT RELATED/OTHER: Sinusitis/Blocked Sinuses	2	6	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14SEP2020	
Withdrawn	VACCINATION	05JAN2021	PROTOCOL DEVIATION
Completed	REPEAT SCREENING 1	09JAN2021	
Completed	OPEN LABEL TREATMENT	26FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.99 cm	129.77 kg	42.8 kg/m2	22AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Gout	Gout	1992	Present
Hypercholesterolemia	Hypercholesterolaemia	2010	Present
Hypertension	Hypertension	2010	Present
Diabetes Mellitus 1	Type 1 diabetes mellitus	2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	22AUG2020 (1)	08:55
2	BNT162b2	24SEP2020 (34)	07:52

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Ankle fracture	Shattered Ankle/Tibia	24FEB2021 (187)		25FEB2021 (188)		2	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (25FEB2021)	NOT RELATED/OTHER: Fell from tree ladder	2	154	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22AUG2020	
Completed	VACCINATION	26OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	123.64 kg	35.9 kg/m2	22AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic Kidney Disease Stage 1	Chronic kidney disease	2016	Present
Chronic Gout	Gout	2016	Present
hypertension	Hypertension	2016	Present
Hypercholesterolemia	Hypercholesterolaemia	2017	Present
Diabetes Mellitus Type 2	Type 2 diabetes mellitus	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22AUG2020 (1)	10:07
2	Placebo	11SEP2020 (21)	16:34
3	BNT162b2	22JAN2021 (154)	13:21
4	BNT162b2	12FEB2021 (175)	11:32

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	METAB	Diabetes mellitus inadequate control	worsening diabetes type 11	25FEB2021 (188)		ONGOING			4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Yes	NOT RELATED/OTHER: PREVIOUS HX OF DIABETES TYPE 11	4	14	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22AUG2020	
Completed	VACCINATION	09OCT2020	
Completed	REPEAT SCREENING 1	22JAN2021	
Completed	OPEN LABEL TREATMENT	12MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	37	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	92.73 kg	36.1 kg/m2	22AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
CODEINE ALLERGY	Drug hypersensitivity	2010	Present
Hypertension	Hypertension	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	22AUG2020 (1)	11:06
2	BNT162b2	10SEP2020 (20)	15:52

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Idiopathic intracranial hypertension	Pseudotumor Cerebri	JAN2021 ()		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC	Y	Yes	NOT RELATED/OTHER: Weight Gain	2		Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	22AUG2020	
Completed	VACCINATION	08OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	105.45 kg	33.3 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Smoker	Tobacco user	1989	Present
Tubal Ligation	Female sterilisation	27FEB1992	Past
Chronic Back Pain	Back pain	1997	Present
Prolapsed Lumbar Intervertebral Disc	Intervertebral disc protrusion	1997	Present
Cyst of Skin Lower Back	Dermal cyst	1999	Present
History of Drug Abuse	Drug abuse	2002	Present
Chronic Hepatitis C	Chronic hepatitis C	2009	Present
Insomnia	Insomnia	2009	Present
Hypertension	Hypertension	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bipolar II Disorder	Bipolar II disorder	2011	Present
Major Depressive Disorder	Major depression	2011	Present
Anxiety Disorder	Anxiety disorder	2017	Present
History of Adenomatous Polyp of Colon	Colon adenoma	2018	Present
depression	Depression	2018	Present
Post menopausal	Postmenopause	17OCT2018	Present
R Ankle pain	Arthralgia	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	09:40

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Hypertension	exacerbation of hypertension	04SEP2020 (11)		ONGOING			3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Y	Yes	NOT RELATED/OTHER: environmental factors, psychiatric factors	1	11	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25AUG2020	
Withdrawn	VACCINATION	03NOV2020	PHYSICIAN DECISION
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	74.09 kg	28 kg/m2	29AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
constipation	Constipation	1990	Present
post menopausal	Postmenopause	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	29AUG2020 (1)	09:33
2	Placebo	17SEP2020 (20)	13:59

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Uterine cancer	Uterine Cancer	28JAN2021 (153)		28JAN2021 (153)		1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (28JAN2021)	NOT RELATED/OTHER: Do not know what caused cancer	2	134	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccination	INFLUENZA VACCINE	31OCT2020
Moderna covid-19 vaccine	COVID-19 VACCINE MRNA (MRNA 1273)	11JAN2021
Moderna Covid 19 Vaccine	COVID-19 VACCINE MRNA (MRNA 1273)	08FEB2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	71.36 kg	23.9 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERTENSION	Hypertension	1982	Present
COPD	Chronic obstructive pulmonary disease	2001	Present
STROKE	Cerebrovascular accident	2002	Present
HYPOTHYROIDISM	Hypothyroidism	2005	Present
DEPRESSION	Depression	2007	Present
ENLARGED PROSTATE	Prostatomegaly	2012	Present
EMPHYSEMA	Emphysema	2016	Present
neck pain	Neck pain	2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
left arm pain	Pain in extremity	2017	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	JAN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	10:36
2	Placebo	01OCT2020 (22)	10:36
3	BNT162b2	24FEB2021 (168)	11:02

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Spinal fracture	Broken Vertebrae	08MAR2021 (180)		10MAR2021 (182)	12:00	3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	Y	Resolved (10MAR2021)	NOT RELATED/OTHER: trauma	3	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	29OCT2020	
Completed	REPEAT SCREENING 1	24FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	119.55 kg	43.8 kg/m2	13OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergies Seasonal	Seasonal allergy	1980	Present
Obesity	Obesity	1990	Present
Tubal Ligation	Female sterilisation	1993	Past
Schizophrenia	Schizophrenia	2005	Present
Depression	Depression	2006	Present
Hypertension	Hypertension	2010	Present
Hysterectomy Partial	Hysterectomy	2010	Past
Heavy Mentrual Bleeding	Menorrhagia	2010	Past
Diabetes Mellitus Type II	Type 2 diabetes mellitus	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cholecystectomy	Cholecystectomy	2011	Past
Cholecystitis	Cholecystitis	2011	Past
Hypercholesterolemia	Hypercholesterolaemia	2014	Present
Diabetic Neuropathy	Diabetic neuropathy	21NOV2014	Present
Postmenopausal	Postmenopause	2015	Present
Knee Pain B/L	Arthralgia	2017	Present
Sulfa Allergy	Drug hypersensitivity	2017	Present
Osteoarthritis Knee Bilateral	Osteoarthritis	2017	Present
Congestive Heart Failure	Cardiac failure congestive	2018	Present
Fluid Retention	Fluid retention	2018	Present
chest pain	Chest pain	AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	13OCT2020 (1)	12:00
2	BNT162b2	02NOV2020 (21)	11:05

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Myocardial ischaemia	Myocardial ischemia	13NOV2020 (32)		16NOV2020 (35)		4	4

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	Y	Resolved (16NOV2020)	NOT RELATED/OTHER: Congestive Heart Failure	2	12	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13OCT2020	
Completed	VACCINATION	30NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	66	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	102.73 kg	32.4 kg/m2	20OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tobacco Dependence 1/2 ppd	Nicotine dependence	1968	Present
osteoarthritis right knee	Osteoarthritis	2000	Present
knee arthroscopy right	Arthroscopy	2005	Past
partial knee replacement	Knee arthroplasty	2009	Past
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	2015	Present
Gout	Gout	JAN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20OCT2020 (1)	10:37
2	Placebo	11NOV2020 (23)	09:12

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Arthralgia	increased pain with activities-right knee	02DEC2020 (44)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/TCN	Y	Yes	NOT RELATED/OTHER: increased activities	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20OCT2020	
Completed	VACCINATION	09DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1935	84	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	63.64 kg	21.3 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Gerd	Gastrooesophageal reflux disease	2008	Present
Osteoarthritis in back	Spinal osteoarthritis	2009	Present
Chronic obstructive lung disease	Chronic obstructive pulmonary disease	2010	Present
Insomnia	Insomnia	2015	Present
Hypogonadism	Hypogonadism	2016	Present
Benign Prostatic Hyperplasia	Benign prostatic hyperplasia	2017	Present
Coronary artery disease	Coronary artery disease	APR2018	Present
Angioplasty	Angioplasty	09APR2018	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	09APR2018	Present
Anxiety	Anxiety	04MAR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	16:50
2	BNT162b2	09SEP2020 (24)	09:40

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	BLOOD	Anaemia	Anemia	06JAN2021 (143)	16:53	10JAN2021 (147)	10:10	5	1	N	N
2	RESP	Chronic obstructive pulmonary disease	COPD exacerbation	06JAN2021 (143)	16:53	10JAN2021 (147)	10:10	5	3	TC	Y
3	METAB	Hyperkalaemia	Hyperkalemia	06JAN2021 (143)	16:53	10JAN2021 (147)	10:10	5	1	N	N
4	INV	Lymphocyte count decreased	Low Lymphocytes	06JAN2021 (143)	16:53	10JAN2021 (147)	10:10	5	1	N	N
5	INV	Platelet count decreased	Low platelets	06JAN2021 (143)	16:53	10JAN2021 (147)	10:10	5	1	N	N

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
6	RESP	Respiratory failure	Chronic Hypoxic respiratory failure	06JAN2021 (143)	16:53	10JAN2021 (147)	10:10	5	2	N	N
7	INFEC	Sepsis	Sepsis	06JAN2021 (143)	16:53	10JAN2021 (147)	10:10	5	2	TC	N
8	INV	Troponin increased	Elevated Troponin	06JAN2021 (143)	16:53	10JAN2021 (147)	10:10	5	2	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (10JAN2021)	NOT RELATED/OTHER: Probably due to anemia of chronic disease and without any symptoms of bleeding.	2	120	N
2	Resolved (10JAN2021)	NOT RELATED/OTHER: Increased shortness of breath	2	120	Y
3	Resolved (10JAN2021)	NOT RELATED/OTHER: Potassium level high in blood	2	120	N
4	Resolved (10JAN2021)	NOT RELATED/OTHER: Infection	2	120	N
5	Resolved (10JAN2021)	NOT RELATED/OTHER: Low number of platelets in blood	2	120	N
6	Resolved (10JAN2021)	NOT RELATED/OTHER: Not enough of oxygen in the blood	2	120	N
7	Resolved (10JAN2021)	NOT RELATED/OTHER: Probably due to Pneumonia	2	120	N
8	Resolved (10JAN2021)	NOT RELATED/OTHER: Heart problem	2	120	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	12OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
195 cm	77 kg	20.2 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
MYOPIA	Myopia	1970	Present
ear infections, intermittent	Ear infection	2000	Present
tinnitus, intermittent	Tinnitus	2000	Present
PRESBYOPIA	Presbyopia	2010	Present
CONSTIPATION	Constipation	2012	Present
URINARY BLADDER CALCULI	Calculus bladder	2014	Present
RENAL CALCULI	Nephrolithiasis	2014	Present
URINARY TRACT INFECTIONS	Urinary tract infection	2014	Present
benign prostatic hyperplasia	Benign prostatic hyperplasia	2015	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
overactive bladder	Hypertonic bladder	2015	Present
DEPRESSION CHRONIC	Depression	2018	Present
LEFT URETER STENT Insertion	Ureteral stent insertion	FEB2020	Past
RIGHT URETER STENT Insertion	Ureteral stent insertion	MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28AUG2020 (1)	10:55
2	BNT162b2	18SEP2020 (22)	12:23

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INFEC	Clostridium difficile colitis	Clostridium Difficile Colitis	21JAN2021 (147)		01FEB2021 (158)		12	4	TC
2	GENRL	Injection site pain	SORENESS AT INJECTION SITE	18SEP2020 (22)	17:00	19SEP2020 (23)		2	1	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (01FEB2021)	NOT RELATED/OTHER: colitis due to Amoxicillin for ear infection	2	126	Y
2	N	Resolved (19SEP2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	16OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166.88 cm	109.91 kg	39.4 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
menopause	Menopause	2005	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	15:04
2	Placebo	21SEP2020 (22)	15:48

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	13JAN2021 (136)	15:37
4	BNT162b2	04MAR2021 (186)	10:11

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	NERV	Arachnoid cyst	arachnoid cyst	31JAN2021 (154)	15:45	02FEB2021 (156)		3	2	TC	N
2	INJ&P	Fall	fall from walking dog	31JAN2021 (154)	15:45	02FEB2021 (156)		3	1	TC	N
3	NERV	Headache	headache	01SEP2020 (2)	07:30	28SEP2020 (29)	09:00	28	2	TC	N
4	GENRL	Injection site pain	soreness at the injection site	13JAN2021 (136)	18:00	14JAN2021 (137)	08:00	2	1	N	N
5	INJ&P	Lip injury	lip laceration	31JAN2021 (154)	15:45	02FEB2021 (156)		3	1	TC	N
6	NEOPL	Meningioma	calcified meningioma	31JAN2021 (154)	15:45	02FEB2021 (156)		3	2	TC	N
7	INJ&P	Subdural haematoma	traumatic subdural hemorrhage	31JAN2021 (154)	15:45	02FEB2021 (156)	17:00	3	3	TC	N
8	INJ&P	Tooth fracture	chipped teeth	31JAN2021 (154)	15:45	04FEB2021 (158)	09:00	5	1	TC	N
9	INJ&P	Traumatic intracranial haemorrhage	traumatic subarachnoid hemorrhage	31JAN2021 (154)	15:45	02FEB2021 (156)	17:00	3	3	TC	Y

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (02FEB2021)	NOT RELATED/OTHER: incidental finding not requiring surgery after fall from walking dog	3	19	N
2	Resolved (02FEB2021)	NOT RELATED/OTHER: fall from walking dog	3	19	N
3	Resolved (28SEP2020)	Study Treatment	1	2	N
4	Resolved (14JAN2021)	Study Treatment	3	1	N
5	Resolved (02FEB2021)	NOT RELATED/OTHER: fall from walking dog	3	19	N
6	Resolved (02FEB2021)	NOT RELATED/OTHER: incidental finding not requiring surgery after fall from walking dog	3	19	N
7	Resolved (02FEB2021)	NOT RELATED/OTHER: fall from walking dog	3	19	N
8	Resolved (04FEB2021)	NOT RELATED/OTHER: fall from walking dog	3	19	N
9	Resolved (02FEB2021)	NOT RELATED/OTHER: fall from walking dog	3	19	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccination	INFLUENZA VACCINE	14OCT2020
Tetanus vaccine	TETANUS VACCINE	02FEB2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	26OCT2020	
Completed	REPEAT SCREENING 1	13JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.45 cm	69.18 kg	23.5 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
colon cancer	Colon cancer	2010	Past
S/P Colostomy	Colostomy	2010	Past
Hyperlipidemia	Hyperlipidaemia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01SEP2020 (1)	10:23
2	BNT162b2	22SEP2020 (22)	09:23

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Injection site pain	Soreness at injection site	23SEP2020 (23)	03:30	24SEP2020 (24)	08:00	2	1
2	GENRL	Injection site pain	soreness at injection site	02SEP2020 (2)	04:00	04SEP2020 (4)	04:00	3	1
3	GASTR	Small intestinal obstruction	small bowel obstruction	29OCT2020 (59)		05NOV2020 (66)		8	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (24SEP2020)	Study Treatment	2	2	N
2	N	N	Resolved (04SEP2020)	Study Treatment	1	2	N
3	TC/TCN	Y	Resolved (05NOV2020)	NOT RELATED/OTHER: small bowel obstruction	2	38	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	20OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	42	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	81.2 kg	29.8 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
graves disease	Basedow's disease	2000	Present
thyroidectomy	Thyroidectomy	2000	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	15:04

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	01OCT2020 (22)	17:00
3	BNT162b2	14JAN2021 (127)	15:08
4	BNT162b2	01FEB2021 (145)	12:18

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	INJ&P	Ankle fracture	Closed trimalleolar fracture of right ankle	09MAR2021 (181)	21:07	ONGOING			3	TC	Y
2	NERV	Encephalopathy	acute encephalopathy	09MAR2021 (181)	21:07	10MAR2021 (182)		2	2	TC	N
3	INJ&P	Fall	fall	09MAR2021 (181)	21:07	ONGOING			3	TC	N
4	VASC	Hypotension	hypotension	10MAR2021 (182)		ONGOING			2	TC	N
5	GENRL	Injection site pain	soreness at injection site	02OCT2020 (23)	17:00	03OCT2020 (24)	05:00	2	1	N	N
6	PSYCH	Mental status changes	Altered Mental Status	09MAR2021 (181)	21:07	10MAR2021 (182)		2	2	TC	N
7	INFEC	Urinary tract infection	Urinary Tract Infection	09MAR2021 (181)	21:07	12MAR2021 (184)		4	2	TC	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Yes	NOT RELATED/OTHER: subject fell	4	37	Y
2	Resolved (10MAR2021)	NOT RELATED/OTHER: complicated UTI, metabolic hypothyroid and possible side effects of gabapentin	4	37	N
3	Yes	NOT RELATED/OTHER: subject fell and injured ankle	4	37	N
4	Yes	NOT RELATED/OTHER: received fluids as maintenance until discharge to correct hypotension	4	38	N
5	Resolved (03OCT2020)	Study Treatment	2	2	N
6	Resolved (10MAR2021)	NOT RELATED/OTHER: UTI, acute encephalopathy	4	37	N
7	Resolved (12MAR2021)	Study Treatment	4	37	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	29OCT2020	
Completed	REPEAT SCREENING 1	14JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	92.9 kg	32.9 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hydrocele Repair	Hydrocele operation	15JUN2009	Past
vasectomy	Vasectomy	15JUN2013	Past
Rash to antibiotics of unclear type	Drug eruption	15JUN2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27AUG2020 (1)	14:50
2	BNT162b2	17SEP2020 (22)	14:38

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Abscess	Lip Abscess	23SEP2020 (28)		01OCT2020 (36)		9	3
2	INFEC	Cellulitis	Lip cellulitis	23SEP2020 (28)		01OCT2020 (36)		9	3
3	GENRL	Chills	CHILLS - ADVERSE REACTION TO VACCINATION 1	28AUG2020 (2)	03:00	30AUG2020 (4)	21:00	3	1
4	IMMUN	Drug hypersensitivity	Hypersensitivity to antibiotics	26SEP2020 (31)		27SEP2020 (32)		2	3
5	NERV	Headache	HEADACHE - ADVERSE REACTION TO VACCINATION 1	28AUG2020 (2)	03:00	30AUG2020 (4)	21:00	3	1
6	MUSC	Myalgia	DIFFUSE MYALGIA - ADVERSE REACTION TO VACCINATION 1	28AUG2020 (2)	03:00	30AUG2020 (4)	21:00	3	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (01OCT2020)	NOT RELATED/OTHER: unrelated medical condition	2	7	Y
2	TC	Y	Resolved (01OCT2020)	NOT RELATED/OTHER: Unrelated medical condition	2	7	Y
3	TC	N	Resolved (30AUG2020)	Study Treatment	1	2	N

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	TC	Y	Resolved (27SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	10	Y
5	TC	N	Resolved (30AUG2020)	Study Treatment	1	2	N
6	TC	N	Resolved (30AUG2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	75	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.5 cm	68.9 kg	23.4 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy - aspirin	Drug hypersensitivity	1956	Present
Asthma	Asthma	1982	Present
Hyperlipidemia	Hyperlipidaemia	1990	Present
GERD	Gastrooesophageal reflux disease	1991	Present
Allergy - shellfish	Food allergy	2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	09SEP2020 (1)	11:29
2	BNT162b2	28SEP2020 (20)	09:24

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Headache	Headache	29SEP2020 (21)		30SEP2020 (22)		2
2	CARD	Myocardial infarction	Myocardial Infarction	20FEB2021 (165)	02:17	28FEB2021 (173)	12:34	9
3	GASTR	Nausea	Nausea	29SEP2020 (21)		30SEP2020 (22)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (30SEP2020)	Study Treatment	2	2	N
2	4	TC	Y	Resolved (28FEB2021)	NOT RELATED/OTHER: N/A	2	146	Y
3	1	N	N	Resolved (30SEP2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine	INFLUENZA VACCINE	20OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	30OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168.7 cm	97.6 kg	34.3 kg/m2	27OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ACL repair, left	Ligament operation	1990	Past
Meniscus tear repair, left	Meniscus operation	1990	Past
Vasectomy	Vasectomy	1991	Past
Hypertension	Hypertension	2010	Present
Lupus	Systemic lupus erythematosus	2010	Present
Meniscus tear repair, right	Meniscus operation	2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27OCT2020 (1)	14:26
2	Placebo	16NOV2020 (21)	09:52
3	BNT162b2	27JAN2021 (93)	16:12
4	BNT162b2	17FEB2021 (114)	08:15

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	RESP	Pulmonary embolism	Pulmonary embolism	07DEC2020 (42)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		4	TC	Y	Yes	NOT RELATED/OTHER: Not specified	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27OCT2020	
Completed	VACCINATION	18DEC2020	
Completed	REPEAT SCREENING 1	27JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
149.9 cm	81 kg	36 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Fallopian tube ligation	Female sterilisation	1998	Past
Irritable bowel syndrome	Irritable bowel syndrome	17JUN2004	Present
Syncope and collapse	Syncope	07OCT2005	Past
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	10APR2006	Present
Chronic abdominal pain	Abdominal pain	17AUG2006	Present
Fatty liver	Hepatic steatosis	18OCT2006	Present
Major depressive disorder, recurrent episode	Major depression	25JAN2007	Present
Single seizure, unspecified type	Seizure	05JUN2007	Past
Sinus tachycardia	Sinus tachycardia	05JUN2007	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Fibromyalgia	Fibromyalgia	02NOV2007	Present
Drug allergy - Nexium [Esomeprazole Magnesium]	Drug hypersensitivity	17JAN2008	Present
Generalized anxiety disorder	Generalised anxiety disorder	28FEB2008	Present
Bipolar 1 disorder, mixed, moderate	Bipolar I disorder	26JAN2010	Present
Overactive bladder	Hypertonic bladder	06AUG2010	Present
Colonoscopy with biopsy	Biopsy colon	15NOV2010	Past
Obesity	Obesity	13APR2011	Present
Diabetes mellitus, type 2	Type 2 diabetes mellitus	26MAY2011	Present
Peripheral neuropathy	Neuropathy peripheral	03MAY2013	Present
Dyslipidemia	Dyslipidaemia	27JUN2013	Present
Benign fasciculation cramp syndrome	Cramp-fasciculation syndrome	30AUG2013	Present
Laparoscopic hysterectomy	Hysterectomy	12DEC2013	Past
Laparascopic salpingectomy (bilateral)	Salpingectomy	12DEC2013	Past
Chronic kidney disease, stage 2	Chronic kidney disease	11FEB2014	Present
Colonoscopy with biopsy	Biopsy colon	08JUL2014	Past
Right blepharospasm	Blepharospasm	09OCT2014	Present
Gastroparesis	Impaired gastric emptying	31DEC2014	Present
Laparascopic lysis of intra-abdominal adhesion	Adhesiolysis	15MAY2015	Past
Diagnostic laparoscopy	Laparoscopy	15MAY2015	Past
Asthma	Asthma	16AUG2016	Present
Hypertension	Hypertension	19JAN2017	Present
Chronic pancreatitis	Pancreatitis chronic	19JAN2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	12:02
2	Placebo	30SEP2020 (20)	11:53
3	BNT162b2	16FEB2021 (159)	09:17
4	BNT162b2	08MAR2021 (179)	09:00

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain	Abdominal pain	25SEP2020 (15)		08OCT2020 (28)		14	2
2	PSYCH	Confusional state	Confusion/altered mental status	28SEP2020 (18)		29SEP2020 (19)		2	2
3	IMMUN	Hypersensitivity	Allergic reaction	30OCT2020 (50)		01NOV2020 (52)		3	1
4	METAB	Hypoglycaemia	Hypoglycemia	12SEP2020 (2)		13SEP2020 (3)		2	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (08OCT2020)	NOT RELATED/OTHER: Suspected irritable bowel syndrome	1	15	N
2	N	N	Resolved (29SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	18	N
3	TC	N	Resolved (01NOV2020)	NOT RELATED/OTHER: None	2	31	N
4	TC	Y	Resolved (13SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flulaval Quadrivalent	INFLUENZA VACCINE INACT SPLIT 4V	22OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	11NOV2020	
Completed	REPEAT SCREENING 1	16FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	60.4 kg	22.2 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Idiopathic thrombocytopenic purpura	Immune thrombocytopenia	01MAR2010	Past
left ovarian cyst	Ovarian cyst	10SEP2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21SEP2020 (1)	12:54

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	04NOV2020 (45)	10:05
3	BNT162b2	02FEB2021 (135)	17:48
4	BNT162b2	22FEB2021 (155)	16:34

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	REPRO	Haemorrhagic ovarian cyst	Hemorrhagic cyst of the right ovary	21OCT2020 (31)		19NOV2020 (60)		30	1
2	INJ&P	Procedural haemorrhage	Intraoperative hemorrhage during an elective laparoscopic ovarian cystectomy	03OCT2020 (13)	07:30	07OCT2020 (17)	10:00	5	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (19NOV2020)	NOT RELATED/OTHER: Unknown	1	31	N
2	TC	Y	Resolved (07OCT2020)	NOT RELATED/OTHER: Laparoscopic surgery	1	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Completed	VACCINATION	27NOV2020	
Completed	REPEAT SCREENING 1	02FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	117 kg	39.5 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
smoking	Tobacco user	1996	Present
Arterial hypertension	Hypertension	08SEP2010	Present
Alcoholic cirrhosis	Cirrhosis alcoholic	2013	Present
COPD	Chronic obstructive pulmonary disease	20MAY2013	Present
portal hypertension	Portal hypertension	10MAY2014	Present
esophageal varices	Varices oesophageal	10MAY2014	Present
Obesity	Obesity	2015	Present
Insomnia	Insomnia	01NOV2015	Present
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21SEP2020 (1)	18:10
2	BNT162b2	13OCT2020 (23)	17:00

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Coronary artery disease	Coronary heart disease	01OCT2020 (11)	10:00	17FEB2021 (150)	10:00	140	2	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (17FEB2021)	NOT RELATED/OTHER: Cardiovascular risk factors (hypertension, smoker, obesity, sex and age)	1	11	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Completed	VACCINATION	11NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	53	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	87.3 kg	29.2 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 2 diabetes	Type 2 diabetes mellitus	01MAR2019	Present
Right Inguinal Hernia	Inguinal hernia	01JUL2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21SEP2020 (1)	20:25
2	BNT162b2	12OCT2020 (22)	10:48

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Incarcerated inguinal hernia	Incarcerated right inguinal hernia	05OCT2020 (15)	16:00	22OCT2020 (32)	15:00	18	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (22OCT2020)	NOT RELATED/OTHER: complication of right inguinal hernia	1	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21SEP2020	
Completed	VACCINATION	11NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	74.9 kg	26.5 kg/m2	22SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Uterine myomatosis	Uterine leiomyoma	01JUN2017	Present
Gastric bypass surgery	Gastric bypass	25MAR2019	Past
Hormone intrauterine device placement	Intra-uterine contraceptive device insertion	01FEB2020	Past
Venous insufficiency	Peripheral venous disease	22AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22SEP2020 (1)	10:37
2	Placebo	12OCT2020 (21)	13:26
3	BNT162b2	05MAR2021 (165)	14:47

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INFEC	Postoperative wound infection	Surgical site infection	16NOV2020 (56)	08:00	27NOV2020 (67)	18:45	12	2	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (27NOV2020)	NOT RELATED/OTHER: Infection post elective hysterectomy for preexisting uterine myomatosis	2	36	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	22SEP2020	
Completed	VACCINATION	11NOV2020	
Completed	REPEAT SCREENING 1	05MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	100 kg	37.2 kg/m2	22SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypercholesterolemia	Hypercholesterolaemia	01JUL2014	Present
Carotid obstruction	Carotid artery occlusion	01NOV2014	Present
Stroke	Cerebrovascular accident	01NOV2014	Past
Arterial hypertension	Hypertension	01NOV2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22SEP2020 (1)	13:35
2	Placebo	13OCT2020 (22)	17:25
3	BNT162b2	26FEB2021 (158)	15:46

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	COVID-19	Covid-19 Illness	15JAN2021 (116)	18:00	03FEB2021 (135)	19:00	20

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (03FEB2021)	NOT RELATED/OTHER: it is unknown	2	95	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	22SEP2020	
Completed	VACCINATION	12NOV2020	
Completed	REPEAT SCREENING 1	26FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	68	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	81 kg	28 kg/m2	22SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Horton migraine	Cluster headache	01FEB1980	Present
Resolved prostate cancer	Prostate cancer	01MAR2012	Past
Hypercholesterolemia	Hypercholesterolaemia	22SEP2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22SEP2020 (1)	13:47
2	Placebo	13OCT2020 (22)	11:48
3	BNT162b2	03FEB2021 (135)	15:14
4	BNT162b2	08MAR2021 (168)	10:30

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	VASC	Aortic aneurysm	Abdominal Aortic Aneurysm	08FEB2021 (140)	10:50	26FEB2021 (158)	16:30	19
2	VASC	Aortic stenosis	Severe Aortic Stenosis	27JAN2021 (128)	12:00	09MAR2021 (169)	19:00	42
3	CARD	Ischaemic cardiomyopathy	Ischemic myocardiopathy worsening	05FEB2021 (137)	12:00	09MAR2021 (169)	19:00	33

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (26FEB2021)	NOT RELATED/OTHER: unknown	3	6	N
2	3	TC/TCN	Y	Resolved (09MAR2021)	NOT RELATED/OTHER: unknown	2	107	Y
3	3	TC/TCN	Y	Resolved (09MAR2021)	NOT RELATED/OTHER: unknown	3	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	22SEP2020	
Completed	VACCINATION	11NOV2020	
Completed	REPEAT SCREENING 1	03FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	99 kg	32.3 kg/m2	22SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypercholesterolemia	Hypercholesterolaemia	02JUN2003	Present
Arterial hypertension	Hypertension	02JUN2003	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	22SEP2020 (1)	15:17
2	BNT162b2	12OCT2020 (21)	12:12

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Adenocarcinoma of colon	Poorly differentiated colon adenocarcinoma	20JAN2021 (121)	15:00	ONGOING		
2	MUSC	Pain in extremity	Pain in left heel	28SEP2020 (7)	10:00	28SEP2020 (7)	18:00	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Yes	NOT RELATED/OTHER: unknown	2	101	Y
2	1	TC	N	Resolved (28SEP2020)	NOT RELATED/OTHER: spur background	1	7	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	22SEP2020	
Completed	VACCINATION	11NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	88 kg	30.8 kg/m2	22SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22SEP2020 (1)	17:25
2	Placebo	13OCT2020 (22)	12:22
3	BNT162b2	05MAR2021 (165)	12:19

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Pneumonia	Community-acquired pneumonia	29JAN2021 (130)	15:00	02MAR2021 (162)	20:00	33

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (02MAR2021)	NOT RELATED/OTHER: unknown	2	109	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22SEP2020	
Completed	VACCINATION	12NOV2020	
Completed	REPEAT SCREENING 1	05MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	76	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	85 kg	28.4 kg/m2	22SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
smoking	Tobacco user	01OCT1959	Past
Biliary lithiasis	Cholelithiasis	16MAY1993	Present
Anterior descending coronary artery obstruction	Coronary artery occlusion	07FEB1999	Past
low back pain	Back pain	01FEB2005	Past
Hypercholesterolemia	Hypercholesterolaemia	03MAR2005	Present
Arterial Hypertension	Hypertension	03MAR2005	Present
Benign prostatic hyperplasia	Benign prostatic hyperplasia	01MAR2010	Present
Basal cell carcinoma	Basal cell carcinoma	01MAR2018	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
surgical treatment for basal cell carcinoma	Skin neoplasm excision	01MAR2018	Past
Anterior descending coronary artery stenosis	Coronary artery stenosis	14MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	22SEP2020 (1)	17:57
2	BNT162b2	13OCT2020 (22)	13:20

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	HEPAT	Cholelithiasis	Worsening of biliary lithiasis	02NOV2020 (42)	22:00	03MAR2021 (163)	18:00	122	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (03MAR2021)	NOT RELATED/OTHER: History of gallstones	2	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	22SEP2020	
Completed	VACCINATION	12NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	48	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	59 kg	20.4 kg/m2	23SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Climacteric syndrome	Menopausal symptoms	01JAN2012	Present
gallstones	Cholelithiasis	01FEB2020	Past
bilateral breast implant placement	Mammoplasty	13FEB2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	23SEP2020 (1)	10:00
2	BNT162b2	15OCT2020 (23)	10:56

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Intestinal perforation	Intestinal perforation	23DEC2020 (92)	09:00	13JAN2021 (113)	15:00	22	3
2	INFEC	Pneumonia	Hospital-acquired pneumonia	30DEC2020 (99)	09:00	13JAN2021 (113)	15:00	15	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (13JAN2021)	NOT RELATED/OTHER: surgical intervention	2	70	Y
2	TC	Y	Resolved (13JAN2021)	NOT RELATED/OTHER: Intestinal perforation	2	77	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	23SEP2020	
Completed	VACCINATION	12NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	83 kg	25.6 kg/m2	23SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 2 diabetes	Type 2 diabetes mellitus	01MAR1995	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23SEP2020 (1)	12:22

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	14OCT2020 (22)	09:50
3	BNT162b2	13MAR2021 (172)	12:09

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	VASC	Hypertension	arterial hypertension	28JAN2021 (128)	20:00	ONGOING		
2	VASC	Hypertensive emergency	Hypertensive emergency	28JAN2021 (128)	20:00	04FEB2021 (135)	16:00	8
3	METAB	Hyponatraemia	Hyponatremia	31JAN2021 (131)	20:00	04FEB2021 (135)	16:00	5

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Yes	NOT RELATED/OTHER: unknown	2	107	N
2	3	TC	Y	Resolved (04FEB2021)	NOT RELATED/OTHER: unknown	2	107	Y
3	2	TCN	Y	Resolved (04FEB2021)	NOT RELATED/OTHER: unknown	2	110	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23SEP2020	
Completed	VACCINATION	11NOV2020	
Completed	REPEAT SCREENING 1	13MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186 cm	118 kg	34.1 kg/m2	23SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
obesity	Obesity	17MAR2000	Present
bariatric surgery	Metabolic surgery	09OCT2013	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	23SEP2020 (1)	12:35
2	BNT162b2	14OCT2020 (22)	11:18

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Cholecystitis acute	Acute cholecystitis	28DEC2020 (97)	08:00	04JAN2021 (104)	15:00	8

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (04JAN2021)	NOT RELATED/OTHER: unknown	2	76	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23SEP2020	
Completed	VACCINATION	12NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	128 kg	47 kg/m2	23SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
gallstones	Cholelithiasis	MAY1990	Past
cholecystectomy	Cholecystectomy	01JUL1990	Past
Hysterectomy	Hysterectomy	05SEP1996	Past
Arterial hypertension	Hypertension	09SEP2005	Present
Gastritis	Gastritis	09SEP2010	Present
Obesity	Obesity	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23SEP2020 (1)	13:57
2	Placebo	14OCT2020 (22)	17:47
3	BNT162b2	05FEB2021 (136)	12:05
4	BNT162b2	26FEB2021 (157)	16:58

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GASTR	Diarrhoea	Acute diarrhea	17OCT2020 (25)	13:00	19OCT2020 (27)	13:00	3	1	N	N
2	GENRL	Pelvic mass	Pelvic mass	06FEB2021 (137)	10:00	ONGOING			2	TC/TCN	Y
3	RENAL	Renal failure	Renal insufficiency	15JAN2021 (115)	10:00	17FEB2021 (148)	08:00	34	1	N	N
4	INFEC	Urinary tract infection	URINARY TRACT INFECTION	15JAN2021 (115)	08:00	08FEB2021 (139)	08:00	25	1	TC	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (19OCT2020)	NOT RELATED/OTHER: increased consumption of fruits and vegetables	2	4	N
2	Yes	NOT RELATED/OTHER: unknown	3	2	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
3	Resolved (17FEB2021)	NOT RELATED/OTHER: Unknown	2	94	N
4	Resolved (08FEB2021)	NOT RELATED/OTHER: unknown	2	94	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23SEP2020	
Completed	VACCINATION	11NOV2020	
Completed	REPEAT SCREENING 1	05FEB2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	51	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159 cm	61 kg	24.1 kg/m2	23SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	03SEP2014	Present
Anxiety disorder	Anxiety disorder	07SEP2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23SEP2020 (1)	17:26

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	14OCT2020 (22)	15:42
3	BNT162b2	06MAR2021 (165)	14:57

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Oesophageal food impaction	esophageal impaction with food	28SEP2020 (6)	21:00	29SEP2020 (7)	10:30	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	Y	Resolved (29SEP2020)	NOT RELATED/OTHER: food impaction	1	6	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	23SEP2020	
Completed	VACCINATION	12NOV2020	
Completed	REPEAT SCREENING 1	06MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	51	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	73.9 kg	29.6 kg/m2	23SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Familial hypercholesterolemia	Type IIa hyperlipidaemia	01JAN1990	Present
Vertigo	Vertigo	01JAN2000	Present
low back pain	Back pain	15FEB2020	Present
Spondylosis between L5 and S1	Spinal osteoarthritis	15FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	23SEP2020 (1)	18:58
2	BNT162b2	15OCT2020 (23)	12:10

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Back pain	Exacerbation of low back pain	02NOV2020 (41)	20:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Yes	NOT RELATED/OTHER: Chronic pain missed on visit 1	2	19	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23SEP2020	
Completed	VACCINATION	13NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1945	75	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	110.7 kg	37 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Clear cell renal cell carcinoma	Clear cell renal cell carcinoma	01OCT1999	Past
Left nephrectomy	Nephrectomy	18OCT1999	Past
Mild intermittent asthma	Asthma	03JAN2000	Present
Arterial hypertension	Hypertension	01MAR2000	Present
Prostate cancer	Prostate cancer	03DEC2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25SEP2020 (1)	12:30
2	BNT162b2	15OCT2020 (21)	12:56

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Cholelithiasis	Gallstones (gallbladder stones)	13DEC2020 (80)	20:00	07JAN2021 (105)	16:00	26
2	GASTR	Pancreatitis acute	Acute pancreatitis	16DEC2020 (83)	12:00	07JAN2021 (105)	16:00	23

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TCN	Y	Resolved (07JAN2021)	NOT RELATED/OTHER: unknown	2	60	Y
2	3	TC/TCN	Y	Resolved (07JAN2021)	NOT RELATED/OTHER: gallstones	2	63	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25SEP2020	
Completed	VACCINATION	12NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	81.7 kg	27.3 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Ventricular extrasystole	Ventricular extrasystoles	03MAR2015	Present
Surgical ablation for ventricular extrasystole	Cardiac ablation	03APR2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25SEP2020 (1)	18:43
2	BNT162b2	15OCT2020 (21)	13:43

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Ankle fracture	Right ankle fracture	15NOV2020 (52)	10:00	21JAN2021 (119)	15:00	68
2	INJ&P	Fall	fall from a bicycle	15NOV2020 (52)	10:00	15NOV2020 (52)	10:01	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (21JAN2021)	NOT RELATED/OTHER: bike fall	2	32	Y
2	2	TCN	N	Resolved (15NOV2020)	NOT RELATED/OTHER: fall from a bicycle	2	32	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
Completed	VACCINATION	13NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	47.6 kg	17.9 kg/m2	25SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25SEP2020 (1)	18:39
2	Placebo	16OCT2020 (22)	16:35
3	BNT162b2	10MAR2021 (167)	12:25

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	PSYCH	Adjustment disorder with depressed mood	Reactive depression	25JAN2021 (123)	12:00	ONGOING			1	TC
2	INJ&P	Fall	Fall down stairs	05DEC2020 (72)	12:00	05DEC2020 (72)	12:03	1	1	N
3	INJ&P	Humerus fracture	Right displaced proximal humeral fracture	05DEC2020 (72)	12:00	14JAN2021 (112)	18:00	41	2	TC/TCN

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Yes	NOT RELATED/OTHER: Related to his history of humerus fracture.	2	102	N
2	N	Resolved (05DEC2020)	NOT RELATED/OTHER: Accidental slip	2	51	N
3	Y	Resolved (14JAN2021)	NOT RELATED/OTHER: Fall down stairs	2	51	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
Completed	VACCINATION	13NOV2020	
Completed	REPEAT SCREENING 1	10MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179 cm	132 kg	41.2 kg/m2	27SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	01SEP2013	Present
obesity	Obesity	10JAN2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27SEP2020 (1)	17:08
2	BNT162b2	15OCT2020 (19)	15:27

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Hypertensive urgency	Hypertensive urgency	04MAR2021 (159)	20:00	04MAR2021 (159)	20:30	1	3
2	GENRL	Pyrexia	Fever	16OCT2020 (20)	11:07	17OCT2020 (21)	20:06	2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (04MAR2021)	NOT RELATED/OTHER: Worsening of high blood pressure	2	141	Y
2	TC	N	Resolved (17OCT2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27SEP2020	
Completed	VACCINATION	13NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	74	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	78 kg	27 kg/m2	13OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Gastrooesophageal reflux disease	Gastrooesophageal reflux disease	1978	Present
Hypertension	Hypertension	1978	Present
High cholesterol	Blood cholesterol increased	1986	Present
Deviated septum repair	Nasal septal operation	1986	Past
Ethmoid sinus surgery	Ethmoid sinus surgery	1988	Past
Ethmoid sinus surgery	Ethmoid sinus surgery	1991	Past
Type 2 diabetes mellitus	Type 2 diabetes mellitus	1991	Present
Sulfonamide allergy	Drug hypersensitivity	1996	Present
Lumbar discectomy	Intervertebral disc operation	1996	Past
Herniated disc	Intervertebral disc protrusion	1996	Past

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	13OCT2020 (1)	11:51
2	Placebo	14DEC2020 (63)	11:13
3	BNT162b2	19JAN2021 (99)	10:11
4	BNT162b2	09FEB2021 (120)	12:57

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	EAR	Deafness	hearing loss	01NOV2020 (20)		20JAN2021 (100)		81	2	TC	N
2	GENRL	Injection site pain	Injection site soreness	19JAN2021 (99)	16:00	20JAN2021 (100)		2	1	N	N

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (20JAN2021)	NOT RELATED/OTHER: injury due recreational firearm noise exposure	1	20	Y
2	Resolved (20JAN2021)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13OCT2020	
Completed	VACCINATION	14JAN2021	
Completed	REPEAT SCREENING 1	19JAN2021	
Completed	OPEN LABEL TREATMENT	09MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2003	17	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161 cm	53.2 kg	20.5 kg/m2	04NOV2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Acne	Acne	2015	Present
Insomnia	Insomnia	2016	Present
Anxiety	Anxiety	2017	Present
Depression	Depression	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04NOV2020 (1)	14:14
2	Placebo	25NOV2020 (22)	09:11
3	BNT162b2	24FEB2021 (113)	11:07

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NERV	Generalised tonic-clonic seizure	Grand Mal Seizure	29NOV2020 (26)		29NOV2020 (26)		1	3	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (29NOV2020)	NOT RELATED/OTHER: Not related as have additional data now showing relatedness to other cause	2	5	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04NOV2020	
Completed	VACCINATION	21DEC2020	
Completed	REPEAT SCREENING 1	24FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.3 cm	147.1 kg	47.9 kg/m2	23SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	23SEP2020 (1)	18:31
2	BNT162b2	14OCT2020 (22)	10:23

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	SKIN	Angioedema	Angioedema face	16OCT2020 (24)		17OCT2020 (25)	
2	GENRL	Chills	chills	15OCT2020 (23)		15OCT2020 (23)	
3	GENRL	Fatigue	fatigue	14OCT2020 (22)	18:00	16OCT2020 (24)	
4	NERV	Headache	headache	14OCT2020 (22)	18:00	16OCT2020 (24)	
5	GENRL	Injection site pain	injection site pain	14OCT2020 (22)		15OCT2020 (23)	
6	GENRL	Pyrexia	fever	15OCT2020 (23)		16OCT2020 (24)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (17OCT2020)	Study Treatment	2	3	Y
2	1	1	N	N	Resolved (15OCT2020)	Study Treatment	2	2	N
3	3	1	N	N	Resolved (16OCT2020)	Study Treatment	2	1	N
4	3	1	N	N	Resolved (16OCT2020)	Study Treatment	2	1	N
5	2	1	N	N	Resolved (15OCT2020)	Study Treatment	2	1	N
6	2	1	N	N	Resolved (16OCT2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccine	INFLUENZA VACCINE	09NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23SEP2020	
Completed	VACCINATION	11NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	65 kg	23.8 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Migraine	Migraine	1995	Present
Immune mediated thyroiditis	Immune-mediated thyroiditis	2010	Present
Hysterectomy	Hysterectomy	2011	Past

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	09SEP2020 (1)	15:49
2	Placebo	30SEP2020 (22)	13:31
3	BNT162b2	30DEC2020 (113)	12:15
4	BNT162b2	20JAN2021 (134)	10:06

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Fatigue	FATIGUE	11SEP2020 (3)	07:00	12SEP2020 (4)	07:00	2
2	EAR	Hypoacusis	decreased hearing right ear	30NOV2020 (83)		21JAN2021 (135)		53

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (12SEP2020)	Study Treatment	1	3	N
2	2	N	N	Resolved (21JAN2021)	NOT RELATED/OTHER: covid-19	2	62	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	04NOV2020	
Completed	REPEAT SCREENING 1	30DEC2020	
Completed	OPEN LABEL TREATMENT	08MAR2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159 cm	77 kg	30.5 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
asthma	Asthma	1998	Past
anxiety (intermittent)	Anxiety	2001	Present
environmental allergies	Hypersensitivity	2014	Present
cholecystectomy	Cholecystectomy	2017	Past
gallstones	Cholelithiasis	2017	Past
salpingectomy, bilateral	Salpingectomy	2018	Past
scar in abdomen	Scar	2018	Present
TMJ dysfunction	Temporomandibular joint syndrome	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	09:02
2	Placebo	18SEP2020 (22)	08:33
3	BNT162b2	03FEB2021 (160)	09:50
4	BNT162b2	26FEB2021 (183)	08:48

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	EAR	Ear disorder	fluid R ear	22SEP2020 (26)		13FEB2021 (170)		145	1	TC	N
2	NERV	Headache	Headache	28AUG2020 (1)	17:30	29AUG2020 (2)	15:00	2	2	TC/TCN	N
3	NERV	Headache	headache	18SEP2020 (22)	18:00	19SEP2020 (23)	10:00	2	2	TC	N
4	EAR	Hypoacusis	decreased hearing R ear	20SEP2020 (24)		ONGOING			2	TC	N
5	MUSC	Temporomandibular joint syndrome	worsening R TMJ dysfunction	12FEB2021 (169)		ONGOING			1	N	N
6	EAR	Tinnitus	Tinnitus R ear	20SEP2020 (24)		ONGOING			2	TC	N
7	EAR	Vertigo	vertigo	20SEP2020 (24)		22SEP2020 (26)		3	1	N	N

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (13FEB2021)	NOT RELATED/OTHER: unknown, possible allergy	2	5	N
2	Resolved (29AUG2020)	Study Treatment	1	1	N
3	Resolved (19SEP2020)	Study Treatment	2	1	N
4	Yes	NOT RELATED/OTHER: unknown, possible allergy	2	3	Y
5	Yes	NOT RELATED/OTHER: TMJ 2/2 increased stress, has a h/o TMJ dysfunction	3	10	N
6	Yes	NOT RELATED/OTHER: unknown, possible allergy	2	3	N
7	Resolved (22SEP2020)	NOT RELATED/OTHER: unknown, possible allergy	2	3	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	16OCT2020	
Completed	REPEAT SCREENING 1	03FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168.5 cm	75.2 kg	26.5 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Uterine ablation	Endometrial ablation	2008	Past
Menorrhagia	Menorrhagia	2008	Past
Oxycodone Allergy	Drug hypersensitivity	2018	Present
Gastric Bypass	Gastric bypass	2018	Past
Hypothyroidism	Hypothyroidism	2018	Present
Postmenopausal	Postmenopause	JAN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14SEP2020 (1)	14:28
2	BNT162b2	07OCT2020 (24)	13:58

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	EAR	Deafness unilateral	HEARING LOSS IN RIGHT EAR	08OCT2020 (25)	08:00	ONGOING	
2	NERV	Dizziness	DIZZINESS	07OCT2020 (24)	21:00	ONGOING	
3	INJ&P	Fall	FALL	24NOV2020 (72)	18:00	24NOV2020 (72)	18:00
4	INJ&P	Upper limb fracture	BROKEN RIGHT ARM	24NOV2020 (72)	18:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	N	N	Yes	Study Treatment	2	2	Y
2		2	N	N	Yes	Study Treatment	2	1	N
3	1	2	N	N	Resolved (24NOV2020)	Study Treatment	2	49	N
4		1	TCN	N	Yes	Study Treatment	2	49	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	12NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1993	27	Black or African American	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	67.1 kg	24.1 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HEARING DEFICIT RIGHT EAR	Hypoacusis	1999	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03SEP2020 (1)	15:55
2	BNT162b2	24SEP2020 (22)	11:21

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	NERV	Seizure like phenomena	Subject reports Seizure like activity	27FEB2021 (178)	02:30	27FEB2021 (178)	02:31	1	2

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (27FEB2021)	NOT RELATED/OTHER: NEW NEUROLOGIC EVENT	2	157	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	22OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
181.61 cm	152.95 kg	46.3 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypertension	Hypertension	DEC2005	Present
obesity	Obesity	2010	Present
allergic rhinitis	Rhinitis allergic	2010	Present
Hypercholesterolemia	Hypercholesterolaemia	2012	Present
diabetes mellitus type II	Type 2 diabetes mellitus	2012	Present
osteoarthritis bilateral knees	Osteoarthritis	2013	Present
sleep apnea	Sleep apnoea syndrome	2013	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03AUG2020 (1)	16:51
2	BNT162b2	24AUG2020 (22)	17:06

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	EAR	Deafness neurosensory	Sudden sensorineural hearing loss - Left Ear	18OCT2020 (77)	00:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	TC	N	Yes	NOT RELATED/OTHER: Hearing Loss	2	56	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	21SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178.4 cm	80.6 kg	25.3 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis	Rhinitis allergic	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	12:08
2	Placebo	29SEP2020 (20)	09:25

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
3	BNT162b2	16DEC2020 (98)	13:24
4	BNT162b2	04JAN2021 (117)	09:26

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	SKIN	Angioedema	periorbital angioedema	11SEP2020 (2)		13SEP2020 (4)		3	1
2	SKIN	Angioedema	periorbital angioedema	27SEP2020 (18)		28SEP2020 (19)		2	1
3	GENRL	Fatigue	fatigue	04JAN2021 (117)	16:00	05JAN2021 (118)		2	2
4	NERV	Headache	headache	16DEC2020 (98)	14:00	16DEC2020 (98)	14:30	1	1
5	GENRL	Injection site pain	pain at injection site	17DEC2020 (99)		18DEC2020 (100)		2	1

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (13SEP2020)	NOT RELATED/OTHER: seasonal allergies	1	2	Y
2	TC/TCN	N	Resolved (28SEP2020)	NOT RELATED/OTHER: seasonal allergies	1	18	Y
3	N	N	Resolved (05JAN2021)	Study Treatment	4	1	N
4	N	N	Resolved (16DEC2020)	Study Treatment	3	1	N
5	N	N	Resolved (18DEC2020)	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	27OCT2020	
Completed	REPEAT SCREENING 1	16DEC2020	
Completed	OPEN LABEL TREATMENT	08FEB2021	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184.15 cm	113 kg	33.2 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Muscle spasms (back)	Muscle spasms	1983	Present
Hypertension	Hypertension	2002	Present
Farsighted	Hypermetropia	2004	Present
Kidney stones	Nephrolithiasis	2008	Past
Overweight	Overweight	2008	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	11AUG2020 (1)	11:11
2	BNT162b2	01SEP2020 (22)	11:26

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	SKIN	Angioedema	Angioedema (isolated around lips)	20FEB2021 (194)		21FEB2021 (195)		2	1
2	SKIN	Angioedema	Angioedema (left hand center palm to heel of hand)	06FEB2021 (180)		07FEB2021 (181)		2	1
3	SKIN	Angioedema	Angioedema (left side of jaw bone area)	23FEB2021 (197)		25FEB2021 (199)		3	1
4	SKIN	Angioedema	Angioedema (left sole of foot)	06FEB2021 (180)		07FEB2021 (181)		2	1
5	SKIN	Angioedema	Angioedema (right side of face)	29JAN2021 (172)		31JAN2021 (174)		3	1
6	SKIN	Angioedema	Intermittent Angioedema (lips)	01SEP2020 (22)		24DEC2020 (136)		115	1
7	GASTR	Tongue oedema	Intermittent Angioedema (tongue)	01SEP2020 (22)		24DEC2020 (136)		115	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (21FEB2021)	NOT RELATED/OTHER: unknown	2	173	Y
2	N	N	Resolved (07FEB2021)	NOT RELATED/OTHER: unknown	2	159	Y
3	N	N	Resolved (25FEB2021)	NOT RELATED/OTHER: unknown	2	176	Y
4	N	N	Resolved (07FEB2021)	NOT RELATED/OTHER: unknown	2	159	Y
5	N	N	Resolved (31JAN2021)	NOT RELATED/OTHER: unknown	2	151	Y

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
6	N	N	Resolved (24DEC2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	1	Y
7	N	N	Resolved (24DEC2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	1	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
Flulaval Quadrivalent	INFLUENZA VACCINE INACT SPLIT 4V	02OCT2020

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	01OCT2020	
	REPEAT SCREENING 1		

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156.21 cm	59.27 kg	24.2 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
broken fibula	Fibula fracture	1983	Past
broken tibia	Tibia fracture	1983	Past
Breast augmentation	Mammoplasty	2004	Past
Hypothyroidism	Hypothyroidism	2005	Present
Farsighted	Hypermetropia	2009	Present
Partial Hysterectomy	Hysterectomy	2012	Past
Abnormal pap smear	Smear cervix abnormal	2012	Past
Back Pain	Back pain	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	17:27

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	SKIN	Angioedema	ANGIO-EDEMA BOTH EYES	23AUG2020 (13)		ONGOING			1	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Yes	NOT RELATED/OTHER: Subject equates it to allergies as she is scheduled to see Allergist	1	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Withdrawn	VACCINATION	20OCT2020	WITHDRAWAL BY SUBJECT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.21 cm	105.73 kg	35.6 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Demerol induced anaphylaxis	Anaphylactic reaction	1991	Past
Allergy, Demerol	Drug hypersensitivity	1991	Present
elbow repair, left	Elbow operation	1991	Past
Elbow, left, displaced fracture	Upper limb fracture	1991	Past
Myopia, bilateral	Myopia	1993	Present
appendectomy	Appendicectomy	1996	Past
appendicitis	Appendicitis	1996	Past
Allergy, seasonal	Seasonal allergy	2001	Present
Pain, tooth	Toothache	2002	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tooth extraction, wisdom	Wisdom teeth removal	2002	Past
Alcohol use, 2/week	Alcohol use	2005	Present
Sinusitis, chronic	Chronic sinusitis	2005	Present
Hip scope, right	Arthroscopy	DEC2005	Past
hip fracture, right	Hip fracture	DEC2005	Past
anxiety	Anxiety	2015	Present
pneumonia	Pneumonia	2016	Past
C-Section	Caesarean section	15OCT2016	Past
pneumonia	Pneumonia	2018	Past
hypertension	Hypertension	JAN2020	Present
Radial head fracture, Left, non-displaced	Radius fracture	22JUL2020	Present
Pain, elbow, left	Arthralgia	25JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15SEP2020 (1)	10:06
2	Placebo	06OCT2020 (22)	17:09
3	BNT162b2	18JAN2021 (126)	09:58
4	BNT162b2	08FEB2021 (147)	09:43

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	SKIN	Angioedema	ANGIOEDEMA	31OCT2020 (47)	08:00	03NOV2020 (50)		4	1	TC

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Resolved (03NOV2020)	NOT RELATED/OTHER: CONMED REACTION, LISINOPRIL	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
FLU VACCINE	INFLUENZA VACCINE	01SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15SEP2020	
Completed	VACCINATION	05NOV2020	
Completed	REPEAT SCREENING 1	18JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	42	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	65.91 kg	23.4 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	1988	Present
migraine headaches	Migraine	1991	Present
epilepsy	Epilepsy	2002	Present
asthma	Asthma	2007	Present
pneumonia	Pneumonia	2007	Past
laparoscopic hysterectomy	Hysterectomy	2013	Past
uterine fibroids	Uterine leiomyoma	2013	Past
nasal polyps	Nasal polyps	2014	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
sinus surgery	Sinus operation	2014	Past
generalized anxiety	Generalised anxiety disorder	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	14:02
2	BNT162b2	11SEP2020 (23)	15:44

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Seizure	worsening of intermittent seizures	01DEC2020 (104)	00:00	25JAN2021 (159)	00:00	56	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (25JAN2021)	NOT RELATED/OTHER: Med Hx of epilepsy	2	82	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	12OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	37	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176 cm	75 kg	24.2 kg/m2	04NOV2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypercholesterol	Blood cholesterol increased	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04NOV2020 (1)	09:50

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	25NOV2020 (22)	10:30
3	BNT162b2	03MAR2021 (120)	10:25

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	EAR	Deafness unilateral	Acute hearing loss in right ear	JAN2021 ()		18JAN2021 (76)		
2	MUSC	Pain in extremity	Injection arm pain	03MAR2021 (120)	15:00	06MAR2021 (123)	11:00	4
3	EAR	Tinnitus	Tinnitus in right ear	08JAN2021 (66)		18JAN2021 (76)		11

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (18JAN2021)	NOT RELATED/OTHER: Unknown	2		Y
2	1	N	N	Resolved (06MAR2021)	Study Treatment	3	1	N
3	1	TC	N	Resolved (18JAN2021)	NOT RELATED/OTHER: unknown	2	45	N

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Prednol (methylprednisolone)	METHYLPREDNISOLONE	15JAN2021	17JAN2021	ORAL

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Prednol (methylprednisolone)	METHYLPREDNISOLONE	18JAN2021	20JAN2021	ORAL
Prednol (methylprednisolone)	METHYLPREDNISOLONE	21JAN2021	23JAN2021	ORAL
Prednol (methylprednisolone)	METHYLPREDNISOLONE	24JAN2021	26JAN2021	ORAL
Prednol (methylprednisolone)	METHYLPREDNISOLONE	27JAN2021	29JAN2021	ORAL
Prednol (methylprednisolone)	METHYLPREDNISOLONE	30JAN2021	01FEB2021	ORAL

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04NOV2020	
Completed	VACCINATION	23DEC2020	
Completed	REPEAT SCREENING 1	03MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	43	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159 cm	66.8 kg	26.4 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chagas disease, AKA American trypanosomiasis	American trypanosomiasis	02NOV1999	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	15:59
2	BNT162b2	01SEP2020 (22)	12:29

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	EAR	Deafness unilateral	hearing loss in the left ear	27SEP2020 (48)	09:00	08OCT2020 (59)	15:00	12	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (08OCT2020)	NOT RELATED/OTHER: Cerum in external auditory canal	2	27	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	01OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	51	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	75 kg	26 kg/m2	21AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	11:29
2	BNT162b2	11SEP2020 (22)	10:05

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Pyrexia	fever	12SEP2020 (23)	08:30	12SEP2020 (23)	13:00	1
2	EAR	Sudden hearing loss	sudden hearing loss in the right ear	02OCT2020 (43)	13:00	16OCT2020 (57)	07:00	15

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	N	Resolved (12SEP2020)	Study Treatment	2	2	N
2	1	TC	N	Resolved (16OCT2020)	NOT RELATED/OTHER: Unknown	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182 cm	116.65 kg	35.2 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Supraventricular extrasystoles	Supraventricular extrasystoles	20APR2016	Present
Type 2 diabetes	Type 2 diabetes mellitus	13JUN2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	18:50
2	BNT162b2	14SEP2020 (20)	12:14

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	EAR	Deafness neurosensory	Bilateral moderate sensorineural hearing loss	20SEP2020 (26)	08:00	22FEB2021 (181)	09:00	156

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (22FEB2021)	NOT RELATED/OTHER: unknown	2	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	16OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	25	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	78.9 kg	28.3 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bronchial asthma	Asthma	01MAY2005	Past
Pneumonia	Pneumonia	01JUN2005	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	17:15

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	16SEP2020 (20)	18:55
3	BNT162b2	09MAR2021 (194)	17:41

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Myocarditis	right retroatrial inflammation	21SEP2020 (25)	08:00	21SEP2020 (25)	20:00	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (21SEP2020)	NOT RELATED/OTHER: Unkonwn	2	6	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	19OCT2020	
Completed	REPEAT SCREENING 1	09MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	32	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	109.09 kg	33.5 kg/m2	27OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypertension	Hypertension	2007	Present
Depression	Depression	2015	Present
substance abuse disorder	Substance abuse	2015	Present
diabetes mellitus Type 2	Type 2 diabetes mellitus	2016	Present
hx of atrial fibrilation	Atrial fibrillation	2018	Present
hepatitis C	Hepatitis C	2018	Present
epilepsy	Epilepsy	01APR2018	Present
gout	Gout	01AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27OCT2020 (1)	12:43
2	BNT162b2	17NOV2020 (22)	09:37

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	NERV	Dizziness	moderate dizziness	18DEC2020 (53)	13:48	18DEC2020 (53)	14:50	1	1	TCN
2	NERV	Seizure	seizure	15DEC2020 (50)		15DEC2020 (50)		1	3	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Resolved (18DEC2020)	NOT RELATED/OTHER: possible vasovagal response	2	32	N
2	N	Resolved (15DEC2020)	NOT RELATED/OTHER: methamphetamine usage 12/13/20 hx of afib	2	29	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27OCT2020	
Completed	VACCINATION	18DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	84 kg	29.4 kg/m2	21SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21SEP2020 (1)	13:45
2	Placebo	12OCT2020 (22)	13:30

Reason(s) for Narrative: Adverse Event of Special Interest With Numerical Imbalance Between Vaccine Groups
Unique Subject ID: C4591001 4444 44441035; Country: Argentina
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: 21SEP2020; Date of Last Dose: 17FEB2021
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	29JAN2021 (131)	15:20
4	BNT162b2	17FEB2021 (150)	16:25

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	EAR	Deafness	Hearing loss	14JAN2021 (116)	09:13	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	N	N	Yes	NOT RELATED/OTHER: Unknown	2	95	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Completed	VACCINATION	18NOV2020	
Completed	REPEAT SCREENING 1	29JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.2 cm	93.3 kg	32.2 kg/m2	12OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergy	Seasonal allergy	1992	Present
Hysterectomy	Hysterectomy	2003	Past
Obesity	Obesity	2003	Present
Salpingo-oophorectomy unilateral	Salpingo-oophorectomy unilateral	2003	Past
Asthma	Asthma	06JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12OCT2020 (1)	15:31
2	Placebo	02NOV2020 (22)	13:44

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Pneumonia	left lower lobe pneumonia	19FEB2021 (131)		ONGOING			3
2	INFEC	Sepsis	sepsis	19FEB2021 (131)		06MAR2021 (146)		16	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Yes	NOT RELATED/OTHER: Legionella bacteria	2	110	Y
2	TC/TCN	Y	Resolved (06MAR2021)	NOT RELATED/OTHER: Legionella bacteria	2	110	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	12OCT2020 (1)	12OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	12OCT2020 (1)	12OCT2020 (1)	SERUM	NEGATIVE
Visit 2	02NOV2020 (22)	02NOV2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 01JAN2021 (82)/ 31DEC2020 (81)/ 16JAN2021 (97)	NO		Chest discomfort
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	
	YES	DIARRHEA	
	NO		Fatigue
	YES	NEW OR INCREASED COUGH	
	YES	CHILLS	
	NO		Headache
COVID Illness Visit 2 / 23FEB2021 (135)/ 19FEB2021 (131)/ ONGOING	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	FEVER	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	01JAN2021 (82)	COVID-19	03JAN2021 (84)	2	COVID-19
COVID Illness Visit 2	23FEB2021 (135)	Pneumonia	23FEB2021 (135)	3	Pneumonia

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	01JAN2021 (82)	01JAN2021 (82)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	01JAN2021 (82)	03JAN2021 (84)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 2	23FEB2021 (135)	23FEB2021 (135)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	CLIA certified lab
2	NEGATIVE		ABBOTT DIAGNOSTICS ID NOW COVID-19	

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	01JAN2021 (82)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA
COVID Illness Visit 2	23FEB2021 (135)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		EMERGENCY ROOM	YES	1	NA
		URGENT CARE	YES	1	NA

Hospitalization Details					
Visit	**Visit Date (Study Day)**	**Hospitalization Category**	**Hospitalization Term**	**Admission Date (Study Day)**	**Discharge Date or Ongoing (Study Day)**
COVID Illness Visit 1	01JAN2021 (82)	HOSPITALIZATION STATUS	HOSPITAL	11JAN2021 (92)	12JAN2021 (93)
COVID Illness Visit 2	23FEB2021 (135)	HOSPITALIZATION STATUS	HOSPITAL	23FEB2021 (135)	26FEB2021 (138)

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry							
Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	01JAN2021 (82)	11JAN2021 (92)	Alkaline Phosphatase	0.8	ukat/L	0.58	2.25
			Alanine Aminotransferase	0.26672	ukat/L	0.1667	1.0002
			Bilirubin	10.3	umol/L	0	20.5
			Creatinine	61	umol/L	53	106.1
			C Reactive Protein	160	mg/L	0	4.9
			Urea Nitrogen	5	mmol/L	2.86	9.28
		12JAN2021 (93)	Creatinine	54.8	umol/L	53	106.1
			Urea Nitrogen	6.78	mmol/L	2.86	9.28
COVID Illness Visit 2	23FEB2021 (135)	23FEB2021 (135)	Creatinine	106.1	umol/L	53	106.1
			Urea Nitrogen	6.78	mmol/L	2.86	9.28

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	01JAN2021 (82)	11JAN2021 (92)	Basophils	0	10^9/L	0	0.2
			Eosinophils	0	10^9/L	0.03	0.45
			Hematocrit	0.37	L/L	0.36	0.46
			Hemoglobin	12.4	g/L	12	15.2
			Lymphocytes	11	10^9/L	1	4
			Monocytes	8	10^9/L	0.2	0.9
			Neutrophils	81	10^9/L	1.8	7.7
			Platelets	319	10^9/L	140	375
			Erythrocytes	4.31	10^12/L	3	5.2
			Leukocytes	5.3	10^9/L	3.6	10.5
COVID Illness Visit 2	23FEB2021 (135)	23FEB2021 (135)	Basophils	0	10^9/L	0	0.2
			Eosinophils	0	10^9/L	0.03	0.45
			Hematocrit	0.38	L/L	0.36	0.46
			Hemoglobin	12.6	g/L	12	15.2
			Lymphocytes	0.6	10^9/L	0.2	0.9
			Monocytes	0.7	10^9/L	0.2	0.9
			Neutrophils	14.9	10^9/L	1.8	7.7
			Platelets	372	10^9/L	140	375
			Erythrocytes	4.31	10^12/L	3.8	5.2
			Leukocytes	16.2	10^9/L	3.6	5.2

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	01JAN2021 (82)	11JAN2021 (92)	1	134 mmHg	70 mmHg	24 breaths/min	104 beats/min	93 %
		12JAN2021 (93)	2	127 mmHg	68 mmHg	20 breaths/min	87 beats/min	99 %
COVID Illness Visit 2	23FEB2021 (135)	23FEB2021 (135)	3	103 mmHg	91 mmHg	19 breaths/min	127 beats/min	98 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify
1	COVID Illness Visit 1	01JAN2021 (82)	11JAN2021	CHEST	
2	COVID Illness Visit 1	01JAN2021 (82)	11JAN2021	CHEST	
3	COVID Illness Visit 2	23FEB2021 (135)	23FEB2021	CHEST	

Imaging				
Assessment Number	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	CT SCAN	NA	NORMAL	
2	X-RAY	NA	ABNORMAL	Patchy left bibasilar airspace disease consistent with pneumonia
3	X-RAY	NA	ABNORMAL	left lower lobe pneumonia

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12OCT2020	
Completed	VACCINATION	30NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1007 10071306, a 58-year-old white female with a height of 170.2 cm, a weight of 93.3 kg, and a BMI of 32.2 kg/m^2, received Dose 1 on 12 Oct 2020 and Dose 2 on 02 Nov 2020 (Day 22). The subject had a reported medical history of seasonal allergy (since 1992), hysterectomy and salpingo-oophorectomy unilateral (both in 2003), obesity (since 2003), and asthma (since 06 Jan 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1.

Narrative Comment
On 03 Jan 2021 (Day 84), the subject was diagnosed with severe COVID-19 and reported chest discomfort, new or increased shortness of breath, new or increased sore throat, diarrhea, fatigue, new or increased cough, chills, and headache, with the first symptom starting on 31 Dec 2020, 59 days after receiving Dose 2, and the last symptom resolved on 16 Jan 2021. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 01 Jan 2021 (Day 82) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 03 Jan 2021 (Day 84) was positive. The subject had an urgent care visit (once). On 11 Jan 2021 (Day 92), the subject had a heart rate of 104 beats/min, blood pressure of 134/70 mmHg, respiratory rate of 24 breaths/min, and oxygen saturation of 93%. On 12 Jan 2021 (Day 93), the subject had a heart rate of 87 beats/min, blood pressure of 127/68 mmHg, respiratory rate of 20 breaths/min, and oxygen saturation of 99%. On 11 Jan 2021 (Day 92), a chest radiograph revealed patchy left bibasilar airspace disease consistent with pneumonia, and a computed tomography scan of the chest was normal. The subject was hospitalized on 11 Jan 2021 (Day 92) for 2 days and discharged on 12 Jan 2021 (Day 93). On 11 Jan 2021 (Day 92), the subject's laboratory test results showed elevated C-reactive protein of 160 mg/L (normal range [NR]: 0-4.9 mg/L), lymphocytes of 11 × 10^9/L (NR: 1-4 × 10^9/L), neutrophils of 81 × 10^9/L (NR: 1.8-7.7 × 10^9/L), and monocytes of 8 × 10^9/L (NR: 0.2-0.9 × 10^9/L); decreased eosinophils of 0 × 10^9/L (NR: 0.03-0.45 × 10^9/L); and alkaline phosphatase, alanine aminotransferase, bilirubin, creatinine, blood urea nitrogen, basophils, hematocrit, hemoglobin, platelets, leukocytes, and erythrocytes all within normal limits. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and oxygen saturation ≤93%). On 19 Feb 2021 (Day 131), the subject reported fever of 102.6°F, moderate cough, and moderate shortness of breath starting on 19 Feb 2021 (Day 131). On 20 Feb 2021 (Day 132), the subject visited a local urgent care center. She was tested for COVID-19 (rapid antigen test) and influenza, which were both negative. She was diagnosed with an upper respiratory infection and was started on amoxicillin orally and salbutamol (Albuterol) inhaler as needed. On 23 Feb 2021 (Day 135), the subject was seen at the emergency department for continued fever, cough, and increasing shortness of breath. Her physical examination was significant for decreased breath sounds in the left lower lobe of her lungs. She was tachycardic (heart rate of 127 beats/min), with oxygen saturation of 92% to 97% on 2 to 4 liters of oxygen. Blood pressure was 103/91 mmHg and respiratory rate was 19 breaths/min. The subject's laboratory results showed elevated white blood cell count: 16.2 × 10^9/L (normal range [NR]: 3.6-10.5 × 10^9/L), red blood cell count: 4.31 × 10^{12}/L (NR: 3.80-5.20 × 10^{12}/L), hemoglobin: 12.5 g/dL (NR: 12.0-15.2 g/dL), hematocrit: 37.8% (NR: 36%-46%), platelets: 372 × 10^9/L (NR: 140-375 × 10^9/L), neutrophils: 14.9 × 10^9/L (NR: 1.80-7.70 × 10^9/L), lymphocytes: 0.60 × 10^9/L (NR: 1.00-4.00 × 10^9/L), monocytes: 0.7 × 10^9/L (NR: 0.20-0.90 × 10^9/L), eosinophils: 0.00 × 10^9/L (NR: 0.03-0.45 × 10^9/L), basophils: 0.00 × 10^9/L (NR: 0.00-0.20 × 10^9/L), and elevated procalcitonin: 1.15 ng/mL (NR: less than 0.10 ng/mL); a COVID-19 test (Abbott ID NOW assay using isothermal nucleic acid amplification technology) was negative. A chest x-ray and computerized tomogram (CT) angiogram were consistent with left lower lobe pneumonia. The chest CT angiogram showed no evidence of pulmonary embolism; dense left lower lobe infiltrate with air bronchograms consistent with pneumonia, suspicious for acute bacterial pneumonia; and small mediastinal and left hilar lymph nodes, suggesting reactive nodes. An electrocardiogram (ECG) showed sinus tachycardia with nonspecific T-wave inversion in the lateral leads. On 23 Feb 2021

Narrative Comment
(Day 135), the subject was hospitalized with the diagnosis of left lower lobe pneumonia (attributed to Legionella during hospitalization) and sepsis (unspecified with no growth on blood culture). On 25 Feb 2021 (Day 137), a urine Legionella antigen test was positive. The subject received intravenous vancomycin and cefepime with rapid improvement after being transitioned to oral levofloxacin (Levaquin). On 26 Feb 2021 (Day 138), the subject was discharged with no oxygen requirement, no fever, and improving shortness of breath. She was discharged on levofloxacin (Levaquin) 750 mg for 8 days, prednisone 40 mg daily for 3 days, and salbutamol (Albuterol) metered-dose inhaler (MDI) every 4 hours as needed. She was scheduled to undergo an outpatient chest x-ray in approximately 6 weeks to ensure resolution of the pneumonia. On 04 Mar 2021 (Day 144), the subject remained at home, with improving shortness of breath and cough and oxygen saturation ≥95% on room air. On 09 Mar 2021 (Day 149), the subject was seen by her primary care physician for follow-up from her hospitalization. Her sepsis resolved on 06 Mar 2021 (Day 146), with the completion of the oral levofloxacin on 06 Mar 2021 (Day 146). She remained afebrile. Her respiratory status improved with physical examination findings of normal breath sounds and no wheezing, rhonchi, or rales. Her cough resolved, but she reported continued mild shortness of breath with exertion and continued to use the albuterol MDI 3 times daily.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	51	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	102.64 kg	37.6 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OBESITY	Obesity	1990	Present
HYPOTHYROIDISM	Hypothyroidism	1998	Present
Back Pain	Back pain	2016	Present
Eczema	Eczema	JAN2016	Present
Erectile Dysfunction	Erectile dysfunction	30AUG2016	Present
SEASONAL ALLERGIES	Seasonal allergy	2018	Present
HYPERTENSION	Hypertension	2019	Present
PENICILLIN ALLERGY-HIVES	Urticaria	JAN2019	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
KEFLEX ALLERGY-HIVES	Urticaria	JAN2019	Present
GASTRIC BYPASS	Gastric bypass	JUN2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	11:09
2	Placebo	16SEP2020 (20)	10:48
3	BNT162b2	10MAR2021 (195)	11:08

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	28AUG2020 (1)	28AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	28AUG2020 (1)	28AUG2020 (1)	SERUM	NEGATIVE
Visit 2	16SEP2020 (20)	16SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 19OCT2020 (53)/ 15OCT2020 (49)/ 24FEB2021 (181)	NO		Tongue dry
	NO		Tachycardia
	NO		Productive cough
	NO		Palpitations
	YES	NEW OR INCREASED SORE THROAT	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED COUGH	
	YES	NEW LOSS OF TASTE OR SMELL	
	NO		Dizziness
	NO		Chest pain
	YES	CHILLS	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	19OCT2020 (53)	COVID-19	16OCT2020 (50)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	19OCT2020 (53)	20OCT2020 (54)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	19OCT2020 (53)	16OCT2020 (50)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		LABCORP COVID-19 RT-PCR TEST	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	19OCT2020 (53)	OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	19OCT2020 (53)	21NOV2020 (86)	Basophils	0.8	%	0	2
			Eosinophils	3.1	%	0	5
			Hematocrit	0.46	L/L	0.41	0.53
			Hemoglobin	162	g/L	135	175
			Lymphocytes	2.8	10^9/L	1.2	3.4
			Monocytes	5.9	%	2	12
			Neutrophils	4.7	10^9/L	1.8	6.8
			Platelets	204	10^9/L	150	400
			Erythrocytes	4.83	10^12/L	4.5	5.9
			Leukocytes	8.3	10^9/L	3.6	10.6

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	19OCT2020 (53)	21NOV2020 (86)	1					90 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	10MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1009 10091128, a 51-year-old white male with a height of 165.1 cm, a weight of 102.64 kg, and a BMI of 37.6 kg/m2, received Dose 1 on 28 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 20). The subject had a reported medical history of obesity (since 1990); hypothyroidism (since 1998); back pain (since 2016); eczema (since Jan 2016); erectile dysfunction (since 30 Aug 2016); seasonal allergy (since 2018); hypertension (since 2019); urticaria (Keflex allergy - hives, and penicillin allergy - hives, since Jan 2019); and gastric bypass (in Jun 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 16 Oct 2020 (Day 50), the subject was diagnosed with severe COVID-19 and reported dry tongue, tachycardia, productive cough, palpitations, new or increased sore throat, new or increased shortness of breath, new or increased muscle pain, new or increased cough, new loss of taste or smell, dizziness, chest pain, and chills, with the first symptom starting on 15 Oct 2020, 29 days after receiving Dose 2, and the last symptom resolved on 24 Feb 2021. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 20 Oct 2020 (Day 54) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 16 Oct 2020 (Day 50) was positive. The subject went to his primary care physician (once) and went to the emergency room (once). On 21 Nov 2020 (Day 86), the subject had an oxygen saturation of 90% on room air. On 21 Nov 2020 (Day 86), the subject's laboratory test results showed neutrophils, basophils, eosinophils, hematocrit, hemoglobin, lymphocytes, monocytes, platelets, erythrocytes, and leukocytes within normal limits. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and oxygen saturation ⩽93%). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first dose of BNT162b2 on 10 Mar 2021 (Day 195) and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	111.73 kg	36.3 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic Pain Syndrome	Pain	1992	Present
Lumbar Vertebral Fusion	Spinal fusion surgery	1995	Past
Facet Arthroplasty, cervical	Facet joint syndrome	1996	Past
Lumbar Radiculopathy	Lumbar radiculopathy	1996	Present
Severe Obesity	Obesity	2000	Present
Type 2 Diabetes Mellitus	Type 2 diabetes mellitus	2001	Present
Hyperlipidemia	Hyperlipidaemia	2002	Present
Diabetic Neuropathy	Diabetic neuropathy	2010	Present
Hypertension	Hypertension	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Insomnia	Insomnia	2010	Present
Osteoarthritis,multiple sites	Osteoarthritis	2014	Present
Right Knee Replacement	Knee arthroplasty	2018	Past
Left Knee Replacemnent	Knee arthroplasty	DEC2019	Past
Right Hand Trigger Finger	Trigger finger	FEB2020	Present
Left Hand Trigger Finger	Trigger finger	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	16:49
2	Placebo	18SEP2020 (23)	14:36
3	BNT162b2	25JAN2021 (152)	14:11
4	BNT162b2	17FEB2021 (175)	14:50

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	27AUG2020 (1)	27AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	27AUG2020 (1)	27AUG2020 (1)	SERUM	NEGATIVE
Visit 2	18SEP2020 (23)	18SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09NOV2020 (75)/ 07NOV2020 (73)/ 25NOV2020 (91)	NO		Chest discomfort
	YES	FEVER	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	09NOV2020 (75)	COVID-19	10NOV2020 (76)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	09NOV2020 (75)	09NOV2020 (75)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	09NOV2020 (75)	10NOV2020 (76)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	Hologic Aptima SARS-CoV-2 assay

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	09NOV2020 (75)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details					
Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	09NOV2020 (75)	HOSPITALIZATION STATUS	ICU	17NOV2020 (83)	22NOV2020 (88)

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	09NOV2020 (75)	18NOV2020 (84)	Alkaline Phosphatase	0.93	ukat/L	0.65	1.95
			Alanine Aminotransferase	0.23338	ukat/L	0	0.6668
			Aspartate Aminotransferase	0.35007	ukat/L	0	0.65013
			Bilirubin	6.8	umol/L	5.1	20.5
			Creatinine	75.1	umol/L	44.2	119.3
			Urea Nitrogen	7.5	mmol/L	2.14	8.21

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	09NOV2020 (75)	18NOV2020 (84)	Basophils	0	10^9/L	0	0
			Eosinophils	0	10^9/L	0	0.001
			Hematocrit	0.38	L/L	0.41	0.51
			Hemoglobin	126	g/L	139	168
			Lymphocytes	0.001	10^9/L	0.001	0.004
			Monocytes	0	10^9/L	0	0.001
			Neutrophils	0.004	10^9/L	0.002	0.008
			Platelets	0.17	10^9/L	0.15	0.4
			Erythrocytes	4.24	10^12/L	4.22	5.81
			Leukocytes	0.01	10^9/L	0	0.01

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	09NOV2020 (75)	17NOV2020 (83)	1					97 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging						
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam
1	COVID Illness Visit 1	09NOV2020 (75)	17NOV2020	CHEST		X-RAY

Imaging			
Assessment Number	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	NA	ABNORMAL	pneumonia due to COVID-19 virus:Lung opacities most noticeable in the Right Upper Lobe

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	20OCT2020	
Completed	REPEAT SCREENING 1	25JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1038 10381051, a 69-year-old white male with a height of 175.26 cm, a weight of 111.73 kg, and a BMI of 36.3 kg/m2, received Dose 1 on 27 Aug 2020 and Dose 2 on 18 Sep 2020 (Day 23). The subject had a reported medical history of pain (since 1992); spinal fusion surgery (in 1995); facet joint syndrome (in 1996); lumbar radiculopathy (since 1996); obesity (since 2000); type 2 diabetes mellitus (since 2001); hyperlipidemia (since 2002); diabetic neuropathy, hypertension, and insomnia (all since 2010); osteoarthritis (since 2014); knee arthroplasty (right knee replacement in 2018, left knee replacement in Dec 2019); and trigger finger (both left and right hand trigger finger, since Feb 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 10 Nov 2020 (Day 76), the subject was diagnosed with severe COVID-19 and reported chest discomfort, fever, new or increased shortness of breath, new or increased sore throat, and new or increased cough, with the first symptom starting on 07 Nov 2020, 50 days after receiving Dose 2, and the last symptom resolved on 25 Nov 2020. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 09 Nov 2020 (Day 75) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 10 Nov 2020 (Day 76) was positive. The subject had a telephone consultation (once) and went to the emergency room (once). On 17 Nov 2020 (Day 83), the subject had an oxygen saturation of 97%. On 17 Nov 2020 (Day 83), a chest radiograph revealed COVID-19 pneumonia with lung opacities most noticeable in the right upper lobe (abnormal). The subject was hospitalized on 17 Nov 2020 (Day 83) for 6 days and discharged on 22 Nov 2020 (Day 88). He was in the intensive care unit (ICU). On 18 Nov 2020 (Day 84), the subject's laboratory test results showed a decreased hematocrit of 38% (normal range [NR]: 41%-51%) and hemoglobin of 12.6 g/dL (NR: 13.9-16.8 g/dL); alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, bilirubin, creatinine, blood urea nitrogen, basophils, eosinophils, lymphocytes, monocytes, neutrophils, platelets, erythrocytes, and leukocytes were within normal limits. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and admission to an ICU). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 25 Jan 2021 (Day 152) and 17 Feb 2021 (Day 175), respectively, and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	111.36 kg	32.3 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
bilateral broken ankles	Ankle fracture	2010	Past
bilateral fused ankles	Arthrodesis	2010	Past
cholecystectomy	Cholecystectomy	2010	Past
gallstones	Cholelithiasis	2010	Past
rotator cuff repair (right)	Rotator cuff repair	2010	Past
torn rotator cuff (right)	Rotator cuff syndrome	2010	Past
diabetes type II	Type 2 diabetes mellitus	2010	Present
atrial fibrillation	Atrial fibrillation	2012	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ace inhibitor allergy	Drug hypersensitivity	2015	Present
left knee replacement	Knee arthroplasty	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21SEP2020 (1)	14:10
3	BNT162b2	10FEB2021 (143)	15:29
4	BNT162b2	01MAR2021 (162)	14:03

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	CARD	Acute coronary syndrome	acute coronary syndrome	25SEP2020 (5)	10:43	27SEP2020 (7)		3	2	TC/TCN
2	CARD	Bundle branch block left	left bundle branch block	25SEP2020 (5)	10:43	27SEP2020 (7)		3	2	TC/TCN

Adverse Events					
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (27SEP2020)	NOT RELATED/OTHER: history of diabetes type 2 and atrial fibrillation	1	5	Y
2	N	Resolved (27SEP2020)	NOT RELATED/OTHER: history of diabetes type 2 and atrial fibrllation	1	5	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21SEP2020 (1)	21SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21SEP2020 (1)	21SEP2020 (1)	SERUM	NEGATIVE
Visit 2	13NOV2020 (54)	13NOV2020 (54)	NASAL_SWAB	POSITIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 14OCT2020 (24)/ 12OCT2020 (22)/ 15NOV2020 (56)	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED COUGH	
	NO		Headache
	YES	FEVER	
	YES	DIARRHEA	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	14OCT2020 (24)	Covid-19	14OCT2020 (24)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	14OCT2020 (24)	14OCT2020 (24)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	14OCT2020 (24)	SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		OTHER	YES	1	Covid Test Center/Regional hospital

Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	14OCT2020 (24)	HOSPITALIZATION STATUS	HOSPITAL	16OCT2020 (26)	20OCT2020 (30)

Respiratory Treatment

Visit	Visit Date (Study Day)	Treatment Identifier	Prespecified Concomitant Nondrug Treatment	Treatment	Start Date (Study Day)	End Date or Ongoing (Study Day)
COVID Illness Visit 1	14OCT2020 (24)	1	YES	HIGH FLOW OXYGEN THERAPY	16OCT2020 (26)	ONGOING

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	14OCT2020 (24)	16OCT2020 (26)	Creatinine	114.9	umol/L	61.9	106.1
			Urea Nitrogen	10	mmol/L	2.86	8.21
		17OCT2020 (27)	Alkaline Phosphatase	1.22	ukat/L	0.65	2.84
			Alanine Aminotransferase	0.5001	ukat/L	0.65013	0.65013
			Aspartate Aminotransferase	0.86684	ukat/L	0.70014	0.70014
			Bilirubin	6.8	umol/L	17.1	17.1
			Creatinine	114.9	umol/L	61.9	106.1
			C Reactive Protein	1.1	mg/L	0.5	0.5
			Urea Nitrogen	10.71	mmol/L	2.86	8.21
		18OCT2020 (28)	Alkaline Phosphatase	1.2	ukat/L	0.65	1.95
			Alanine Aminotransferase	0.63346	ukat/L	0.70014	0.70014
			Aspartate Aminotransferase	0.3334	ukat/L	0.65013	0.65013
			Bilirubin	5.1	umol/L	17.1	17.1
			Creatinine	88.4	umol/L	61.9	106.1
			Urea Nitrogen	8.57	mmol/L	2.86	8.21
		19OCT2020 (29)	Alkaline Phosphatase	1.12	ukat/L	0.48	1.95
			Alanine Aminotransferase	0.51677	ukat/L	0.70014	0.70014
			Aspartate Aminotransferase	0.28339	ukat/L	0.65013	0.65013
			Bilirubin	5.1	umol/L	17.1	17.1
			Creatinine	70.7	umol/L	61.9	106.1
			Urea Nitrogen	10.36	mmol/L	1.79	10
		23OCT2020 (33)	Alkaline Phosphatase	1.08	ukat/L	0.65	1.95
			Alanine Aminotransferase	0.55011	ukat/L	0.70014	0.70014
			Aspartate Aminotransferase	0.35007	ukat/L	0.65013	0.65013
			Bilirubin	5.1	umol/L	17.1	17.1

Laboratory Results - Clinical Chemistry							
Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
			Creatinine	79.6	umol/L	61.9	106.1
			Urea Nitrogen	8.93	mmol/L	7.86	10.36

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	14OCT2020 (24)	16OCT2020 (26)	Basophils	0	10^9/L	0	0.01
			Eosinophils	0	10^9/L	0	0.5
			Hematocrit	0.44	L/L	0.38	0.49
			Hemoglobin	154	g/L	122	167
			Lymphocytes	1.21	10^9/L	1.1	3.4
			Monocytes	0.48	10^9/L	0.3	1.1
			Neutrophils	2.94	10^9/L	1.5	7.9
			Platelets	160	10^9/L	137	352
			Erythrocytes	5.27	10^12/L	4.4	5.5
			Leukocytes	4.63	10^9/L	4.1	12.2
		18OCT2020 (28)	Basophils	0.01	10^9/L	0	0.3
			Eosinophils	0	10^9/L	0	0.5
			Hematocrit	0.37	L/L	0.38	0.49
			Hemoglobin	129	g/L	122	167
			Lymphocytes	1.58	10^9/L	1.1	3.4
			Monocytes	0.45	10^9/L	0.3	1.1
			Neutrophils	2.39	10^9/L	1.5	7.9
			Platelets	165	10^9/L	137	352
			Erythrocytes	4.34	10^12/L	4.4	5.5
			Leukocytes	4.45	10^9/L	4.1	12.2
		19OCT2020 (29)	Basophils	0	10^9/L	0	0.3
			Eosinophils	0	10^9/L	0	0.5
			Hematocrit	0.37	L/L	0.38	0.49
			Hemoglobin	131	g/L	122	167
			Lymphocytes	2.94	10^9/L	1.5	7.9

Laboratory Results - Hematology							
Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
			Monocytes	0.48	10^9/L	0.3	1.1
			Neutrophils	12.5	10^9/L	1.5	7.9
			Platelets	160	10^9/L	137	352
			Erythrocytes	4.31	10^12/L	4.4	5.5
			Leukocytes	4.63	10^9/L	4.1	12.2
		20OCT2020 (30)	Basophils	0.02	10^9/L	0	0.5
			Eosinophils	0	10^9/L	0	0.5
			Hematocrit	0.37	L/L	0.38	0.49
			Hemoglobin	131	g/L	122	167
			Lymphocytes	1.86	10^9/L	1.1	3.4
			Monocytes	0.44	10^9/L	0.3	1.1
			Neutrophils	3.35	10^9/L	1.5	7.9
			Platelets	172	10^9/L	137	352
			Erythrocytes	4.36	10^12/L	4.4	5.5
			Leukocytes	5.8	10^9/L	4.1	12.2

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	14OCT2020 (24)	16OCT2020 (26)	1					80 %
		18OCT2020 (28)	2	130 mmHg	72 mmHg		47 beats/min	
		19OCT2020 (29)	3					95 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment
1	COVID Illness Visit 1	14OCT2020 (24)	16OCT2020	CHEST		CT SCAN	NA	ABNORMAL

Imaging	
Assessment Number	**If Abnormal, Specify Findings**
1	Lungs: Multifocal ground glass opacities scattered throughout the lungs bilaterally. No Pleura effusions. Extensive coronary atherosclerotic classifications. Normal thickness of the Pericardium.

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Withdrawn	VACCINATION	12OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
Completed	REPEAT SCREENING 1	10FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1047 10471252, a 63-year-old white male with a height of 185.42 cm, a weight of 111.36 kg, and a BMI of 32.3 kg/m^2, received Dose 1 on 21 Sep 2020. The subject had a reported medical history of ankle fracture, arthrodesis, cholelithiasis, cholecystectomy, right rotator cuff syndrome, and right rotator cuff repair (all in 2010); type 2 diabetes mellitus (since 2010); atrial fibrillation (since 2012); knee arthroplasty (in 2015); and drug hypersensitivity (angiotensin-converting enzyme [ACE] inhibitor allergy, since 2015). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and positive at Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 25 Sep 2020 (Day 5), the subject presented to the emergency room with persistent chest pain. An electrocardiogram (ECG) on that same day showed sinus rhythm with first-degree atrioventricular block, and a new left bundle branch block; ventricular rate was 63 beats/min, RR interval was 948, PR interval was 250, QRS duration was 152,

Narrative Comment
corrected QT interval (QTc) was 450, P-axis was 15, T-axis was 84, QRS axis was -29, corrected QT inverval (Bazett) (QTcB) was 450, and corrected QT inverval (Fridericia) (QTcF) was 447 (normal ranges [NRs] and units not provided). Troponin was elevated (80 ng/L [NR: <20 ng/L]) and a coronary angiogram revealed 100% thrombotic occlusion of the proximal right coronary artery. The subject was diagnosed with acute coronary syndrome and left bundle branch block on that same day (Day 5) and was subsequently hospitalized. He underwent a percutaneous coronary intervention with stent placement in the right coronary artery. He was started on antiplatelet therapy, the atorvastatin dose was increased to 40 mg at night, and metoprolol was started. A SARS-CoV-2 test was negative and a chest radiograph showed no acute cardiopulmonary process. On 27 Sep 2020 (Day 7), a repeat troponin level was high at 177 ng/L. On the same day (Day 7), the acute coronary syndrome and left bundle branch block were considered resolved and the subject was discharged from the hospital. On 14 Oct 2020 (Day 24), the subject was diagnosed with severe COVID-19 and reported new or increased shortness of breath, new or increased muscle pain, new or increased cough, headache, fever, and diarrhea, with the first symptom starting on 12 Oct 2020, 21 days after receiving Dose 1, and the last symptom resolved on 15 Nov 2020. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 14 Oct 2020 (Day 24) was positive. The Quidel Sofia 2 SARS antigen fluorescent immunoassay (done at a local hospital) result at the time of the COVID-19 illness on 14 Oct 2020 (Day 24) was positive. The subject went to the emergency room (once), went to his primary care physician (once), and visited a COVID-19 test center/regional hospital (once). The subject was hospitalized on 16 Oct 2020 (Day 26) for 5 days and discharged on 20 Oct 2020 (Day 30). On 16 Oct 2020 (Day 26), the subject had an oxygen saturation of 80% and required high-flow oxygen therapy. On 18 Oct 2020 (Day 28), he had a heart rate of 47 beats/min and blood pressure of 130/72 mmHg. On 19 Oct 2020 (Day 29), the subject had an oxygen saturation of 95%. On 16 Oct 2020 (Day 26), the laboratory test results showed elevated creatinine of 114.9 µmol/L (NR: 61.9-106.1 µmol/L) and blood urea nitrogen (BUN) of 10 mmol/L (NR: 2.86-8.21 mmol/L); basophils, eosinophils, hematocrit, hemoglobin, lymphocytes, monocytes, neutrophils, platelets, erythrocytes, and leukocytes were within normal limits. On 17 Oct 2020 (Day 27), the laboratory test results showed elevated aspartate aminotransferase (AST) of 0.86684 µkat/L (NR: <0.70014 µkat/L), creatinine of 114.9 µmol/L, C-reactive protein of 1.1 mg/L (NR: <0.5 mg/L), and BUN of 10.71 mmol/L; alanine aminotransferase (ALT), bilirubin, and alkaline phosphatase (ALP) were within normal limits. On 18 Oct 2020 (Day 28), the laboratory test results showed elevated BUN of 8.57 mmol/L; low erythrocytes of 4.34×10^{12}/L (NR: $4.4\text{-}5.5 \times 10^{12}$/L), and hematocrit of 36.7% (NR: 38.2-49.2%); ALT, AST, bilirubin, ALP, creatinine, basophils, eosinophils, hemoglobin, lymphocytes, monocytes, neutrophils, platelets, and leukocytes were within normal limits. On 19 Oct 2020 (Day 29), the laboratory test results showed elevated BUN of 10.36 mmol/L (NR: 1.79-10 mmol/L), neutrophils of 12.5×10^{9}/L (NR: $1.5\text{-}7.9 \times 10^{9}$/L); low hematocrit of 37%, and erythrocytes of 4.31×10^{12}/L; ALT, AST, bilirubin, ALP, creatinine, basophils, eosinophils, hemoglobin, lymphocytes, monocytes, platelets, and leukocytes were within normal limits. On 20 Oct 2020 (Day 30), the laboratory test results showed low hematocrit of 37.1% and erythrocytes of 4.36×10^{12}/L; basophils, eosinophils, hemoglobin, lymphocytes, monocytes, neutrophils, platelets, and leukocytes were within normal limits. On 23 Oct 2020 (Day 33), the ALT, AST, bilirubin, ALP, creatinine, and BUN were all within normal limits.

Narrative Comment
On 16 Oct 2020 (Day 26), a computed tomography scan of the chest showed multifocal ground-glass opacities scattered throughout the lungs bilaterally; no pleural effusions; and extensive coronary atherosclerotic calcifications with normal thickness of the pericardium. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19, oxygen saturation ≤93%, and requirement for high-flow oxygen therapy). The subject was discontinued from the study intervention on 12 Oct 2020 since he no longer met the eligibility criteria. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 10 Feb 2021 (Day 143) and 01 Mar 2021 (Day 162), respectively, and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	76.36 kg	28.8 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bilateral tubal ligation	Female sterilisation	1983	Past
Uterine Ablation	Endometrial ablation	2004	Past
Menorrhagia	Menorrhagia	2004	Past
Depression	Depression	2005	Present
Mild Hypertension	Hypertension	2005	Present
Brain Arteriovenous Malformation	Cerebrovascular arteriovenous malformation	2008	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	13:50
2	Placebo	07OCT2020 (45)	12:34
3	BNT162b2	20FEB2021 (181)	11:36
4	BNT162b2	11MAR2021 (200)	12:25

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccine	INFLUENZA VACCINE	08SEP2020
Shingrix	VARICELLA ZOSTER VACCINE RGE (CHO)	08SEP2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	24AUG2020 (1)	24AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	24AUG2020 (1)	24AUG2020 (1)	SERUM	NEGATIVE
Visit 2	09SEP2020 (17)	07OCT2020 (45)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 21DEC2020 (120)/ 18DEC2020 (117)/ 02JAN2021 (132)	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW LOSS OF TASTE OR SMELL	
	NO		Fatigue
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	21DEC2020 (120)	COVID-19 pneumonia	27DEC2020 (126)	3	COVID-19 pneumonia

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	21DEC2020 (120)	21DEC2020 (120)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	21DEC2020 (120)	27DEC2020 (126)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ABBOTT MOLECULAR REALTIME SARS-COV-2 ASSAY	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	21DEC2020 (120)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	21DEC2020 (120)	HOSPITALIZATION STATUS	HOSPITAL	27DEC2020 (126)	02JAN2021 (132)

Respiratory Treatment

Visit	Visit Date (Study Day)	Treatment Identifier	Prespecified Concomitant Nondrug Treatment	Treatment	Start Date (Study Day)	End Date or Ongoing (Study Day)
COVID Illness Visit 1	21DEC2020 (120)	1	YES	HIGH FLOW OXYGEN THERAPY	27DEC2020 (126)	ONGOING

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	21DEC2020 (120)	27DEC2020 (126)	Alkaline Phosphatase	2.23	ukat/L	0.88	2.35
			Alanine Aminotransferase	0.48343	ukat/L	0.11669	0.93352
			Aspartate Aminotransferase	0.60012	ukat/L	0.08335	0.6668
			Bilirubin	5.1	umol/L	0	6.8
			Creatinine	79.6	umol/L	44.2	88.4
			C Reactive Protein	54	mg/L	30	100
			Urea Nitrogen	5.71	mmol/L	1.79	10

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	21DEC2020 (120)	27DEC2020 (126)	Basophils	0	10^9/L	0	0.3
			Eosinophils	0	10^9/L	0	0.5
			Hematocrit	0.38	L/L	0.35	0.44
			Hemoglobin	129	g/L	115	147
			Lymphocytes	13.1	10^9/L	0.8	5
			Monocytes	0.29	10^9/L	0.3	1.1
			Neutrophils	2.68	10^9/L	1.5	7.9
			Platelets	121	10^9/L	137	353
			Erythrocytes	4.39	10^12/L	4	4.9
			Leukocytes	3.4	10^9/L	4.1	12.2

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	21DEC2020 (120)	29DEC2020 (128)	1					97 %

Oxygenation Parameters				
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Arterial Blood Gases PaO2 (mmHg)	FiO2 (Fraction of Inhaled Oxygen)
COVID Illness Visit 1	21DEC2020 (120)	27DEC2020 (126)	23	

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging						
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam
1	COVID Illness Visit 1	21DEC2020 (120)	27DEC2020	CHEST		X-RAY
2	COVID Illness Visit 1	21DEC2020 (120)	27DEC2020	CHEST		CT SCAN

Imaging			
Assessment Number	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	NA	ABNORMAL	bilateral airspace disease, most compatible with multifocal pneumonia.
2	NA	ABNORMAL	moderate mixed groundglass and airspace opacities consistent with a COVID pneumonia

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	06NOV2020	
Completed	REPEAT SCREENING 1	20FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1072 10721037, a 71-year-old white female with a height of 162.56 cm, a weight of 76.36 kg, and a BMI of 28.8 kg/m2, received Dose 1 on 24 Aug 2020 and Dose 2 on 07 Oct 2020 (Day 45). The subject had a reported medical history of female sterilization (in 1983); endometrial ablation and menorrhagia (both in 2004); depression and hypertension (both since 2005); and cerebrovascular arteriovenous malformation (since 2008). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 27 Dec 2020 (Day 126), the subject was diagnosed with severe COVID-19 pneumonia and reported new or increased shortness of breath, new loss of taste or smell, fatigue, fever, and new or increased cough, with the first symptom starting on 18 Dec 2020, 72 days after receiving Dose 2, and the last symptom resolved on 02 Jan 2021. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 21 Dec 2020 (Day 120) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 27 Dec 2020 (Day 126) was positive. The subject went to the emergency room (once). The subject was hospitalized on 27 Dec 2020 (Day 126) for 7 days and discharged on 02 Jan 2021 (Day 132). The subject required high-flow oxygen therapy since 27 Dec 2020 (Day 126). On 27 Dec 2020 (Day 126), measurement of arterial blood gases revealed that the partial pressure of oxygen (PaO2) was 23 mmHg. On 27 Dec 2020 (Day 126), a chest radiograph revealed bilateral airspace disease, which was most compatible with multifocal pneumonia, and a computed tomography scan of the chest revealed moderate mixed ground-glass and airspace opacities, which were consistent with COVID-19 pneumonia. On 27 Dec 2020 (Day 126), the subject's laboratory test results showed elevated lymphocytes of 13.1× 109/L (normal range [NR]: 0.8-5.0 × 109/L); and low leukocytes of 3.4 × 109/L (NR: 4.1-12.2 × 109/L), monocytes of 0.29 × 109/L (NR: 0.3-1.1 × 109/L), and platelets of 121 × 109/L (NR: 137 - 353× 109/L); alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, bilirubin, creatinine, C-reactive protein, blood urea nitrogen, basophils, eosinophils, hematocrit, hemoglobin, neutrophils, and erythrocytes were within normal limits. On 29 Dec 2020 (Day 128), the subject had an oxygen saturation of 97%. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and requirement for high-flow oxygen therapy). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 20 Feb 2021 (Day 181) and 11 Mar 2021 (Day 200), respectively, and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
195.58 cm	85.45 kg	22.3 kg/m2	05SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ALLERGY TO PENICILLIN	Drug hypersensitivity	1980	Present
ALLERGY TO ASPIRIN	Drug hypersensitivity	1980	Present
CROHN'S DISEASE	Crohn's disease	01JAN2013	Present
MIGRAINE HEADACHES	Migraine	01JAN2015	Present
MUSCLE SPASMS 1	Muscle spasms	01JAN2015	Present
TACHYCARDIA	Tachycardia	01JAN2015	Present
VITAMIN B DEFICIENCY	Vitamin B complex deficiency	01JUN2015	Present
HASHIMOTO DISEASE	Autoimmune thyroiditis	01JAN2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	05SEP2020 (1)	14:04
2	Placebo	26SEP2020 (22)	12:46
3	BNT162b2	03FEB2021 (152)	11:41
4	BNT162b2	25FEB2021 (174)	10:20

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Syncope	Syncopal episode	29DEC2020 (116)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC	N	Yes	NOT RELATED/OTHER: COVID-19	2	95	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	05SEP2020 (1)	05SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	05SEP2020 (1)	05SEP2020 (1)	SERUM	NEGATIVE
Visit 2	26SEP2020 (22)	26SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 29DEC2020 (116)/ 27DEC2020 (114)/ 18JAN2021 (136)	NO		Syncope
	YES	NEW OR INCREASED SORE THROAT	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED COUGH	
	YES	FEVER	
	YES	CHILLS	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	29DEC2020 (116)	COVID-19	29DEC2020 (116)	3	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	29DEC2020 (116)	29DEC2020 (116)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	29DEC2020 (116)	29DEC2020 (116)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT Unknown

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	29DEC2020 (116)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details					
Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	29DEC2020 (116)	HOSPITALIZATION STATUS	HOSPITAL	29DEC2020 (116)	31DEC2020 (118)

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	29DEC2020 (116)	29DEC2020 (116)	Alkaline Phosphatase	1.38	ukat/L	0.77	1.93
			Alanine Aminotransferase	0.95019	ukat/L	0.23338	0.90018
			Aspartate Aminotransferase	1.06688	ukat/L	0.25005	0.61679
			Bilirubin	5.1	umol/L	3.4	17.1
			Creatinine	83.1	umol/L	38.9	88.4
			Urea Nitrogen	3.21	mmol/L	2.5	6.43

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	29DEC2020 (116)	29DEC2020 (116)	Hematocrit	0.38	L/L	0.34	0.44
			Hemoglobin	126	g/L	118	151
			Platelets	157	10^9/L	145	355

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	29DEC2020 (116)	29DEC2020 (116)	1	114 mmHg	55 mmHg	18 breaths/min	84 beats/min	95 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam
1	COVID Illness Visit 1	29DEC2020 (116)	29DEC2020	CHEST		X-RAY

Imaging			
Assessment Number	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	NA	ABNORMAL	Hazy right basilar opacities which may reflect atelectasis versus atypical/viral pneumonia

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	05SEP2020	
Completed	VACCINATION	24OCT2020	
Completed	REPEAT SCREENING 1	03FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091415, a 48-year-old white female with a height of 195.58 cm, a weight of 85.45 kg, and a BMI of 22.3 kg/m2, received Dose 1 on 05 Sep 2020 and Dose 2 on 26 Sep 2020 (Day 22). The subject had a reported medical history of drug hypersensitivity (allergy to aspirin and penicillin; since 1980), Crohn's disease (since 01 Jan 2013), migraine, muscle spasms, and tachycardia (all since 01 Jan 2015), vitamin B complex deficiency (since 01 Jun 2015), and autoimmune thyroiditis (since 01 Jan 2017). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 29 Dec 2020 (Day 116), the subject was diagnosed with severe COVID-19 and reported syncope, new or increased sore throat, new or increased shortness of breath, new or increased cough, fever, and chills, with the first symptom starting on 27 Dec 2020, 92 days after receiving Dose 2, and the last symptom resolved on 18 Jan 2021. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Dec 2020 (Day 116) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Dec 2020 (Day 116) was positive. The subject went to the emergency room (once). On 29 Dec 2020 (Day 116), the subject had a heart rate of 84 beats/min, blood pressure of 114/55 mmHg, respiratory rate of 18 breaths/min, and oxygen saturation of 95%. On 29 Dec 2020 (Day 116), a chest radiograph revealed hazy right basilar opacities, which might reflect atelectasis versus atypical/viral pneumonia. On 29 Dec 2020 (Day 116), the laboratory results showed elevated alanine aminotransferase of 0.95019 µkat/L (normal range [NR]: 0.23338-0.90018 µkat/L) and aspartate aminotransferase of 1.06688 µkat/L (NR: 0.25005-0.61679 µkat/L); alkaline phosphatase, bilirubin, creatinine, blood urea nitrogen, hematocrit, hemoglobin, and platelets were within normal limits. The subject was hospitalized on 29 Dec 2020 (Day 116) for 3 days and discharged on 31 Dec 2020 (Day 118). The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and presented evidence of shock: diastolic blood pressure <60 mmHg). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 03 Feb 2021 (Day 152) and 25 Feb 2021 (Day 174), respectively, and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	47	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	77.27 kg	23.7 kg/m2	12OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2005	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12OCT2020 (1)	17:33
2	Placebo	02NOV2020 (22)	13:42

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	11FEB2021 (123)	17:58
4	BNT162b2	03MAR2021 (143)	14:17

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	12OCT2020 (1)	12OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	12OCT2020 (1)	12OCT2020 (1)	SERUM	NEGATIVE
Visit 2	02NOV2020 (22)	02NOV2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 28NOV2020 (48)/ 28NOV2020 (48)/ 19DEC2020 (69)	NO		Sputum increased
	NO		Rhinorrhoea
	NO		Nausea
	NO		Nasal congestion
	YES	NEW OR INCREASED SORE THROAT	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED COUGH	
	YES	CHILLS	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	28NOV2020 (48)	Pneumonia	08DEC2020 (58)	3	Pneumonia

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	28NOV2020 (48)	29NOV2020 (49)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	28NOV2020 (48)	19DEC2020 (69)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	NEGATIVE		IPSUM COV-19 IDX ASSAY	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	28NOV2020 (48)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	28NOV2020 (48)	HOSPITALIZATION STATUS	HOSPITAL	08DEC2020 (58)	09DEC2020 (59)

Respiratory Treatment

Visit	Visit Date (Study Day)	Treatment Identifier	Prespecified Concomitant Nondrug Treatment	Treatment	Start Date (Study Day)	End Date or Ongoing (Study Day)
COVID Illness Visit 1	28NOV2020 (48)	1	YES	HIGH FLOW OXYGEN THERAPY	08DEC2020 (58)	09DEC2020 (59)

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry							
Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	28NOV2020 (48)	08DEC2020 (58)	Creatinine	93.7	umol/L	61.9	106.1
			Urea Nitrogen	7.86	mmol/L	2.14	7.14

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	28NOV2020 (48)	08DEC2020 (58)	Basophils	0.03	10^9/L	0	0.3
			Eosinophils	0.04	10^9/L	0.1	0.5
			Hematocrit	0.49	L/L	0.39	0.5
			Hemoglobin	173	g/L	135	175
			Lymphocytes	2.81	10^9/L	1.5	4
			Monocytes	0.83	10^9/L	0.3	0.9
			Neutrophils	4.86	10^9/L	1.7	7
			Platelets	197	10^9/L	150	450

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	28NOV2020 (48)	08DEC2020 (58)	1	120 mmHg	83 mmHg	27 breaths/min	77 beats/min	99 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging									
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 1	28NOV2020 (48)	08DEC2020	CHEST		X-RAY	NA	NORMAL	

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12OCT2020	
Completed	VACCINATION	04JAN2021	
Completed	REPEAT SCREENING 1	11FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1112 11121301, a 47-year-old white male with a height of 180.34 cm, a weight of 77.27 kg, and a BMI of 23.7 kg/m2, received Dose 1 on 12 Oct 2020 and Dose 2 on 02 Nov 2020 (Day 22). The subject had a reported medical history of hypertension (since 2005). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 08 Dec 2020 (Day 58), the subject was diagnosed with severe pneumonia and reported increased sputum, rhinorrhea, nausea, nasal congestion, new or increased sore throat, new or increased muscle pain, new or increased cough, and chills, with the first symptom starting on 28 Nov 2020, 26 days after receiving Dose 2, and the last symptom resolved on 19 Dec 2020. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Nov 2020 (Day 49) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 19 Dec 2020 (Day 69) was negative. The subject went to the emergency room (once). On 08 Dec 2020 (Day 58), the subject had a heart rate of 77 beats/min, blood pressure of 120/83 mmHg, respiratory rate of 27 breaths/min, and oxygen saturation of 99%. On 08 Dec 2020 (Day 58), a chest radiograph was normal. On 08 Dec 2020 (Day 58), the subject's laboratory results showed elevated blood urea nitrogen of 7.86 mmol/L (normal range [NR]: 2.14-7.14 mmol/L); low eosinophils of 0.04 × 109/L (NR: 0.1-0.5 × 109/L); and creatinine, basophils, hematocrit, hemoglobin, lymphocytes, monocytes, neutrophils, and platelets within normal limits. The subject was hospitalized on 08 Dec 2020 (Day 58) for 2 days and discharged on 09 Dec 2020 (Day 59). The subject required high-flow oxygen therapy from 08 Dec 2020 (Day 58) to 09 Dec 2020 (Day 59). The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and requirement for high-flow oxygen therapy). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 11 Feb 2021 (Day 123) and 03 Mar 2021 (Day 143), respectively, and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1980	40	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.5 cm	99.7 kg	35.5 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
myopia	Myopia	1993	Present
tinea versicolor	Tinea versicolour	1994	Present
anxiety	Anxiety	2000	Present
allergic to latex	Rubber sensitivity	2000	Present
allergic to Intravenous iodine	Iodine allergy	2006	Present
fallopian tube defect	Fallopian tube disorder	2007	Past
hysterectomy	Hysterectomy	2007	Past
appendectomy	Appendicectomy	2017	Past
appendicitis	Appendicitis	2017	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
cholecystectomy	Cholecystectomy	2017	Past
cholelithiasis	Cholelithiasis	2017	Past
depression	Depression	2019	Present
allergic to scopolamine patch	Drug hypersensitivity	2019	Present
hyperlipidemia	Hyperlipidaemia	2019	Present
neck pain	Neck pain	2019	Present
sleep apnea	Sleep apnoea syndrome	2019	Present
neck fusion	Spinal fusion surgery	2019	Past
water retention	Fluid retention	JAN2020	Present
seasonal allergies	Seasonal allergy	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	17:42
2	Placebo	10SEP2020 (21)	14:56

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21AUG2020 (1)	21AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21AUG2020 (1)	21AUG2020 (1)	SERUM	NEGATIVE
Visit 2	10SEP2020 (21)	10SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 2	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 20OCT2020 (61)/ 18OCT2020 (59)/ 14DEC2020 (116)	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	DIARRHEA	
	YES	NEW OR INCREASED COUGH	
	YES	FEVER	
COVID Illness Visit 2 / 04JAN2021 (137)/ 28DEC2020 (130)/ 16FEB2021 (180)	NO		Nasal congestion
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED COUGH	
	YES	FEVER	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	20OCT2020 (61)	Covid-19	17NOV2020 (89)	1	COVID-19
COVID Illness Visit 2	04JAN2021 (137)	Covid-19 pneumonia	07JAN2021 (140)	1	COVID-19 pneumonia

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	20OCT2020 (61)	20OCT2020 (61)	NASAL_SWAB	NEGATIVE
2	COVID Illness Visit 2	04JAN2021 (137)	04JAN2021 (137)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	20OCT2020 (61)	17NOV2020 (89)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 2	04JAN2021 (137)	05JAN2021 (138)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT Unknown
2	POSITIVE	Reactive A	OTHER	NALT Unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	20OCT2020 (61)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
COVID Illness Visit 2	04JAN2021 (137)	OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details					
Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 2	04JAN2021 (137)	HOSPITALIZATION STATUS	HOSPITAL	05JAN2021 (138)	13JAN2021 (146)

Respiratory Treatment						
Visit	Visit Date (Study Day)	Treatment Identifier	Prespecified Concomitant Nondrug Treatment	Treatment	Start Date (Study Day)	End Date or Ongoing (Study Day)
COVID Illness Visit 2	04JAN2021 (137)	1	YES	HIGH FLOW OXYGEN THERAPY	05JAN2021 (138)	11JAN2021 (144)

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry							
Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 2	04JAN2021 (137)	06JAN2021 (139)	Alkaline Phosphatase	1.58	ukat/L	0.63	2.1
			Alanine Aminotransferase	0.98353	ukat/L	0.01667	0.58345
			Aspartate Aminotransferase	1.06688	ukat/L	0.23338	0.60012
			Bilirubin	6.8	umol/L	3.4	22.2
			Creatinine	70.7	umol/L	61.9	106.1
			C Reactive Protein	54.8	mg/L	0	9
			Urea Nitrogen	5.71	mmol/L	2.5	6.07

Laboratory Results - Hematology							
Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 2	04JAN2021 (137)	06JAN2021 (139)	Basophils	0	%	0	2
			Eosinophils	0	%	0	4
			Hematocrit	0.42	L/L	0.36	0.46
			Hemoglobin	139	g/L	120	160
			Lymphocytes	800	10^9/L	1000	4800
			Monocytes	6	%	0	9
			Neutrophils	4500	10^9/L	1800	7700
			Platelets	239	10^9/L	130	400
			Erythrocytes	5.07	10^12/L	4	5.2

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	20OCT2020 (61)	20OCT2020 (61)	1	124 mmHg	82 mmHg	16 breaths/min	74 beats/min	
COVID Illness Visit 2	04JAN2021 (137)	05JAN2021 (138)	2					86 %
		06JAN2021 (139)	3	118 mmHg	79 mmHg	19 breaths/min	93 beats/min	

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment
1	COVID Illness Visit 2	04JAN2021 (137)	05FEB2021	CHEST		X-RAY	NA	INDETERMINATE
2	COVID Illness Visit 2	04JAN2021 (137)	07FEB2021	CHEST		CT SCAN	NA	ABNORMAL

Imaging	
Assessment Number	**If Abnormal, Specify Findings**
1	
2	Pulmonary findings consistent with COVID-19 pneumonia of moderate severity. Developing bacterial superinfection in the lower lobes cannot be excluded.

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1114 11141075, a 40-year-old white female with a height of 167.5 cm, a weight of 99.7 kg, and a BMI of 35.5 kg/m2, received Dose 1 on 21 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 21). The subject had a reported medical history of myopia (since 1993); tinea versicolor (since 1994); anxiety and rubber sensitivity (both since 2000); iodine allergy (since 2006); fallopian tube disorder and hysterectomy (both in 2007); appendicitis, appendectomy, cholelithiasis, and cholecystectomy (all in 2017); spinal fusion surgery (in 2019); depression, drug hypersensitivity (allergic to scopolamine patch), hyperlipidemia, neck pain, and sleep apnea syndrome (all since 2019); fluid retention (since Jan 2020); and seasonal allergy (since Jun 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 17 Nov 2020 (Day 89), the subject was diagnosed with COVID-19 and reported new or increased muscle pain, new or increased sore throat, new or increased shortness of breath, diarrhea, new or increased cough, and fever, with the first symptom starting on 18 Oct 2020, 38 days after receiving Dose 2, and the last symptom resolved on 14 Dec 2020. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 20 Oct 2020 (Day 61) was negative and on 04 Jan 2021 (Day 137) the result was positive. The local laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on 17 Nov 2020 (Day 89) and on 05 Jan 2021 (Day 138) were positive. On 20 Oct 2020 (Day 61), the subject had a heart rate of 74 beats/min, blood pressure of 124/82 mmHg, and respiratory rate of 16 breaths/min. On 07 Jan 2021 (Day 140), the subject was diagnosed with severe COVID-19 pneumonia and reported nasal congestion, new or increased shortness of breath, new or increased muscle pain, new or increased cough, and fever, with the first symptom starting on 28 Dec 2020, 109 days after receiving Dose 2, and the last symptom resolved on 16 Feb 2021. The subject went to her primary care physician (once) at the time of the first and second COVID-19 illnesses and went to the emergency room (once) at the time of the second COVID-19 illness. On 05 Jan 2021 (Day 138), the subject had an oxygen saturation of 86%, and on 06 Jan 2021 (Day 139), the subject had a heart rate of 93 beats/min, blood pressure of 118/79 mmHg, and respiratory rate of 19 breaths/min. The subject required high-flow oxygen therapy from 05 Jan 2021 (Day 138) to 11 Jan 2021 (Day 144). The subject was hospitalized on 05 Jan 2021 (Day 138) for 9 days and discharged on 13 Jan 2021 (Day 146). On 06 Jan 2021 (Day 139), the subject's laboratory results showed elevated alanine aminotransferase of 0.98353 µkat/L (normal range [NR]: 0.01667-0.58345 µkat/L), aspartate aminotransferase of 1.06688 µkat/L (NR: 0.23338-0.60012 µkat/L), and C-reactive protein of 54.8 mg/L (NR: 0-9 mg/L); and low lymphocyte count of 800 cells/µL (NR: 1000-4800 cells/µL); alkaline phosphatase, bilirubin, creatinine, blood urea nitrogen, basophils, eosinophils, hematocrit, hemoglobin, monocytes, neutrophils, platelets, and erythrocytes were within normal limits. On 05 Feb 2021 (Day 169), a chest radiograph was performed and the result was reported as indeterminate. On 07 Feb 2021 (Day 171), a computed tomography scan of the chest showed pulmonary findings consistent with COVID-19 pneumonia of moderate severity, and a developing bacterial superinfection in the lower lobes could not be excluded. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19, oxygen saturation ≤93%, and requirement for high-flow oxygen therapy).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	47	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	93.18 kg	27 kg/m2	09SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09SEP2020 (1)	09:48
2	Placebo	28SEP2020 (20)	15:55
3	BNT162b2	01MAR2021 (174)	09:32

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	09SEP2020 (1)	09SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	09SEP2020 (1)	09SEP2020 (1)	SERUM	NEGATIVE
Visit 2	28SEP2020 (20)	28SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 13JAN2021 (127)/ 08JAN2021 (122)/ 18JAN2021 (132)	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	CHILLS	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	13JAN2021 (127)	COVID-19	13JAN2021 (127)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	13JAN2021 (127)	13JAN2021 (127)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	13JAN2021 (127)	13JAN2021 (127)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT UNKNOWN

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	13JAN2021 (127)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	COUNTY HEALTH DEPARTMENT

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	13JAN2021 (127)	13JAN2021 (127)	1	129 mmHg	78 mmHg	16 breaths/min	89 beats/min	93 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	26OCT2020	
Completed	REPEAT SCREENING 1	01MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1116 11161160, a 47-year-old white male with a height of 185.42 cm, a weight of 93.18 kg, and a BMI of 27 kg/m2, received Dose 1 on 09 Sep 2020 and Dose 2 on 28 Sep 2020 (Day 20). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 13 Jan 2021 (Day 127), the subject was diagnosed with severe COVID-19 and reported new or increased cough, new or increased muscle pain, new loss of taste or smell, and chills, with the first symptom starting on 08 Jan 2021, 102 days after receiving Dose 2, and the last symptom resolved on 18 Jan 2021. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 13 Jan 2021 (Day 127) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 13 Jan 2021 (Day 127) was positive. The subject went to the county health department (once). On 13 Jan 2021 (Day 127), the subject had a heart rate of 89 beats/min, blood pressure of 129/78 mmHg, respiratory rate of 16 breaths/min, and oxygen saturation of 93% on room air. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and oxygen saturation ⩽93%). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first dose of BNT162b2 on 01 Mar 2021 (Day 174) and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	84 kg	27.3 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tilted Uterus	Uterine malposition	1990	Past
gall bladder removal	Cholecystectomy	2000	Past
Gall Stones	Cholelithiasis	2000	Past
Three Herniated Disc L2, 4 and 5	Intervertebral disc protrusion	2005	Past
Anxiety	Anxiety	2008	Present
Depression	Depression	2008	Present
Insomnia	Insomnia	2008	Present
Right Arthritis Knee	Arthritis	2014	Past
Right Knee Meniscus Torn	Meniscus injury	2014	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bilateral Breast Augmentation Cosmetic	Mammoplasty	2015	Past
Obesity	Obesity	2015	Past
Gastric Sleeve Surgery	Gastrectomy	OCT2015	Past
Acid Reflux	Gastrooesophageal reflux disease	2016	Present
Bilateral Oopherectomy	Oophorectomy bilateral	2017	Past
Left Ovarian Cyst	Ovarian cyst	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	16:32
2	Placebo	30SEP2020 (20)	09:10
3	BNT162b2	03MAR2021 (174)	15:06

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	11SEP2020 (1)	11SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	11SEP2020 (1)	11SEP2020 (1)	SERUM	NEGATIVE
Visit 2	30SEP2020 (20)	30SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No
COVID Illness Visit 2	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 16NOV2020 (67)/ 14NOV2020 (65)/ 20NOV2020 (71)	YES	FEVER	
	YES	CHILLS	
	NO		Dry throat
	NO		Headache
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED COUGH	
	NO		Throat irritation
	YES	NEW OR INCREASED SORE THROAT	
COVID Illness Visit 2 / 23DEC2020 (104)/ 20DEC2020 (101)/ 15JAN2021 (127)	YES	NEW LOSS OF TASTE OR SMELL	
	YES	FEVER	
	YES	NEW OR INCREASED MUSCLE PAIN	
COVID Illness Visit 3 / 11FEB2021 (154)/ 10FEB2021 (153)/ 15FEB2021 (158)	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	16NOV2020 (67)	COVID-19 Infection	16NOV2020 (67)	2	COVID-19
COVID Illness Visit 2	23DEC2020 (104)	COVID-19	22DEC2020 (103)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	16NOV2020 (67)	16NOV2020 (67)	NASAL_SWAB	POSITIVE
2	COVID Illness Visit 2	23DEC2020 (104)	23DEC2020 (104)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location	Test Result
1	COVID Illness Visit 1	16NOV2020 (67)	14NOV2020 (65)	SWABBED MATERIAL	NASOPHARYNX	NEGATIVE
2	COVID Illness Visit 1	16NOV2020 (67)	15NOV2020 (66)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE
3	COVID Illness Visit 2	23DEC2020 (104)	22DEC2020 (103)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1		OTHER	NALT Unknown
2	Subject was also tested on 14NOV2020 with a negative result	OTHER	NALT Unknown
3		OTHER	NALT UNKNOWN

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	16NOV2020 (67)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	2	NA
COVID Illness Visit 2	23DEC2020 (104)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 3	11FEB2021 (154)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details					
Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 2	23DEC2020 (104)	HOSPITALIZATION STATUS	HOSPITAL	23DEC2020 (104)	25DEC2020 (106)

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 2	23DEC2020 (104)	22DEC2020 (103)	Alkaline Phosphatase	2.33	ukat/L	0.63	2.1
			Alanine Aminotransferase	15%	U/L	7	56
			Aspartate Aminotransferase	0.60012	ukat/L	0.08335	0.58345
			Creatinine	397.8	umol/L	44.2	123.8
			Urea Nitrogen	10	mmol/L	2.5	7.5

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	16NOV2020 (67)	16NOV2020 (67)	1	124 mmHg	78 mmHg	20 breaths/min	98 beats/min	97 %
COVID Illness Visit 2	23DEC2020 (104)	23DEC2020 (104)	2	107 mmHg	77 mmHg	20 breaths/min	104 beats/min	

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 2	23DEC2020 (104)	22DEC2020	CHEST		X-RAY	NA	UNKNOWN	
2	COVID Illness Visit 2	23DEC2020 (104)	22DEC2020	OTHER	abdominal	CT SCAN	NA	NORMAL	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	28OCT2020	
Completed	REPEAT SCREENING 1	03MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1116 11161224, a 52-year-old white female with a height of 175.26 cm, a weight of 84 kg, and a BMI of 27.3 kg/m2, received Dose 1 on 11 Sep 2020 and Dose 2 on 30 Sep 2020 (Day 20). The subject had a reported medical history of uterine malposition (in 1990); cholelithiasis and cholecystectomy (both in 2000); intervertebral disc protrusion (in 2005); anxiety, depression, and insomnia (all since 2008); right knee meniscus injury and arthritis (both in 2014); mammoplasty and obesity (both in 2015); gastrectomy (in Oct 2015); gastroesophageal reflux disease (since 2016); and left ovarian cyst and bilateral oophorectomy (both in 2017). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject experienced 2 protocol-defined COVID-19 illnesses. On 16 Nov 2020 (Day 67), the subject was diagnosed with COVID-19 for the first time and reported fever, chills, dry throat, headache, new or increased muscle pain, new or increased cough, throat irritation, and new or increased sore throat, with the first symptom starting on 14 Nov 2020, 45 days after receiving Dose 2, and the last symptom resolved on 20 Nov 2020. On 22 Dec 2020 (Day 103), the subject was diagnosed with COVID-19 for the second time and reported new loss of taste or smell, fever, and new or increased muscle pain, with the first symptom starting on 20 Dec 2020, 81 days after receiving Dose 2, and the last symptom resolved on 15 Jan 2021. The central laboratory SARS-CoV-2 NAAT results at the time of the first and second COVID-19 illnesses on 16 Nov 2020 (Day 67) and 23 Dec 2020 (Day 104) were positive. The local laboratory SARS-CoV-2 NAAT result at the time of the first COVID-19 illness on 14 Nov 2020 (Day 65) was negative and on 15 Nov 2020 (Day 66) the result was positive; and at the time of the second COVID-19 illness on 22 Dec 2020 (Day 103), the result was positive. The subject had an urgent care visit (twice) at the time of the first COVID-19 illness and went to the emergency room (once) at the time of the second COVID-19 illness. On 16 Nov 2020 (Day 67), the subject had a heart rate of 98 beats/min, blood pressure of 124/78 mmHg, respiratory rate of 20 breaths/min, and oxygen saturation of 97%. On 22 Dec 2020 (Day 103), the subject's laboratory test results showed elevated alkaline phosphatase of 2.33 µkat/L (normal range [NR]: 0.63-2.1 µkat/L), elevated aspartate aminotransferase of 0.60012 µkat/L (NR: 0.08335-0.58345 µkat/L), elevated creatinine of 397.8 µmol/L (NR: 44.2-123.8 µmol/L), elevated blood urea nitrogen of 10 mmol/L (NR: 2.5-7.5 mmol/L), and alanine aminotransferase within normal limits. On 22 Dec 2020 (Day 103), a chest radiograph revealed unknown results. A computed tomography scan of the abdomen was normal. On 23 Dec 2020 (Day 104), the subject had a heart rate of 104 beats/min, blood pressure of 107/77 mmHg, and respiratory rate of 20 breaths/min. The subject was hospitalized on 23 Dec 2020 (Day 104) for 3 days and discharged on 25 Dec 2020 (Day 106). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 03 Mar 2021 (Day 174) and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184.79 cm	115.05 kg	33.6 kg/m2	18SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bilateral Eye Radial Keratotomy	Keratotomy	1981	Past
Prostate Cancer	Prostate cancer	2005	Past
Prostatectomy	Prostatectomy	2005	Past
ERECTILE DYSFUNCTION	Erectile dysfunction	2010	Present
Hypertension	Hypertension	2015	Present
Asymptomatic Tachycardia	Tachycardia	18SEP2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18SEP2020 (1)	17:37

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Moderna COVID 19 vaccine	COVID-19 VACCINE MRNA (MRNA 1273)	JAN2021

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	18SEP2020 (1)	18SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	18SEP2020 (1)	18SEP2020 (1)	SERUM	NEGATIVE
Visit 2	08OCT2020 (21)	08OCT2020 (21)	NASAL_SWAB	POSITIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 28SEP2020 (11)/ 25SEP2020 (8)/ 06OCT2020 (19)	YES	FEVER	
	YES	CHILLS	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED COUGH	
COVID Illness Visit 2 / 27OCT2020 (40)/ 25OCT2020 (38)/ 12NOV2020 (56)	NO		Primary cough headache
	YES	NEW OR INCREASED COUGH	
	YES	FEVER	
	YES	CHILLS	
	NO		Pain

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	28SEP2020 (11)	Covid-19	26SEP2020 (9)	3	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	28SEP2020 (11)	28SEP2020 (11)	NASAL_SWAB	POSITIVE
2	COVID Illness Visit 2	27OCT2020 (40)	27OCT2020 (40)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location	Test Result
1	COVID Illness Visit 1	28SEP2020 (11)	26SEP2020 (9)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	The trade name of swab was not in the medical report. CRC called and was given name below.	OTHER	NALT Unknown

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	28SEP2020 (11)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA
COVID Illness Visit 2	27OCT2020 (40)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	28SEP2020 (11)	28SEP2020 (11)	1	118 mmHg	84 mmHg	28 breaths/min	137 beats/min	96 %
COVID Illness Visit 2	27OCT2020 (40)	27OCT2020 (40)	2	125 mmHg	91 mmHg	22 breaths/min	108 beats/min	98 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18SEP2020	
Withdrawn	VACCINATION	28SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	29JAN2021	PROTOCOL DEVIATION

Narrative Comment
Subject C4591001 1116 11161253, a 61-year-old white male with a height of 184.79 cm, a weight of 115.05 kg, and a BMI of 33.6 kg/m2, received Dose 1 on 18 Sep 2020. The subject had a reported medical history of keratotomy (in 1981), prostate cancer and prostatectomy (both in 2005), erectile dysfunction (since 2010), hypertension (since 2015), and tachycardia (since 18 Sep 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and positive at Visit 2 (08 Oct 2020 [Day 21]). The central laboratory N-binding antibody result was negative at Visit 1. On 26 Sep 2020 (Day 9), the subject was diagnosed with severe COVID-19 and reported fever, chills, new or increased muscle pain, and new or increased cough, with the first symptom starting on 25 Sep 2020, 7 days after receiving Dose 1, and the last symptom resolved on 06 Oct 2020. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 28 Sep 2020 (Day 11) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 26 Sep 2020 (Day 9) was positive. On 28 Sep 2020 (Day 11), the subject had a heart rate of 137 beats/min, blood pressure of 118/84 mmHg, respiratory rate of 28 breaths/min, and oxygen saturation of 96% on room air. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and heart rate more than 125 beats/min). The subject had an urgent care visit (once). The subject was discontinued from the study intervention on 28 Sep 2020 since he no longer met the eligibility criteria and he was withdrawn from the study on 29 Jan 2021 because of a protocol deviation (he was symptomatic and tested positive for COVID-19 between Dose 1 and Dose 2).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	102.27 kg	29.7 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	1970	Present
Crohn's Disease	Crohn's disease	1980	Present
High Blood Pressure	Hypertension	1980	Present
Depression	Depression	2002	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	14:00
2	Placebo	21SEP2020 (22)	14:36
3	BNT162b2	03FEB2021 (157)	15:12
4	BNT162b2	26FEB2021 (180)	12:02

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	SKIN	Alopecia	Hair loss	SEP2020 ()		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	N	N	Yes	NOT RELATED/OTHER: alopecia			N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	31AUG2020 (1)	31AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	31AUG2020 (1)	31AUG2020 (1)	SERUM	NEGATIVE
Visit 2	21SEP2020 (22)	21SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 21DEC2020 (113)/ 17DEC2020 (109)/ ONGOING	YES	NEW OR INCREASED SORE THROAT	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED COUGH	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	FEVER	
	YES	DIARRHEA	
	YES	CHILLS	
	NO		Abdominal pain upper

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	21DEC2020 (113)	COVID-19	19DEC2020 (111)	3	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	21DEC2020 (113)	18JAN2021 (141)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	21DEC2020 (113)	19DEC2020 (111)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT Unknown

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	21DEC2020 (113)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details					
Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	21DEC2020 (113)	HOSPITALIZATION STATUS	HOSPITAL	24DEC2020 (116)	30DEC2020 (122)

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	21DEC2020 (113)	22DEC2020 (114)	Alkaline Phosphatase	0.87	ukat/L	0.53	1.75
			Bilirubin	13.7	umol/L	5.1	20.5
			Creatinine	88.4	umol/L	53	106.1
			Urea Nitrogen	4.64	mmol/L	2.86	9.28
		24DEC2020 (116)	Alkaline Phosphatase	0.75	ukat/L	0.53	1.75
			Bilirubin	13.7	umol/L	5.1	20.5
			Creatinine	67.2	umol/L	53	106.1
			C Reactive Protein	121.9	mg/L	0	10
			Urea Nitrogen	3.57	mmol/L	2.86	9.28
		28DEC2020 (120)	Alkaline Phosphatase	0.73	ukat/L	0.53	1.75
			Bilirubin	13.7	umol/L	5.1	20.5
			Creatinine	66.3	umol/L	53	106.1
			C Reactive Protein	12.1	mg/L	0	10
			Urea Nitrogen	6.43	mmol/L	2.86	9.28

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	21DEC2020 (113)	22DEC2020 (114)	Basophils	0	10^9/L	0	0.2
			Eosinophils	0	10^9/L	0	0.6
			Hematocrit	41..5	%	40	52
			Hemoglobin	140	g/L	135	175
			Lymphocytes	1	10^9/L	1.2	4.5
			Monocytes	0.4	10^9/L	0.1	1.2
			Neutrophils	3.9	10^9/L	2.1	7.5
			Platelets	185	10^9/L	140	430
			Leukocytes	5.3	10^9/L	4	10.8
		24DEC2020 (116)	Basophils	0	10^9/L	0	0.2
			Eosinophils	0	10^9/L	0	0.6
			Hematocrit	0.38	L/L	0.4	0.52
			Hemoglobin	130	g/L	135	175
			Lymphocytes	1	10^9/L	1.2	4.5
			Monocytes	0.3	10^9/L	0.1	1.2
			Neutrophils	4.2	10^9/L	2.1	7.5
			Platelets	167	10^9/L	140	430
			Leukocytes	5.6	10^9/L	4	10.8
		28DEC2020 (120)	Basophils	0	%	0	2
			Eosinophils	0	%	0	8
			Hematocrit	0.37	L/L	0.4	0.52
			Hemoglobin	124	g/L	135	175
			Lymphocytes	1.7	10^9/L	1.2	4.5
			Monocytes	8	%	2	12
			Neutrophils	3.9	10^9/L	2.1	7.5

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
			Platelets	285	10^9/L	140	430

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	21DEC2020 (113)	24DEC2020 (116)	1	158 mmHg	90 mmHg	23 breaths/min	91 beats/min	88 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	26OCT2020	
Completed	REPEAT SCREENING 1	03FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1124 11241128, a 67-year-old white male with a height of 185.42 cm, a weight of 102.27 kg, and a BMI of 29.7 kg/m2, received Dose 1 on 31 Aug 2020 and Dose 2 on 21 Sep 2020 (Day 22). The subject had a reported medical history of gastroesophageal reflux disease (since 1970), Crohn's disease and hypertension (both since 1980), and depression (since 2002). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 19 Dec 2020 (Day 111), the subject was diagnosed with severe COVID-19 and reported new or increased sore throat, new or increased shortness of breath, new or increased muscle pain, new or increased cough, new loss of taste or smell, fever, diarrhea, chills, and upper abdominal pain, with the first symptom starting on 17 Dec 2020, 87 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 18 Jan 2021 (Day 141) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 19 Dec 2020 (Day 111) was positive. The subject went to the emergency room (once). On 24 Dec 2020 (Day 116), the subject had a heart rate of 91 beats/min, blood pressure of 158/90 mmHg, respiratory rate of 23 breaths/min, and oxygen saturation of 88%. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and oxygen saturation of ≤93%). The subject was hospitalized on 24 Dec 2020 (Day 116) for 7 days and discharged on 30 Dec 2020 (Day 122). On 28 Dec 2020 (Day 120), the subject's laboratory test results showed low hematocrit of 36.7% (normal range [NR]: 40%-52%) and hemoglobin of 12.4 g/dL (NR: 13.5-17.5 g/dL); basophils, eosinophils, lymphocytes, monocytes, neutrophils, and platelets were within normal limits. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 03 Feb 2021 (Day 157) and 26 Feb 2021 (Day 180), respectively, and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	104.09 kg	38.1 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hyperthyroidism	Hyperthyroidism	1994	Past
Radioactive Iodine Treatment on thyroid	Radioactive iodine therapy	1994	Past
General discomfort	Discomfort	1995	Present
bilateral tubal ligation	Female sterilisation	19AUG2004	Past
Seasonal Allergies	Seasonal allergy	2005	Present
Anxiety	Anxiety	2019	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	12AUG2020 (1)	17:46
2	Placebo	02SEP2020 (22)	08:47

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	MUSC	Pain in extremity	Pain in 3rd digit of Right hand	26NOV2020 (107)		26NOV2020 (107)		1

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	TC	N	Resolved (26NOV2020)	NOT RELATED/OTHER: unknown	2	86	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	12AUG2020 (1)	12AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	12AUG2020 (1)	12AUG2020 (1)	SERUM	NEGATIVE
Visit 2	02SEP2020 (22)	02SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 10NOV2020 (91)/ 30OCT2020 (80)/ 17NOV2020 (98)	YES	NEW OR INCREASED COUGH	
	YES	DIARRHEA	
	YES	CHILLS	
	NO		Fatigue
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	FEVER	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	10NOV2020 (91)	Covid-19	08NOV2020 (89)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	10NOV2020 (91)	10NOV2020 (91)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	10NOV2020 (91)	08NOV2020 (89)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT Unknown

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	10NOV2020 (91)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	10NOV2020 (91)	08NOV2020 (89)	1					86 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	02OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1125 11251014, a 45-year-old white female with a height of 165.1 cm, a weight of 104.09 kg, and a BMI of 38.1 kg/m2, received Dose 1 on 12 Aug 2020 and Dose 2 on 02 Sep 2020 (Day 22). The subject had a reported medical history of hyperthyroidism and radioactive iodine therapy (both in 1994), general discomfort (since 1995), female sterilization (on 19 Aug 2004), seasonal allergy (since 2005), and anxiety (since 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 08 Nov 2020 (Day 89), the subject was diagnosed with severe COVID-19 and reported new or increased cough, diarrhea, chills, fatigue, new or increased muscle pain, new or increased shortness of breath, and fever, with the first symptom starting on 30 Oct 2020, 58 days after receiving Dose 2, and the last symptom resolved on 17 Nov 2020. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 10 Nov 2020 (Day 91) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 08 Nov 2020 (Day 89) was positive. The subject had an urgent care visit (once). On 08 Nov 2020 (Day 89), the subject had an oxygen saturation of 86% on room air. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and oxygen saturation ⩽93%).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	64	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186 cm	111 kg	32.1 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	1965	Past
eye glass wearer	Corrective lens user	1965	Present
myopia	Myopia	1965	Present
recurrent back pain	Back pain	1980	Past
allergic rhinitis, seasonal	Seasonal allergy	1990	Present
type II diabetes, with no history of ketoacidosis	Type 2 diabetes mellitus	1995	Present
high blood pressure	Hypertension	2000	Present
evidence of past cardiac infarction	Myocardial infarction	2000	Past
kidney stones	Nephrolithiasis	2000	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
osteoarthritis in neck	Spinal osteoarthritis	2000	Present
osteoarthritis in lumbar spine	Spinal osteoarthritis	2000	Present
1st degree atrioventricular block	Atrioventricular block first degree	2003	Present
right bundle branch block	Bundle branch block right	2003	Present
chest pain	Chest pain	2003	Past
triple by-pass heart surgery	Coronary artery bypass	2003	Past
hyperlipidemia	Hyperlipidaemia	2005	Present
diabetic neuropathy in both feet	Diabetic neuropathy	2010	Present
inguinal hernia	Inguinal hernia	2011	Past
inguinal hernia surgical repair	Inguinal hernia repair	2011	Past
chronic kidney disease, stage 2	Chronic kidney disease	2013	Present
L4-L5-S1 spinal fusion surgery	Spinal fusion surgery	2013	Past
C-PAP wearer	Continuous positive airway pressure	2015	Present
hypothyroidism	Hypothyroidism	2015	Present
polycythemia	Polycythaemia	2015	Present
sleep apnea	Sleep apnoea syndrome	2015	Present
gallstones	Cholelithiasis	2018	Present
recurrent neck pain	Neck pain	2018	Present
motor vehicle accident	Road traffic accident	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	11:28
2	Placebo	16SEP2020 (20)	16:56

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	01FEB2021 (158)	13:06
4	BNT162b2	22FEB2021 (179)	09:30

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	chills	02FEB2021 (159)		03FEB2021 (160)	
2	GENRL	Fatigue	fatigue	02FEB2021 (159)		04FEB2021 (161)	08:00
3	GENRL	Pain	body aches	02FEB2021 (159)		03FEB2021 (160)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	2	N	N	Resolved (03FEB2021)	Study Treatment	3	2	N
2	3	2	N	N	Resolved (04FEB2021)	Study Treatment	3	2	N
3	2	2	TC	N	Resolved (03FEB2021)	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	28AUG2020 (1)	28AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	28AUG2020 (1)	28AUG2020 (1)	SERUM	NEGATIVE
Visit 2	16SEP2020 (20)	16SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 13NOV2020 (78)/ 12NOV2020 (77)/ 30NOV2020 (95)	NO		Nasal congestion
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	FEVER	
	NO		Chest pain
	YES	CHILLS	
	NO		Blood glucose increased

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	13NOV2020 (78)	Covid-19	16NOV2020 (81)	3	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	13NOV2020 (78)	13NOV2020 (78)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	13NOV2020 (78)	14NOV2020 (79)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	13NOV2020 (78)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	13NOV2020 (78)	HOSPITALIZATION STATUS	HOSPITAL	21NOV2020 (86)	24NOV2020 (89)

Respiratory Treatment

Visit	Visit Date (Study Day)	Treatment Identifier	Prespecified Concomitant Nondrug Treatment	Treatment	Start Date (Study Day)	End Date or Ongoing (Study Day)
COVID Illness Visit 1	13NOV2020 (78)	1	YES	HIGH FLOW OXYGEN THERAPY	21NOV2020 (86)	30NOV2020 (95)

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry							
Visit	**Visit Date (Study Day)**	**Date of Test (Study Day)**	**Laboratory Test**	**Result**	**Units**	**Lower Limit Range**	**Upper Limit Range**
COVID Illness Visit 1	13NOV2020 (78)	23NOV2020 (88)	Alkaline Phosphatase	0.73	ukat/L	0.67	2.13
			Alanine Aminotransferase	0.46676	ukat/L	0.1667	0.6668
			Aspartate Aminotransferase	0.58345	ukat/L	0.25005	0.61679
			Bilirubin	6.8	umol/L	0	17.1
			Creatinine	79.6	umol/L	79.6	114.9
			Urea Nitrogen	18.93	mmol/L	2.14	8.21

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	13NOV2020 (78)	23NOV2020 (88)	Hematocrit	0.29	L/L	0.42	0.52
			Hemoglobin	100	g/L	135	180
			Lymphocytes	23	%	24	44
			Monocytes	8	%	0	4
			Platelets	266	10^9/L	140	440
			Erythrocytes	3.19	10^12/L	4.6	6.2
			Leukocytes	6.6	10^9/L	4	10.5

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	13NOV2020 (78)	24NOV2020 (89)	1	120 mmHg	59 mmHg	16 breaths/min	88 beats/min	95 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging									
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 1	13NOV2020 (78)	20NOV2020	CHEST		X-RAY	NA	UNKNOWN	

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	01FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1131 11311100, a 64-year-old white male with a height of 186 cm, a weight of 111 kg, and a BMI of 32.1 kg/m2, received Dose 1 on 28 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 20). The subject had a reported medical history of appendectomy (in 1965); corrective lens user and myopia (both since 1965); back pain (in 1980); seasonal allergy (since 1990); type 2 diabetes mellitus (since 1995); myocardial infarction and nephrolithiasis (both in 2000); hypertension and spinal osteoarthritis (neck and lumbar spine) (both since 2000); chest pain and coronary artery bypass (both in 2003); first-degree atrioventricular block and right bundle branch block (both since 2003); hyperlipidemia (since 2005); diabetic neuropathy (since 2010); inguinal hernia and inguinal hernia repair (both in 2011); spinal fusion surgery (in 2013); chronic kidney disease (since 2013); continuous positive airway pressure, hypothyroidism, polycythemia, and sleep apnea syndrome (all since 2015); road traffic accident (in 2018); and cholelithiasis and neck pain (both since 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 16 Nov 2020 (Day 81), the subject was diagnosed with severe COVID-19 and reported nasal congestion, new or increased muscle pain, new loss of taste or smell, fever, chest pain, chills, and blood glucose increased, with the first symptom starting on 12 Nov 2020, 57 days after receiving Dose 2, and the last symptom resolved on 30 Nov 2020. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 13 Nov 2020 (Day 78) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 14 Nov 2020 (Day 79) was positive. The subject had an urgent care visit (once). On 20 Nov 2020 (Day 85), a chest radiograph was performed and the result was unknown. The subject was hospitalized on 21 Nov 2020 (Day 86) for 4 days and discharged on 24 Nov 2020 (Day 89). The subject required high-flow oxygen therapy from 21 Nov 2020 (Day 86) to 30 Nov 2020 (Day 95). On 23 Nov 2020 (Day 88), the subject's laboratory test results showed elevated blood urea nitrogen of 18.93 mmol/L (normal range [NR]: 2.14-8.21 mmol/L) and monocytes of 8% (NR: 0%-4%); low hematocrit of 29% (NR: 42%-52%), hemoglobin of 10 g/dL (NR: 13.5-18.0 g/dL), lymphocytes of 23% (NR: 24%-44%), and erythrocytes of 3.19 × 1012/L (NR: 4.6-6.2 × 1012/L); alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, bilirubin, creatinine, platelets, and leukocytes were within normal limits. On 24 Nov 2020 (Day 89), the subject had a heart rate of 88 beats/min, blood pressure of 120/59 mmHg, respiratory rate of 16 breaths/min, and oxygen saturation of 95%. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19, requirement for high-flow oxygen therapy, and presented evidence of shock: diastolic blood pressure <60 mmHg). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 01 Feb 2021 (Day 158) and 22 Feb 2021 (Day 179), respectively, and remains in the study. The subject experienced chills, fatigue, and body aches on 02 Feb 2021, 1 day after receiving the first dose of BNT162b2. The chills and body aches resolved on 03 Feb 2021, 2 days after receiving the first dose of BNT162b2, and the fatigue resolved on 04 Feb 2021, 3 days after receiving the first dose of BNT162b2.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	65	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	128.64 kg	40.6 kg/m2	14SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14SEP2020 (1)	13:28
2	Placebo	05OCT2020 (22)	10:10

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	21JAN2021 (130)	08:32
4	BNT162b2	11FEB2021 (151)	09:39

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	14SEP2020 (1)	14SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	14SEP2020 (1)	14SEP2020 (1)	SERUM	NEGATIVE
Visit 2	05OCT2020 (22)	05OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 15DEC2020 (93)/ 03DEC2020 (81)/ 08DEC2020 (86)	NO		Decreased appetite
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness

Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	15DEC2020 (93)	COVID-19 pneumonia	03DEC2020 (81)	3	COVID-19 pneumonia

SARS-COV-2 Test - Central Laboratory

No SARS-COV-2 Test - Central Laboratory

SARS-COV-2 Test - Local Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	15DEC2020 (93)	03DEC2020 (81)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ROCHE MOLECULAR SYSTEMS COBAS SARS-COV-2	

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	15DEC2020 (93)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details					
Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	15DEC2020 (93)	HOSPITALIZATION STATUS	HOSPITAL	03DEC2020 (81)	07DEC2020 (85)

Respiratory Treatment

Visit	Visit Date (Study Day)	Treatment Identifier	Prespecified Concomitant Nondrug Treatment	Treatment	Start Date (Study Day)	End Date or Ongoing (Study Day)
COVID Illness Visit 1	15DEC2020 (93)	1	YES	NON-INVASIVE POSITIVE PRESSURE VENTILATION	03DEC2020 (81)	07DEC2020 (85)

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	15DEC2020 (93)	03DEC2020 (81)	Alkaline Phosphatase	1.1	ukat/L	0.75	1.95
			Alanine Aminotransferase	0.51677	ukat/L	0.20004	0.98353
			Aspartate Aminotransferase	0.48343	ukat/L	0.25005	0.61679
			Bilirubin	15.4	umol/L	0	18.8
			Creatinine	84	umol/L	53	114.9
			C Reactive Protein	24.7	mg/L	0	9
			Urea Nitrogen	7.86	mmol/L	2.5	6.43

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	15DEC2020 (93)	13DEC2020 (91)	Basophils	0.01	10^9/L	0	0.2
			Eosinophils	0.04	10^9/L	0	0.2
			Hematocrit	0.44	L/L	0.39	0.5
			Hemoglobin	14.6	%	39	50
			Lymphocytes	0.77	10^9/L	0.7	3.7
			Monocytes	0.33	10^9/L	0.2	0.8
			Neutrophils	2.66	10^9/L	2	6.6
			Platelets	122	10^9/L	150	450
			Erythrocytes	4.87	10^12/L	4.2	5.7
			Leukocytes	3.87	10^9/L	4.5	11

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	15DEC2020 (93)	03DEC2020 (81)	1	118 mmHg	69 mmHg	17 breaths/min	93 beats/min	94 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging									
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 1	15DEC2020 (93)	03DEC2020	CHEST		X-RAY	NA	ABNORMAL	Right lower lobe pneumonia

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	02NOV2020	
Completed	REPEAT SCREENING 1	21JAN2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	04MAR2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1146 11461235, a 65-year-old white male with a height of 177.8 cm, a weight of 128.64 kg, and a BMI of 40.6 kg/m2, received Dose 1 on 14 Sep 2020 and Dose 2 on 05 Oct 2020 (Day 22). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 03 Dec 2020 (Day 81), the subject was diagnosed with severe COVID-19 pneumonia and reported decreased appetite, new or increased cough, and new or increased muscle pain, with the first symptom starting on 03 Dec 2020, 59 days after receiving Dose 2, and the last symptom resolved on 08 Dec 2020. No central laboratory SARS-CoV-2 NAAT was done. The local laboratory SARS-CoV-2 NAAT (Roche cobas SARS-CoV-2 real-time RT-PCR) result at the time of the COVID-19 illness on 03 Dec 2020 (Day 81) was positive. The subject had a telephone consultation (once) and went to the emergency room (once). On 03 Dec 2020 (Day 81), the subject had a heart rate of 93 beats/min, blood pressure of 118/69 mmHg, respiratory rate of 17 breaths/min, and oxygen saturation of 94%. On 03 Dec 2020 (Day 81), a chest radiograph revealed right lower lobe pneumonia. The subject required noninvasive positive pressure ventilation from 03 Dec 2020 (Day 81) to 07 Dec 2020 (Day 85). On 03 Dec 2020 (Day 81), the subject's laboratory test results showed elevated C-reactive protein of 24.7 mg/L (normal range [NR]: 0-9 mg/L) and blood urea nitrogen of 7.86 mmol/L (NR: 2.5-6.43 mmol/L); alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, bilirubin, and creatinine were within normal limits. The subject was hospitalized on 03 Dec 2020 (Day 81) for 5 days and discharged on 07 Dec 2020 (Day 85). On 13 Dec 2020 (Day 91), the subject's laboratory test results showed low hemoglobin of 14.6% (NR: 39%-50%), platelet count of 122 × 109/L (NR: 150-450 × 109/L), and leukocytes of 3.87 × 109/L (NR: 4.5-11 × 109/L); basophils, eosinophils, hematocrit, lymphocytes, monocytes, neutrophils, and erythrocytes were within normal limits. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and requirement for noninvasive positive pressure ventilation). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 21 Jan 2021 (Day 130) and 11 Feb 2021 (Day 151), respectively, and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.5 cm	87.05 kg	31 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypertension	Hypertension	2002	Present
mild anxiety depression	Depression	2010	Present
chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2018	Present
fatty liver	Hepatic steatosis	2018	Present
Diabetes Mellitus Type 2	Type 2 diabetes mellitus	25FEB2020	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	27AUG2020 (1)	11:52

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	27AUG2020 (1)	27AUG2020 (1)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	27AUG2020 (1)	27AUG2020 (1)	SERUM	NEGATIVE
Visit 2	09OCT2020 (44)	09OCT2020 (44)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 02SEP2020 (7)/ 01SEP2020 (6)/ 29SEP2020 (34)	YES	NEW OR INCREASED SORE THROAT	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED COUGH	
	YES	FEVER	
	YES	DIARRHEA	
	YES	CHILLS	
COVID Illness Visit 2 / 05MAR2021 (191)/ 04MAR2021 (190)/ ONGOING	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	FEVER	
	YES	DIARRHEA	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	02SEP2020 (7)	COVID-19 PNEUMONIA	05SEP2020 (10)	4	COVID-19 pneumonia

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	02SEP2020 (7)	03SEP2020 (8)	NASAL_SWAB	POSITIVE
2	COVID Illness Visit 2	05MAR2021 (191)	05MAR2021 (191)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	02SEP2020 (7)	03SEP2020 (8)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	02SEP2020 (7)	08SEP2020 (13)	SWABBED MATERIAL	NASOPHARYNX
3	COVID Illness Visit 1	02SEP2020 (7)	09SEP2020 (14)	SWABBED MATERIAL	NASOPHARYNX
4	COVID Illness Visit 1	02SEP2020 (7)	14SEP2020 (19)	SWABBED MATERIAL	NASOPHARYNX
5	COVID Illness Visit 1	02SEP2020 (7)	15SEP2020 (20)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		LABCORP COVID-19 RT-PCR TEST	
2	POSITIVE		THERMOFISHER APPL BIO TAQPATH COVID-19 COMBO KIT	
3	POSITIVE		THERMOFISHER APPL BIO TAQPATH COVID-19 COMBO KIT	
4	POSITIVE		THERMOFISHER APPL BIO TAQPATH COVID-19 COMBO KIT	
5	NEGATIVE		THERMOFISHER APPL BIO TAQPATH COVID-19 COMBO KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	02SEP2020 (7)	OTHER	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		SPECIALIST	YES	1	NA
		EMERGENCY ROOM	YES	1	NA
		PRIMARY CARE PHYSICIAN	YES	5	NA
COVID Illness Visit 2	05MAR2021 (191)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	02SEP2020 (7)	HOSPITALIZATION STATUS	HOSPITAL	05SEP2020 (10)	19SEP2020 (24)
COVID Illness Visit 1	02SEP2020 (7)	HOSPITALIZATION STATUS	ICU	05SEP2020 (10)	19SEP2020 (24)

Respiratory Treatment						
Visit	**Visit Date (Study Day)**	**Treatment Identifier**	**Prespecified Concomitant Nondrug Treatment**	**Treatment**	**Start Date (Study Day)**	**End Date or Ongoing (Study Day)**
COVID Illness Visit 1	02SEP2020 (7)	1	YES	HIGH FLOW OXYGEN THERAPY	05SEP2020 (10)	09SEP2020 (14)

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction							
Visit	**Visit Date (Study Day)**	**Subcategory of Clinical Event**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**End Date or Ongoing**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	02SEP2020 (7)	SIGNIFICANT ACUTE RENAL DYSFUNCTION	ACUTE RENAL AZOTEMIA	03SEP2020 (8)	ONGOING	2	Azotaemia
COVID Illness Visit 1	02SEP2020 (7)	SIGNIFICANT ACUTE HEPATIC DYSFUNCTION	ACUTE LIVER DYSFUNCTION	03SEP2020 (8)	09SEP2020 (14)	2	Hepatic function abnormal

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	02SEP2020 (7)	03SEP2020 (8)	Alkaline Phosphatase	1.2	ukat/L	0.65	1.95
			Alanine Aminotransferase	2.85057	ukat/L	0	0.73348
			Aspartate Aminotransferase	3.21731	ukat/L	0	0.6668
			Bilirubin	10.3	umol/L	0	20.5
			Creatinine	139.7	umol/L	67.2	112.3
			Urea Nitrogen	10.71	mmol/L	2.86	9.64
		05SEP2020 (10)	Alkaline Phosphatase	1.48	ukat/L	0.77	1.93
			Alanine Aminotransferase	2.60052	ukat/L	0.23338	1.05021
			Aspartate Aminotransferase	2.55051	ukat/L	0.25005	0.61679
			Bilirubin	5.1	umol/L	6.8	13.7
			Creatinine	123.8	umol/L	53	114.9
			C Reactive Protein	8	mg/L	0	9
			Urea Nitrogen	11.43	mmol/L	2.5	6.43

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	02SEP2020 (7)	05SEP2020 (10)	Basophils	0.3	%	0	3
			Eosinophils	0.1	%	0	6
			Hematocrit	0.46	L/L	0.42	0.52
			Hemoglobin	154	g/L	140	180
			Lymphocytes	14.7	%	18	46
			Monocytes	9	%	0	11
			Neutrophils	75.9	%	47	75
			Platelets	186	10^9/L	130	400
			Erythrocytes	5.14	10^12/L	4.7	6.1
			Leukocytes	6.3	10^9/L	4.8	10.8

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	02SEP2020 (7)	05SEP2020 (10)	1					88 %
		14SEP2020 (19)	2					84 %
		29SEP2020 (34)	3					89 %
		01OCT2020 (36)	4					92 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging								
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment
1	COVID Illness Visit 1	02SEP2020 (7)	05SEP2020	CHEST		X-RAY	NA	ABNORMAL
2	COVID Illness Visit 1	02SEP2020 (7)	08SEP2020	CHEST		X-RAY	NA	ABNORMAL
3	COVID Illness Visit 1	02SEP2020 (7)	12SEP2020	CHEST		X-RAY	NA	ABNORMAL
4	COVID Illness Visit 1	02SEP2020 (7)	14SEP2020	CHEST		X-RAY	NA	ABNORMAL
5	COVID Illness Visit 1	02SEP2020 (7)	30SEP2020	CHEST		X-RAY	NA	ABNORMAL

Imaging	
Assessment Number	If Abnormal, Specify Findings
1	Bibasilar diffuse mixed infiltrates. No focal infiltrates, effusions or pneumothoraces. Mild overinflation, chronic appearing diffuse interstitial prominence.
2	Bibasilar mixed infiltrates, greater to the LEFT. Mild overinflation mild, chronic appearing diffuse interstitial prominence.
3	Scattered alveolar interstitial changes are seen in the perihilar region and at the lung bases. Findings are consistent with atypical infiltrates.

Imaging	
Assessment Number	**If Abnormal, Specify Findings**
4	There are bilateral interstitial infiltrates within both lungs. Interval improvement is observed. No alveolar consolidation or pleural effusion is noted. No acute osseous abnormality is detected.
5	Chronic interstitial fibrosis in lungs, especially on right side with suggestion of patchy infiltrates in both lower lobes, especially on the left side. No evidence of pleural effusions.

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Withdrawn	VACCINATION	08SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1156 11561044, a 63-year-old white male with a height of 167.5 cm, a weight of 87.05 kg, and a BMI of 31 kg/m^2, received Dose 1 on 27 Aug 2020. The subject had a reported medical history of hypertension (since 2002), depression (since 2010), chronic obstructive pulmonary disease and hepatic steatosis (both since 2018), and type 2 diabetes mellitus (since 25 Feb 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 05 Sep 2020 (Day 10), the subject was diagnosed with severe COVID-19 pneumonia and reported new or increased sore throat, new or increased shortness of breath, new or increased muscle pain, new or increased cough, fever, diarrhea, and chills, with the first symptom starting on 01 Sep 2020, 5 days after receiving Dose 1, and the last symptom resolved on 29 Sep 2020. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 03 Sep 2020 (Day 8) was positive. The local laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on 03 Sep 2020 (Day 8), 08 Sep 2020 (Day 13), 09 Sep 2020 (Day 14), and 14 Sep 2020 (Day 19) were positive, and on 15 Sep 2020 (Day 20) the result was negative. The subject went to his primary care physician (5 times), to the emergency room (once), and to a specialist (once). The subject experienced significant acute renal dysfunction (moderate azotemia) and significant acute hepatic dysfunction (moderate) on 03 Sep 2020 (Day 8). On 03 Sep 2020 (Day 8), the subject's laboratory test results showed elevated alanine aminotransferase (ALT) of 2.85057 µkat/L (normal range [NR]: 0-0.73348 µkat/L), aspartate aminotransferase (AST) of 3.21731 µkat/L (NR: 0-0.6668 µkat/L), creatinine of 139.7 µmol/L (NR: 67.2-112.3 µmol/L), and blood urea nitrogen (BUN) of 10.71 mmol/L (NR: 2.86-9.64 mmol/L); alkaline phosphatase (ALP) and bilirubin were within normal limits. On 05 Sep 2020 (Day 10), the subject's laboratory test results showed elevated ALT of 2.60052 µkat/L (NR: 0.23338-1.05021 µkat/L), AST of 2.55051 µkat/L (NR: 0.25005-0.61679 µkat/L), creatinine of 123.8 µmol/L (NR: 53-114.9 µmol/L), BUN of 11.43 mmol/L (NR: 2.5-6.43 mmol/L), and neutrophils of 75.9% (NR: 47%-75%); and low bilirubin of 5.1 µmol/L (NR: 6.8-13.7 µmol/L) and lymphocytes of 14.7% (NR: 18%-46%); ALP, C-reactive protein, basophils, eosinophils, hematocrit, hemoglobin, monocytes, platelets, erythrocytes, and leukocytes were within normal limits. The subject was hospitalized in the intensive care unit (ICU) on 05 Sep 2020 (Day 10) for 15 days and was discharged on 19 Sep 2020 (Day 24). The subject had oxygen saturation results of 88% on 05 Sep 2020 (Day 10), 84% on 14 Sep 2020 (Day 19), 89% on room air on 29 Sep 2020 (Day 34), and 92% on room air on 01 Oct 2020 (Day 36). The subject required high-flow oxygen therapy from 05 Sep 2020 (Day 10) to 09 Sep 2020 (Day 14). The significant acute hepatic dysfunction resolved on 09 Sep 2020 (Day 14) and the significant acute renal dysfunction (azotemia) was ongoing as of the last available report. Chest radiographs revealed the following: bibasilar diffuse mixed infiltrates, no focal infiltrates, effusions, or pneumothoraxes, mild overinflation, and chronic-appearing diffuse interstitial prominence on 05 Sep 2020 (Day 10); bibasilar mixed infiltrates, greater to the left, mild overinflation, chronic-appearing diffuse interstitial prominence on 08 Sep 2020 (Day 13); scattered alveolar interstitial changes were observed in the perihilar region and at the lung bases, findings were consistent with atypical infiltrates on

Narrative Comment
12 Sep 2020 (Day 17); bilateral interstitial infiltrates within both lungs, interval improvement was observed, no alveolar consolidation or pleural effusion was noted, and no acute osseous abnormality was detected on 14 Sep 2020 (Day 19); and chronic interstitial fibrosis on the right side of the lungs, with patchy infiltrates in both lower lobes, especially on the left side; and no evidence of pleural effusions were observed on 30 Sep 2020 (Day 35). The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19, admission to an ICU, significant acute renal dysfunction, significant acute hepatic dysfunction, oxygen saturation of ≤93%, and requirement for high-flow oxygen therapy). The subject was discontinued from the study intervention on 08 Sep 2020 since he no longer met the eligibility criteria and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1987	33	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
170.18 cm	74 kg	25.5 kg/m2	09SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	09SEP2020 (1)	16:07
2	Placebo	16OCT2020 (38)	15:11
3	BNT162b2	08MAR2021 (181)	09:34

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	09SEP2020 (1)	09SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	09SEP2020 (1)	09SEP2020 (1)	SERUM	NEGATIVE
Visit 2	16OCT2020 (38)	16OCT2020 (38)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 07DEC2020 (90)/ 04DEC2020 (87)/ 30DEC2020 (113)	NO		Pain
	YES	NEW OR INCREASED SORE THROAT	
	NO		Headache
	YES	FEVER	
	YES	CHILLS	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	07DEC2020 (90)	Covid-19 Pneumonia	13DEC2020 (96)	2	COVID-19 pneumonia

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	07DEC2020 (90)	07DEC2020 (90)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	07DEC2020 (90)	12DEC2020 (95)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	Quidel Sofia 2 SARS Antigen FIA

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	07DEC2020 (90)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	07DEC2020 (90)	HOSPITALIZATION STATUS	HOSPITAL	12DEC2020 (95)	18DEC2020 (101)
COVID Illness Visit 1	07DEC2020 (90)	HOSPITALIZATION STATUS	ICU	12DEC2020 (95)	18DEC2020 (101)

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	18NOV2020	
Completed	REPEAT SCREENING 1	08MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1171 11711212, a 33-year-old Asian male with a height of 170.18 cm, a weight of 74 kg, and a BMI of 25.5 kg/m2, received Dose 1 on 09 Sep 2020 and Dose 2 on 16 Oct 2020 (Day 38). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 13 Dec 2020 (Day 96), the subject was diagnosed with severe COVID-19 pneumonia and reported pain, new or increased sore throat, headache, fever, and chills, with the first symptom starting on 04 Dec 2020, 49 days after receiving Dose 2, and the last symptom resolved on 30 Dec 2020. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 07 Dec 2020 (Day 90) was positive. The local laboratory SARS-CoV-2 Quidel Sofia 2 SARS antigen fluorescent immunoassay result at the time of the COVID-19 illness on 12 Dec 2020 (Day 95) was positive. The subject went to the emergency room (once). The subject was hospitalized on 12 Dec 2020 (Day 95) for 7 days and discharged on 18 Dec 2020 (Day 101). He was in the intensive care unit (ICU). The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and admission to an ICU). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first dose of BNT162b2 on 08 Mar 2021 (Day 181) and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	34	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185 cm	97 kg	28.3 kg/m2	04NOV2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04NOV2020 (1)	14:20

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	PSYCH	Anxiety	Anxiety	21NOV2020 (18)		04MAR2021 (121)		104	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (04MAR2021)	NOT RELATED/OTHER: related to the covid-19 disease	1	18	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Influenza vaccine	INFLUENZA VACCINE	15DEC2020
pneumococcal vaccine	PNEUMOCOCCAL VACCINE	15DEC2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	04NOV2020 (1)	04NOV2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	04NOV2020 (1)	04NOV2020 (1)	SERUM	NEGATIVE
Visit 2	10DEC2020 (37)	10DEC2020 (37)	NASAL_SWAB	POSITIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 12NOV2020 (9)/ 10NOV2020 (7)/ 09FEB2021 (98)	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Hyperhidrosis
	YES	FEVER	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW LOSS OF TASTE OR SMELL	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	12NOV2020 (9)	Covid-19	10NOV2020 (7)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	12NOV2020 (9)	12NOV2020 (9)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	12NOV2020 (9)	10NOV2020 (7)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	12NOV2020 (9)	16NOV2020 (13)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	CORONEX-COVID 19 RT-qPCR Test
2	POSITIVE		OTHER	NALT Unknown

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	12NOV2020 (9)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		SPECIALIST	YES	2	NA

Hospitalization Details					
Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	12NOV2020 (9)	HOSPITALIZATION STATUS	HOSPITAL	11NOV2020 (8)	16NOV2020 (13)
COVID Illness Visit 1	12NOV2020 (9)	HOSPITALIZATION STATUS	HOSPITAL	20NOV2020 (17)	29NOV2020 (26)

Respiratory Treatment

Visit	Visit Date (Study Day)	Treatment Identifier	Prespecified Concomitant Nondrug Treatment	Treatment	Start Date (Study Day)	End Date or Ongoing (Study Day)
COVID Illness Visit 1	12NOV2020 (9)	3	YES	HIGH FLOW OXYGEN THERAPY	22NOV2020 (19)	28NOV2020 (25)
COVID Illness Visit 1	12NOV2020 (9)	1	YES	NON-INVASIVE POSITIVE PRESSURE VENTILATION	20NOV2020 (17)	21NOV2020 (18)

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	12NOV2020 (9)	10NOV2020 (7)	Alkaline Phosphatase	1.23	ukat/L	0.5	2
			Alanine Aminotransferase	0.72014	ukat/L	0	0.8335
			Aspartate Aminotransferase	0.48176	ukat/L	0	0.8335
			Bilirubin	8	umol/L	5.1	20.5
			Creatinine	76	umol/L	59.2	103.4
			C Reactive Protein	6.56	mg/L	0	5
		16NOV2020 (13)	Alkaline Phosphatase	0.83	ukat/L	0.5	2
			Alanine Aminotransferase	1.69201	ukat/L	0	0.8335
			Aspartate Aminotransferase	0.81683	ukat/L	0	0.8335
			Bilirubin	9.2	umol/L	5.1	20.5
			Creatinine	67.2	umol/L	59.2	103.4
			C Reactive Protein	4.6	mg/L	0	5
			Urea Nitrogen	4.64	mmol/L	2.5	7.14
		20NOV2020 (17)	Alkaline Phosphatase	0.88	ukat/L	0.5	2
			Alanine Aminotransferase	2.68054	ukat/L	0	0.8335
			Aspartate Aminotransferase	1.11189	ukat/L	0	0.8335
			Bilirubin	10.1	umol/L	5.1	20.5
			Creatinine	82.2	umol/L	59.2	103.4
			C Reactive Protein	44.77	mg/L	0	5
			Urea Nitrogen	4.64	mmol/L	2.5	7.14
		23NOV2020 (20)	Alkaline Phosphatase	0.92	ukat/L	0.5	2
			Alanine Aminotransferase	3.65573	ukat/L	0	0.8335
			Aspartate Aminotransferase	1.27359	ukat/L	0	0.8335
			Bilirubin	8.7	umol/L	5.1	20.5
			Creatinine	71.6	umol/L	59.2	103.4

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
			C Reactive Protein	9.62	mg/L	0	5
			Urea Nitrogen	6.07	mmol/L	2.5	7.14
		29NOV2020 (26)	Alkaline Phosphatase	1.23	ukat/L	0.5	2
			Alanine Aminotransferase	3.11896	ukat/L	0	0.8335
			Aspartate Aminotransferase	0.60512	ukat/L	0	0.8335
			Bilirubin	7.4	umol/L	5.1	20.5
			Creatinine	76.9	umol/L	59.2	103.4
			C Reactive Protein	1.02	mg/L	0	5
			Urea Nitrogen	6.78	mmol/L	2.5	7.14

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	12NOV2020 (9)	10NOV2020 (7)	Basophils	0.027	10^9/L	0	0.1
			Eosinophils	0.095	10^9/L	0	0.5
			Hematocrit	0.43	L/L	0.37	0.47
			Hemoglobin	151.1	g/L	125	163
			Lymphocytes	0.83	10^9/L	1	3.2
			Monocytes	0.871	10^9/L	0.3	1.1
			Neutrophils	6.836	10^9/L	1.7	7.6
			Platelets	240.9	10^9/L	152	348
			Erythrocytes	5.1	10^12/L	4.06	5.63
			Leukocytes	8.66	10^9/L	3.6	10.2
		16NOV2020 (13)	Basophils	0.015	10^9/L	0	0.1
			Eosinophils	0	10^9/L	0	0.5
			Hematocrit	0.45	L/L	0.37	0.47
			Hemoglobin	161.7	g/L	125	163
			Lymphocytes	1.118	10^9/L	1	3.2
			Monocytes	0.386	10^9/L	0.3	1.1
			Neutrophils	5.596	10^9/L	1.7	7.6
			Platelets	200.6	10^9/L	152	348
			Erythrocytes	5.36	10^12/L	4.06	5.63
			Leukocytes	7.12	10^9/L	3.6	10.2
		20NOV2020 (17)	Basophils	0.031	10^9/L	0	0.1
			Eosinophils	0.001	10^9/L	0	0.5
			Hematocrit	0.43	L/L	0.37	0.47
			Hemoglobin	149.4	g/L	125	163
			Lymphocytes	1.226	10^9/L	1	3.2

Laboratory Results - Hematology							
Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
			Monocytes	0.939	10^9/L	0.3	1.1
			Neutrophils	8.717	10^9/L	1.7	7.6
			Platelets	208.8	10^9/L	152	348
			Erythrocytes	5.06	10^12/L	4.06	5.63
			Leukocytes	10.92	10^9/L	3.6	10.2
		23NOV2020 (20)	Basophils	0.048	10^9/L	0	0.1
			Eosinophils	0.053	10^9/L	0	0.5
			Hematocrit	0.43	L/L	0.37	0.47
			Hemoglobin	148.1	g/L	125	163
			Lymphocytes	1.858	10^9/L	1	3.2
			Monocytes	0.478	10^9/L	0.3	1.1
			Neutrophils	5.273	10^9/L	1.7	7.6
			Platelets	304.7	10^9/L	152	348
			Erythrocytes	5.15	10^12/L	4.06	5.63
			Leukocytes	7.71	10^9/L	3.6	10.2
		29NOV2020 (26)	Basophils	0.06	10^9/L	0	0.1
			Eosinophils	0.086	10^9/L	0	0.5
			Hematocrit	0.43	L/L	0.37	0.47
			Hemoglobin	145.3	g/L	125	163
			Lymphocytes	3.11	10^9/L	1	3.2
			Monocytes	1.327	10^9/L	0.3	1.1
			Neutrophils	13.698	10^9/L	1.7	7.6
			Platelets	397.6	10^9/L	152	348
			Erythrocytes	5.11	10^12/L	4.06	5.63
			Leukocytes	18.28	10^9/L	3.6	10.2

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	12NOV2020 (9)	11NOV2020 (8)	1					97 %
		12NOV2020 (9)	2	130 mmHg	80 mmHg	20 breaths/min	95 beats/min	
		20NOV2020 (17)	3	110 mmHg	70 mmHg	22 breaths/min	80 beats/min	94 %

Oxygenation Parameters				
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Arterial Blood Gases PaO2 (mmHg)	FiO2 (Fraction of Inhaled Oxygen)
COVID Illness Visit 1	12NOV2020 (9)	20NOV2020 (17)	65	0.69

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging						
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam
1	COVID Illness Visit 1	12NOV2020 (9)	14NOV2020	CHEST		CT SCAN

Imaging			
Assessment Number	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	NA	ABNORMAL	Report result: COVID-19 category 2; prevalent peripheral ground glass density of the bilateral lung.

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	04NOV2020	
Withdrawn	VACCINATION	10NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	04MAR2021	WITHDRAWAL BY SUBJECT

Narrative Comment
Subject C4591001 1217 12171044, a 34-year-old white male with a height of 185 cm, a weight of 97 kg, and a BMI of 28.3 kg/m^2, received Dose 1 on 04 Nov 2020.

Narrative Comment
The subject had no reported medical history.
The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and positive at Visit 2. The central laboratory N-binding antibody result was negative at Visit 1.
On 10 Nov 2020 (Day 7), the subject was diagnosed with severe COVID-19 and reported new or increased muscle pain, hyperhidrosis, fever, new or increased shortness of breath, and new loss of taste or smell, with the first symptom starting on 10 Nov 2020, 6 days after receiving Dose 1, and the last symptom resolved on 09 Feb 2021.
The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 12 Nov 2020 (Day 9) was positive.
The local laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on 10 Nov 2020 (Day 7) and on 16 Nov 2020 (Day 13) were positive.
The subject went to a specialist (twice).
On 10 Nov 2020 (Day 7), the subject's laboratory test results showed an elevated C-reactive protein of 6.56 mg/L (normal range [NR]: 0-5 mg/L) and low lymphocytes of 0.83×10^9/L (NR: 1-3.2 $\times 10^9$/L); alkaline phosphatase (ALP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin, creatinine, basophils, eosinophils, hematocrit, hemoglobin, monocytes, platelet count, erythrocytes, neutrophils, and leukocytes were within normal limits.
The subject was hospitalized on 11 Nov 2020 (Day 8) for 6 days and discharged on 16 Nov 2020 (Day 13).
On 11 Nov 2020 (Day 8), the subject had an oxygen saturation of 97%.
On 12 Nov 2020 (Day 9), the subject had a heart rate of 95 beats/min, blood pressure of 130/80 mmHg, and respiratory rate of 20 breaths/min.
On 14 Nov 2020 (Day 11), a computed tomography scan of the chest showed COVID-19 category 2; prevalent peripheral ground-glass density of the bilateral lung.
On 16 Nov 2020 (Day 13), the subject's laboratory test results showed an elevated ALT of 1.69201 µkat/L (NR: 0-0.8335 µkat/L); ALP, AST, bilirubin, creatinine, blood urea nitrogen (BUN), C-reactive protein, basophils, eosinophils, hematocrit, hemoglobin, platelet count, erythrocytes, lymphocytes, monocytes, neutrophils, and leukocytes were within normal limits.
The subject was again hospitalized on 20 Nov 2020 (Day 17) for 10 days and discharged on 29 Nov 2020 (Day 26).
On 20 Nov 2020 (Day 17), the subject's laboratory test results showed elevated ALT of 2.68054 µkat/L, AST of 1.11189 µkat/L (NR: 0-0.8335 µkat/L), C-reactive protein of 44.77 mg/L, neutrophils of 8.717×10^9/L (NR: 1.7-7.6 $\times 10^9$/L), and leukocytes of 10.92×10^9/L (NR: 3.6-10.2 $\times 10^9$/L); ALP, bilirubin, creatinine, BUN, basophils, eosinophils, hematocrit, hemoglobin, platelet count, erythrocytes, lymphocytes, and monocytes were within normal limits.
On 20 Nov 2020 (Day 17), the subject had a heart rate of 80 beats/min, blood pressure of 110/70 mmHg, respiratory rate of 22 breaths/min, and oxygen saturation of 94%.
On 20 Nov 2020 (Day 17), measurement of arterial blood gases revealed that the partial pressure of oxygen was 65 mmHg.
On 20 Nov 2020 (Day 17), measurement of the fraction of inspired oxygen (FiO_2) was 0.69.

Narrative Comment
The subject required noninvasive positive pressure ventilation from 20 Nov 2020 (Day 17) to 21 Nov 2020 (Day 18) and high-flow oxygen therapy from 22 Nov 2020 (Day 19) to 28 Nov 2020 (Day 25). On 23 Nov 2020 (Day 20), the subject's laboratory test results showed elevated ALT of 3.65573 µkat/L, AST of 1.27359 µkat/L, and C-reactive protein of 9.62 mg/L; ALP, bilirubin, creatinine, BUN, basophils, eosinophils, hematocrit, hemoglobin, platelet count, erythrocytes, lymphocytes, monocytes, neutrophils, and leukocytes were within normal limits. On 29 Nov 2020 (Day 26), the subject's laboratory test results showed elevated ALT of 3.11896 µkat/L, monocytes of 1.327×10^9/L (NR: 0.3-1.1 $\times 10^9$/L), neutrophils of 13.698×10^9/L, platelet count of 397.6×10^9/L (NR: 152-348 $\times 10^9$/L), and leukocytes of 18.28×10^9/L; ALP, AST, bilirubin, creatinine, BUN, basophils, eosinophils, hematocrit, hemoglobin, erythrocytes, C-reactive protein, and lymphocytes were within normal limits. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and requirement for noninvasive positive pressure ventilation and high-flow oxygen therapy). The subject was discontinued from the study intervention on 10 Nov 2020 since he no longer met the eligibility criteria and he requested withdrawal from the study on 04 Mar 2021.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	American Indian or Alaska Native	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	139.73 kg	40.6 kg/m2	13OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Diabetes Type 2	Type 2 diabetes mellitus	2000	Present
Kidney Stones	Nephrolithiasis	2004	Past
BPH	Benign prostatic hyperplasia	2019	Present
Congesutive Heart Failure	Cardiac failure congestive	JUL2019	Present
Coronary Stent placement	Coronary arterial stent insertion	JUL2019	Past
Circumcision	Circumcision	OCT2019	Past
Coronary Artery Disease	Coronary artery disease	15JUL2020	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypercholesterolemia	Hypercholesterolaemia	15JUL2020	Present
Hypertension	Hypertension	15JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13OCT2020 (1)	11:44
2	Placebo	02NOV2020 (21)	09:52
3	BNT162b2	01FEB2021 (112)	12:43
4	BNT162b2	22FEB2021 (133)	16:44

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	13OCT2020 (1)	13OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	13OCT2020 (1)	13OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 03NOV2020 (22)/ 01NOV2020 (20)/ 20NOV2020 (39)	YES	VOMITING	
	YES	CHILLS	
COVID Illness Visit 2 / 28FEB2021 (139)/ 26FEB2021 (137)/ 02MAR2021 (141)	NO		Nasal congestion
	YES	NEW OR INCREASED COUGH	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	CHILLS	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	03NOV2020 (22)	Viral Pneumonia secondary to COVID-19	03NOV2020 (22)	3	COVID-19 pneumonia
COVID Illness Visit 2	28FEB2021 (139)	COVID-19	04MAR2021 (143)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	03NOV2020 (22)	02NOV2020 (21)	NASAL_SWAB	POSITIVE
2	COVID Illness Visit 2	28FEB2021 (139)	27FEB2021 (138)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	03NOV2020 (22)	03NOV2020 (22)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 2	28FEB2021 (139)	04MAR2021 (143)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ABBOTT MOLECULAR REALTIME SARS-COV-2 ASSAY	
2	POSITIVE	Cepheid IQC4PLEX	CEPHEID XPERT XPRESS SARS-COV-2 TEST	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	03NOV2020 (22)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA
COVID Illness Visit 2	28FEB2021 (139)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	03NOV2020 (22)	HOSPITALIZATION STATUS	HOSPITAL	03NOV2020 (22)	06NOV2020 (25)

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	03NOV2020 (22)	03NOV2020 (22)	Alkaline Phosphatase	2.33	ukat/L	0.63	2.1
			Alanine Aminotransferase	0.8335	ukat/L	0	0.8335
			Aspartate Aminotransferase	0.90018	ukat/L	0.28339	0.98353
			Bilirubin	8.6	umol/L	3.4	22.2
			Creatinine	53	umol/L	61.9	114.9
			C Reactive Protein	<5	mg/L	0	5
			Urea Nitrogen	3.93	mmol/L	3.21	7.14

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	03NOV2020 (22)	03NOV2020 (22)	Basophils	0	10^9/L	0	0.5
			Eosinophils	0	10^9/L	0	1
			Hematocrit	0.48	L/L	0.41	0.49
			Hemoglobin	161	g/L	140	180
			Lymphocytes	0.8	10^9/L	0.9	4.4
			Monocytes	1	10^9/L	0	1
			Neutrophils	3.8	10^9/L	1.5	8
			Platelets	198	10^9/L	180	430
			Erythrocytes	0.01	10^12/L	0	0.01
			Leukocytes	5.7	10^9/L	4.5	11

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	03NOV2020 (22)	03NOV2020 (22)	1	153 mmHg	97 mmHg	32 breaths/min	72 beats/min	95 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging								
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment
1	COVID Illness Visit 1	03NOV2020 (22)	03NOV2020	CHEST		CT SCAN	NA	ABNORMAL
2	COVID Illness Visit 1	03NOV2020 (22)	03NOV2020	CHEST		X-RAY	NA	NORMAL

Imaging	
Assessment Number	If Abnormal, Specify Findings
1	Small patchy density in R Upper lobe, likely inflammatory/infectious with minor bibasilar subsegmental ateletasis; R coronary atherosclerosis vs. stent
2	

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13OCT2020	
Completed	VACCINATION	04DEC2020	
Completed	REPEAT SCREENING 1	01FEB2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1221 12211002, a 43-year-old American Indian or Alaska Native male with a height of 185.42 cm, a weight of 139.73 kg, and a BMI of 40.6 kg/m2, received Dose 1 on 13 Oct 2020 and Dose 2 on 02 Nov 2020 (Day 21). The subject had a reported medical history of type 2 diabetes mellitus (since 2000); nephrolithiasis (in 2004); benign prostatic hyperplasia (since 2019); congestive cardiac failure (since Jul 2019); coronary arterial stent insertion (in Jul 2019); circumcision (in Oct 2019); and coronary artery disease, hypercholesterolemia, and hypertension (all since 15 Jul 2020). The central laboratory SARS-CoV-2 NAAT result was negative at Visit 1. The central laboratory N-binding antibody result was negative at Visit 1. The subject experienced 2 protocol-defined COVID-19 illnesses. On 03 Nov 2020 (Day 22), the subject was diagnosed with severe COVID-19 pneumonia for the first time and reported vomiting and chills, with the first symptom starting on 01 Nov 2020, 19 days after receiving Dose 1, and the last symptom resolved on 20 Nov 2020. The central laboratory SARS-CoV-2 NAAT result at the time of the first COVID-19 illness on 02 Nov 2020 (Day 21) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the first COVID-19 illness on 03 Nov 2020 (Day 22) was positive. The subject went to the emergency room (once) at the time of the first COVID-19 illness. On 03 Nov 2020 (Day 22), the subject had a heart rate of 72 beats/min, blood pressure of 153/97 mmHg, respiratory rate of 32 breaths/min, and oxygen saturation of 95%. The subject was hospitalized on 03 Nov 2020 (Day 22) for 4 days and discharged on 06 Nov 2020 (Day 25). A chest radiograph on 03 Nov 2020 (Day 22) was normal. A computed tomography scan of the chest on 03 Nov 2020 (Day 22) was abnormal with findings of small patchy density in the right upper lobe, likely inflammatory/infectious with minor bibasilar subsegmental atelectasis; right coronary atherosclerosis with stent in place. On 03 Nov 2020 (Day 22), the subject's laboratory test results showed elevated alkaline phosphatase of 2.33 µkat/L (normal range [NR]: 0.63-2.1 µkat/L); and low creatinine of 53 µmol/L (NR: 61.9-114.9 µmol/L) and lymphocyte count of 0.8 × 109/L (NR: 0.9-4.4 × 109/L); alanine aminotransferase, aspartate aminotransferase, bilirubin, C-reactive protein, blood urea nitrogen, basophils, eosinophils, hematocrit, hemoglobin, monocytes, neutrophils, platelets, erythrocytes, and leukocytes were all within normal limits. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and respiratory rate >30 breaths/min). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 01 Feb 2021 (Day 112) and 22 Feb 2021 (Day 133), respectively, and remains in the study. On 04 Mar 2021 (Day 143), the subject was diagnosed with severe COVID-19 for the second time and reported nasal congestion, new or increased cough, new loss of taste or smell, and chills, with the first symptom starting on 26 Feb 2021, 4 days after receiving the second dose of BNT162b2, and the last symptom resolved on 02 Mar 2021, 8 days after receiving the second dose of BNT162b2. The central laboratory SARS-CoV-2 NAAT result at the time of the second COVID-19 illness on 27 Feb 2021 (Day 138) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the second COVID-19 illness on 04 Mar 2021 (Day 143) was positive. The subject did not have any contact with nonstudy healthcare personnel at the time of the second COVID-19 illness.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	81.82 kg	25.8 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2015	Present
Hyperlipidemia	Hyperlipidaemia	AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	12:51
2	Placebo	04NOV2020 (20)	14:51

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Malaise	malaise	05NOV2020 (21)	08:00	06NOV2020 (22)	09:00
2	MUSC	Pain in extremity	left arm pain	04NOV2020 (20)	19:00	06NOV2020 (22)	09:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	2	N	N	Resolved (06NOV2020)	Study Treatment	2	2	N
2	3	1	N	N	Resolved (06NOV2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	16OCT2020 (1)	16OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16OCT2020 (1)	16OCT2020 (1)	SERUM	NEGATIVE
Visit 2	04NOV2020 (20)	04NOV2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19

Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 19JAN2021 (96)/ 10JAN2021 (87)/ 25JAN2021 (102)	NO		Seizure
	NO		Nausea
	NO		Fatigue
	YES	FEVER	

Diagnosis of Potential COVID-19 Illness

Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	19JAN2021 (96)	COVID-19 ILLNESS	15JAN2021 (92)	3	COVID-19

SARS-COV-2 Test - Central Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	19JAN2021 (96)	11JAN2021 (88)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	19JAN2021 (96)	15JAN2021 (92)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	19JAN2021 (96)	20JAN2021 (97)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	CLIA certified lab
2	POSITIVE		HOLOGIC PANTHER FUSION SARS-COV-2	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	19JAN2021 (96)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	19JAN2021 (96)	HOSPITALIZATION STATUS	ICU	19JAN2021 (96)	26JAN2021 (103)

Respiratory Treatment

Visit	Visit Date (Study Day)	Treatment Identifier	Prespecified Concomitant Nondrug Treatment	Treatment	Start Date (Study Day)	End Date or Ongoing (Study Day)
COVID Illness Visit 1	19JAN2021 (96)	1	YES	MECHANICAL VENTILATION	19JAN2021 (96)	21JAN2021 (98)

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	19JAN2021 (96)	19JAN2021 (96)	Alkaline Phosphatase	0.98	ukat/L	0.15	2.03
			Alanine Aminotransferase	0.31673	ukat/L	0.15003	0.98353
			Aspartate Aminotransferase	0.56678	ukat/L	0.1667	0.58345
			Bilirubin	8.6	umol/L	0	20.5
			Creatinine	94.6	umol/L	35.4	114.9
			C Reactive Protein	9.7	mg/L	1	1
			Urea Nitrogen	5	mmol/L	2.14	7.14

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	19JAN2021 (96)	19JAN2021 (96)	Basophils	0.3	%	0	4
			Eosinophils	0	%	0	7
			Hematocrit	0.4	L/L	0.37	0.52
			Hemoglobin	135	g/L	120	180
			Lymphocytes	11.8	%	8	49
			Monocytes	13.1	%	4	15
			Neutrophils	6.9	10^9/L	1	11
			Platelets	208	10^9/L	140	440

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	19JAN2021 (96)	19JAN2021 (96)	1	125 mmHg	72 mmHg	29 breaths/min	102 beats/min	97 %

Oxygenation Parameters				
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Arterial Blood Gases PaO2 (mmHg)	FiO2 (Fraction of Inhaled Oxygen)
COVID Illness Visit 1	19JAN2021 (96)	19JAN2021 (96)	162	1

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging					
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify
1	COVID Illness Visit 1	19JAN2021 (96)	19JAN2021	CHEST	
2	COVID Illness Visit 1	19JAN2021 (96)	20JAN2021	HEAD	

Imaging				
Assessment Number	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	X-RAY	NA	ABNORMAL	SMALL bilateral pleural effusion and bibasilar opacity
2	MRI	NA	NORMAL	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
Completed	VACCINATION	04DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1223 12231252, a 48-year-old white male with a height of 177.8 cm, a weight of 81.82 kg, and a BMI of 25.8 kg/m2, received Dose 1 on 16 Oct 2020 and Dose 2 on 04 Nov 2020 (Day 20). The subject had a reported medical history of hypertension (since 2015) and hyperlipidemia (since Aug 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 15 Jan 2021 (Day 92), the subject was diagnosed with severe COVID-19 and reported seizure, nausea, fatigue, and fever, with the first symptom starting on 10 Jan 2021, 67 days after receiving Dose 2, and the last symptom resolved on 25 Jan 2021. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Jan 2021 (Day 88) was positive. The local laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on 15 Jan 2021 (Day 92) and 20 Jan 2021 (Day 97) were positive. The subject went to the emergency room (once). The subject was hospitalized on 19 Jan 2021 (Day 96) for 8 days and discharged on 26 Jan 2021 (Day 103). He was in the intensive care unit (ICU). On 19 Jan 2021 (Day 96), the subject had a heart rate of 102 beats/min, blood pressure of 125/72 mmHg, respiratory rate of 29 breaths/min, and oxygen saturation of 97%. The subject was on mechanical ventilation from 19 Jan 2021 (Day 96) to 21 Jan 2021 (Day 98). On 19 Jan 2021 (Day 96), the measurement of arterial blood gases revealed that the partial pressure of oxygen was 162 mmHg and measurement of the fraction of inspired oxygen was 1. On 19 Jan 2021 (Day 96), a chest x-ray showed small bilateral pleural effusion and bibasilar opacity, and on 20 Jan 2021 (Day 97), a magnetic resonance imaging of the head was normal. On 19 Jan 2021 (Day 96), the subject's laboratory test results showed elevated C-reactive protein of 9.7 mg/L (normal range: ≤1.0 mg/L); alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, bilirubin, creatinine, blood urea nitrogen, basophils, eosinophils, hematocrit, hemoglobin, monocytes, neutrophils, lymphocytes, and platelets were all within normal limits. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19, admission to an ICU, and requirement for mechanical ventilation).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.9 cm	71.3 kg	27.5 kg/m2	07SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
headache	Headache	2010	Present
Albright's osteodystrophy	Congenital osteodystrophy	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07SEP2020 (1)	13:18
2	BNT162b2	02OCT2020 (26)	13:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Fatigue	fatigue	07SEP2020 (1)	20:00	10SEP2020 (4)		4	1
2	MUSC	Myalgia	myalgia	07SEP2020 (1)	20:00	10SEP2020 (4)		4	1
3	EYE	Ulcerative keratitis	corneal ulcer right eye	20SEP2020 (14)		27SEP2020 (21)		8	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (10SEP2020)	Study Treatment	1	1	N
2	TC	N	Resolved (10SEP2020)	Study Treatment	1	1	N
3	TC	N	Resolved (27SEP2020)	NOT RELATED/OTHER: prolonged use of contact lens	1	14	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	07SEP2020 (1)	07SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	07SEP2020 (1)	07SEP2020 (1)	SERUM	NEGATIVE
Visit 2	02OCT2020 (26)	02OCT2020 (26)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 07NOV2020 (62)/ 06NOV2020 (61)/ 13NOV2020 (68)	NO		Rhinitis
	YES	NEW OR INCREASED SORE THROAT	
	YES	NEW OR INCREASED COUGH	
	YES	NEW LOSS OF TASTE OR SMELL	
COVID Illness Visit 2 / 06FEB2021 (153)/ 04FEB2021 (151)/ ONGOING	YES	NEW OR INCREASED SORE THROAT	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Rhinorrhoea
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	07NOV2020 (62)	COVID-19	07NOV2020 (62)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	07NOV2020 (62)	07NOV2020 (62)	NASAL_SWAB	POSITIVE
2	COVID Illness Visit 1	07NOV2020 (62)	11NOV2020 (66)	NASAL_SWAB_SELF	POSITIVE
3	COVID Illness Visit 2	06FEB2021 (153)	06FEB2021 (153)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	07NOV2020 (62)	07NOV2020 (62)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT Unknown

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	07NOV2020 (62)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 2	06FEB2021 (153)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	07NOV2020 (62)	07NOV2020 (62)	1	133 mmHg	92 mmHg	16 breaths/min	89 beats/min	93 %
COVID Illness Visit 2	06FEB2021 (153)	06FEB2021 (153)	2	139 mmHg	93 mmHg	16 breaths/min	78 beats/min	99 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07SEP2020	
Completed	VACCINATION	03NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261599, a 41-year-old white female with a height of 160.9 cm, a weight of 71.3 kg, and a BMI of 27.5 kg/m2, received Dose 1 on 07 Sep 2020 and Dose 2 on 02 Oct 2020 (Day 26). The subject had a reported medical history of headache (since 2010) and congenital osteodystrophy (since 2017). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 07 Nov 2020 (Day 62), the subject was diagnosed with severe COVID-19 and reported rhinitis, new or increased sore throat, new or increased cough, and new loss of taste or smell, with the first symptom starting on 06 Nov 2020, 35 days after receiving Dose 2, and the last symptom resolved on 13 Nov 2020. The central laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on 07 Nov 2020 (Day 62) and 11 Nov 2020 (Day 66) were positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 07 Nov 2020 (Day 62) was positive. The subject did not have any contact with nonstudy healthcare personnel. On 07 Nov 2020 (Day 62), the subject had a heart rate of 89 beats/min, blood pressure of 133/92 mmHg, respiratory rate of 16 breaths/min, and oxygen saturation of 93% on room air. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and oxygen saturation ⩽93%).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184.3 cm	91.1 kg	26.8 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasectomy	Vasectomy	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	11:46
2	Placebo	30SEP2020 (23)	13:30

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	08FEB2021 (154)	10:30
4	BNT162b2	01MAR2021 (175)	10:25

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Chills	08FEB2021 (154)	18:00	08FEB2021 (154)	20:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	2	TC	N	Resolved (08FEB2021)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	08SEP2020 (1)	08SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	08SEP2020 (1)	08SEP2020 (1)	SERUM	NEGATIVE
Visit 2	30SEP2020 (23)	30SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 05NOV2020 (59)/ 02NOV2020 (56)/ 14NOV2020 (68)	NO		Rhinorrhoea
	YES	NEW OR INCREASED SORE THROAT	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED COUGH	
	NO		Fatigue
	YES	CHILLS	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	05NOV2020 (59)	05NOV2020 (59)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	05NOV2020 (59)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	05NOV2020 (59)	05NOV2020 (59)	1	132 mmHg	78 mmHg	16 breaths/min	83 beats/min	92 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	29OCT2020	
Completed	REPEAT SCREENING 1	08FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261624, a 52-year-old white male with a height of 184.3 cm, a weight of 91.1 kg, and a BMI of 26.8 kg/m2, received Dose 1 on 08 Sep 2020 and Dose 2 on 30 Sep 2020 (Day 23). The subject had a reported medical history of vasectomy (since 2010). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported rhinorrhea, new or increased sore throat, new or increased shortness of breath, new or increased muscle pain, new or increased cough, fatigue, and chills, with the first symptom starting on 02 Nov 2020, 33 days after receiving Dose 2, and the last symptom resolved on 14 Nov 2020. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 05 Nov 2020 (Day 59) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel. On 05 Nov 2020 (Day 59), the subject had a heart rate of 83 beats/min, blood pressure of 132/78 mmHg, respiratory rate of 16 breaths/min, and oxygen saturation of 92% on room air. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and oxygen saturation ≤93%). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 08 Feb 2021 (Day 154) and 01 Mar 2021 (Day 175), respectively, and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	71 kg	27.7 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
breast cancer	Breast cancer	1995	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07AUG2020 (1)	14:18
2	Placebo	26AUG2020 (20)	12:05

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	11FEB2021 (189)	15:12
4	BNT162b2	03MAR2021 (209)	11:01

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	07AUG2020 (1)	07AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	07AUG2020 (1)	07AUG2020 (1)	SERUM	NEGATIVE
Visit 2	26AUG2020 (20)	26AUG2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 08JAN2021 (155)/ 06JAN2021 (153)/ 14JAN2021 (161)	NO		Asthenia
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	08JAN2021 (155)	SARS-CoV-2 pneumonia	11JAN2021 (158)	3	COVID-19 pneumonia

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	08JAN2021 (155)	08JAN2021 (155)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	08JAN2021 (155)	08JAN2021 (155)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	08JAN2021 (155)	08JAN2021 (155)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	POSITIVE		OTHER	NALT unknown

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	08JAN2021 (155)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA
		OTHER	YES	1	home doctor

Hospitalization Details					
Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	08JAN2021 (155)	HOSPITALIZATION STATUS	HOSPITAL	08JAN2021 (155)	14JAN2021 (161)

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry							
Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	08JAN2021 (155)	08JAN2021 (155)	C Reactive Protein	56.64	mg/L	0	5

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	08JAN2021 (155)	08JAN2021 (155)	Basophils	0	%	0	1
			Eosinophils	0	%	1	4
			Hematocrit	0.35	L/L	0.36	0.42
			Hemoglobin	119	g/L	120	150
			Lymphocytes	11	%	25	40
			Monocytes	5	%	4	10
			Neutrophils	83	%	50	70
			Platelets	230	10^9/L	150	450
			Leukocytes	4.94	10^9/L	5	10

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	08JAN2021 (155)	08JAN2021 (155)	1					89 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging								
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment
1	COVID Illness Visit 1	08JAN2021 (155)	08JAN2021	CHEST		CT SCAN	NA	ABNORMAL

Imaging	
Assessment Number	If Abnormal, Specify Findings
1	Multiple opacities with ground glass density distributed in both hemithoraxes are evidenced, compromising the subpleural lung parenchyma, compatible with a viral inflammatory process.

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	29SEP2020	
Completed	REPEAT SCREENING 1	11FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311014, a 62-year-old white female with a height of 160 cm, a weight of 71 kg, and a BMI of 27.7 kg/m2, received Dose 1 on 07 Aug 2020 and Dose 2 on 26 Aug 2020 (Day 20). The subject had a reported medical history of breast cancer (in 1995). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 11 Jan 2021 (Day 158), the subject was diagnosed with severe COVID-19 pneumonia and reported asthenia and new or increased shortness of breath, with the first symptom starting on 06 Jan 2021, 133 days after receiving Dose 2, and the last symptom resolved on 14 Jan 2021. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 08 Jan 2021 (Day 155) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 08 Jan 2021 (Day 155) was positive. The subject had a telephone consultation (once) and went to her home doctor (once). The subject was hospitalized on 08 Jan 2021 (Day 155) for 7 days and discharged on 14 Jan 2021 (Day 161). On 08 Jan 2021 (Day 155), the subject's oxygen saturation level was 89%. On 08 Jan 2021 (Day 155), a computed tomography scan of the chest revealed multiple opacities with ground-glass density distributed in both hemithoraxes compromising the subpleural lung parenchyma, which was compatible with a viral inflammatory process. On 08 Jan 2021 (Day 155), the laboratory results for basophils, eosinophils, monocytes, and platelets were normal; however, the subject's C-reactive protein and neutrophils were elevated at 56.64 mg/L (normal range [NR]: 0-5 mg/L) and 83% (NR: 50-70%), respectively, and the hematocrit, hemoglobin, lymphocytes, and leukocytes were all low at 35% (NR: 36%-42%), 119 g/L (NR: 120-150 g/L), 11% (NR: 25%-40%), and 4.94 × 109/L (NR: 5-10 × 109/L), respectively. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and oxygen saturation ⩽93%). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 11 Feb 2021 (Day 189) and 03 Mar 2021 (Day 209), respectively, and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	35	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	73.75 kg	24.9 kg/m2	20AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	17:40
3	BNT162b2	20FEB2021 (185)	12:40
4	BNT162b2	12MAR2021 (205)	11:48

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
2	INFEC	Otitis externa	External otitis	08MAR2021 (201)	09:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	1	TC	N	Yes	NOT RELATED/OTHER: swimming in the pool	3	17	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	20AUG2020 (1)	20AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	20AUG2020 (1)	20AUG2020 (1)	SERUM	NEGATIVE
Visit 2	14OCT2020 (56)	14OCT2020 (56)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No
COVID Illness Visit 2	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11SEP2020 (23)/ 11SEP2020 (23)/ 23SEP2020 (35)	YES	NEW OR INCREASED COUGH	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Asthenia
COVID Illness Visit 2 / 26NOV2020 (99)/ 26NOV2020 (99)/ 27NOV2020 (100)	YES	VOMITING	
	NO		Headache

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	11SEP2020 (23)	COVID disease with nonspecific symptoms	11SEP2020 (23)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	11SEP2020 (23)	11SEP2020 (23)	NASAL_SWAB	POSITIVE
2	COVID Illness Visit 2	26NOV2020 (99)	26NOV2020 (99)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	11SEP2020 (23)	11SEP2020 (23)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 2	26NOV2020 (99)	26NOV2020 (99)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	11SEP2020 (23)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 2	26NOV2020 (99)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Withdrawn	VACCINATION	14OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
Completed	REPEAT SCREENING 1	20FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312660, a 35-year-old white male with a height of 172 cm, a weight of 73.75 kg, and a BMI of 24.9 kg/m2, received Dose 1 on 20 Aug 2020. The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject experienced 2 protocol-defined COVID-19 illnesses. On 11 Sep 2020 (Day 23), the subject was diagnosed with COVID-19 for the first time and reported new or increased cough, new loss of taste or smell, new or increased sore throat, and asthenia, with the first symptom starting on 11 Sep 2020, 22 days after receiving Dose 1, and the last symptom resolved on 23 Sep 2020. The subject was discontinued from the study intervention on 14 Oct 2020 since he no longer met the eligibility criteria. The subject experienced a second COVID-19 illness and reported vomiting and headache, with the first symptom starting on 26 Nov 2020, 98 days after receiving Dose 1, and the last symptom resolved on 27 Nov 2020. The central laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illnesses on 11 Sep 2020 (Day 23) and 26 Nov 2020 (Day 99) were positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Sep 2020 (Day 23) was positive and on 26 Nov 2020 (Day 99) the result was negative. The subject did not have any contact with nonstudy healthcare personnel at the time of the COVID-19 illnesses. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 20 Feb 2021 (Day 185) and 12 Mar 2021 (Day 205), respectively, and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	32	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	97 kg	31.7 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Psoriasis	Psoriasis	02MAR2002	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	18:11

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	11SEP2020 (23)	11:00
3	BNT162b2	26FEB2021 (191)	16:17

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	20AUG2020 (1)	20AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	20AUG2020 (1)	20AUG2020 (1)	SERUM	NEGATIVE
Visit 2	11SEP2020 (23)	11SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No
COVID Illness Visit 2	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 19SEP2020 (31)/ 14SEP2020 (26)/ 12NOV2020 (85)	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED COUGH	
	YES	FEVER	
	NO		Fatigue
	YES	DIARRHEA	
COVID Illness Visit 2 / 12FEB2021 (177)/ 08FEB2021 (173)/ 17FEB2021 (182)	YES	NEW OR INCREASED SORE THROAT	
	NO		Headache
	YES	DIARRHEA	
	YES	FEVER	
	NO		Arthralgia

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	19SEP2020 (31)	covid-19	20SEP2020 (32)	1	COVID-19
COVID Illness Visit 2	12FEB2021 (177)	pharyngitis	12FEB2021 (177)	2	Pharyngitis

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	19SEP2020 (31)	19SEP2020 (31)	NASAL_SWAB	POSITIVE
2	COVID Illness Visit 2	12FEB2021 (177)	12FEB2021 (177)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	19SEP2020 (31)	19SEP2020 (31)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 2	12FEB2021 (177)	12FEB2021 (177)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	19SEP2020 (31)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 2	12FEB2021 (177)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	home doctor

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	14NOV2020	
Completed	REPEAT SCREENING 1	26FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1231 12312679, a 32-year-old white male with a height of 175 cm, a weight of 97 kg, and a BMI of 31.7 kg/m2, received Dose 1 on 20 Aug 2020 and Dose 2 on 11 Sep 2020 (Day 23).
The subject had a reported medical history of psoriasis (since 02 Mar 2002).
The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1.
The subject experienced 2 protocol-defined COVID-19 illnesses.
On 20 Sep 2020 (Day 32), the subject was diagnosed with COVID-19 for the first time and reported new or increased muscle pain, new or increased cough, fever, fatigue, and diarrhea, with the first symptom starting on 14 Sep 2020, 3 days after receiving Dose 2, and the last symptom resolved on 12 Nov 2020.
On 12 Feb 2021 (Day 177), the subject experienced a second COVID-19 illness and was diagnosed with pharyngitis and reported new or increased sore throat, headache, diarrhea, fever, and arthralgia, with the first symptom starting on 08 Feb 2021, 150 days after receiving Dose 2, and the last symptom resolved on 17 Feb 2021.
The central laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illnesses on 19 Sep 2020 (Day 31) and 12 Feb 2021 (Day 177) were positive.
The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 19 Sep 2020 (Day 31) was positive and on 12 Feb 2021 (Day 177) the result was negative.
The subject did not have any contact with nonstudy healthcare personnel at the time of the first COVID-19 illness. He went to his home doctor (once) at the time of the second COVID-19 illness.
In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first dose of BNT162b2 on 26 Feb 2021 (Day 191) and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171 cm	103 kg	35.2 kg/m2	21AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	16:00
2	Placebo	14SEP2020 (25)	11:00

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21AUG2020 (1)	21AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21AUG2020 (1)	21AUG2020 (1)	SERUM	NEGATIVE
Visit 2	14SEP2020 (25)	14SEP2020 (25)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 2	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 25AUG2020 (5)/ 24AUG2020 (4)/ 16SEP2020 (27)	NO		Rhinorrhoea
	YES	NEW OR INCREASED SORE THROAT	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED COUGH	

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 2 / 29OCT2020 (70)/ 26OCT2020 (67)/ 17NOV2020 (89)	NO		Paroxysmal arrhythmia
	YES	NEW OR INCREASED SORE THROAT	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED COUGH	
	NO		Headache
	NO		Fatigue
	YES	FEVER	
	NO		Atrioventricular block second degree
COVID Illness Visit 3 / 03MAR2021 (195)/ 17FEB2021 (181)/ 06MAR2021 (198)	YES	NEW OR INCREASED COUGH	
	NO		Headache
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 2	29OCT2020 (70)	COVID-19 mild pneumonia	06NOV2020 (78)	2	COVID-19 pneumonia
COVID Illness Visit 3	03MAR2021 (195)	Pharyngitis	03MAR2021 (195)	1	Pharyngitis

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	25AUG2020 (5)	25AUG2020 (5)	NASAL_SWAB	NEGATIVE
2	COVID Illness Visit 2	29OCT2020 (70)	29OCT2020 (70)	NASAL_SWAB	POSITIVE
3	COVID Illness Visit 3	03MAR2021 (195)	03MAR2021 (195)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	25AUG2020 (5)	25AUG2020 (5)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	25AUG2020 (5)	10SEP2020 (21)	SWABBED MATERIAL	NASOPHARYNX
3	COVID Illness Visit 2	29OCT2020 (70)	29OCT2020 (70)	SWABBED MATERIAL	NASOPHARYNX
4	COVID Illness Visit 3	03MAR2021 (195)	03MAR2021 (195)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
3	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
4	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	25AUG2020 (5)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 2	29OCT2020 (70)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	3	NA
COVID Illness Visit 3	03MAR2021 (195)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details					
Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 2	29OCT2020 (70)	HOSPITALIZATION STATUS	HOSPITAL	06NOV2020 (78)	14NOV2020 (86)

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 2	29OCT2020 (70)	10NOV2020 (82)	Alkaline Phosphatase	59	mg/dL	.	.
			Alanine Aminotransferase	1.21691	ukat/L	.	.
			Aspartate Aminotransferase	166	mg/dL	.	.
			Bilirubin	13.7	umol/L	.	.
			Creatinine	96.4	umol/L	.	.
			C Reactive Protein	0	mg/L	.	.

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 2	29OCT2020 (70)	10NOV2020 (82)	Hematocrit	0.42	L/L	.	.
			Hemoglobin	146	g/L	.	.
			Platelets	400	10^9/L	.	.

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 2	29OCT2020 (70)	06NOV2020 (78)	1					92 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 2	29OCT2020 (70)	02NOV2020	CHEST		X-RAY	NA	ABNORMAL	Right lung base abnormal.
2	COVID Illness Visit 2	29OCT2020 (70)	06NOV2020	CHEST		CT SCAN	NA	ABNORMAL	Right lung base infiltration.

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	16OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312914, a 50-year-old white male with a height of 171 cm, a weight of 103 kg, and a BMI of 35.2 kg/m2, received Dose 1 on 21 Aug 2020 and Dose 2 on 14 Sep 2020 (Day 25). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 06 Nov 2020 (Day 78), the subject was diagnosed with severe COVID-19 pneumonia and reported paroxysmal arrhythmia, new or increased sore throat, new or increased muscle pain, new or increased cough, headache, fatigue, fever, and second-degree atrioventricular block, with the first symptom starting on 26 Oct 2020, 42 days after receiving Dose 2, and the last symptom resolved on 17 Nov 2020. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 70) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 70) was positive. The subject went to the emergency room (3 times). On 02 Nov 2020 (Day 74), a chest radiograph revealed an abnormal right lung base. The subject was admitted to the hospital on 06 Nov 2020 (Day 78) for 9 days and discharged on 14 Nov 2020 (Day 86). On 06 Nov 2020 (Day 78), the subject had an oxygen saturation of 92%. On the same day (Day 78), a computed tomography scan of the chest revealed right lung base infiltration. On 10 Nov 2020 (Day 82), the subject's laboratory test results showed alkaline phosphatase of 59 mg/dL, alanine aminotransferase of 1.21691 µkat/L, aspartate aminotransferase of 166 mg/dL, bilirubin of 13.7 µmol/L, creatinine of 96.4 µmol/L, C-reactive protein of 0 mg/L, hematocrit of 42.2%, hemoglobin of 14.6 g/dL, and platelets of 400×109/L (normal ranges were unknown). The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and oxygen saturation ≤93%).

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1986	34	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
172 cm	88 kg	29.7 kg/m2	23AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	23AUG2020 (1)	12:15
2	Placebo	15SEP2020 (24)	19:05

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	29JAN2021 (160)	14:36
4	BNT162b2	18FEB2021 (180)	15:35

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	23AUG2020 (1)	23AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	23AUG2020 (1)	23AUG2020 (1)	SERUM	NEGATIVE
Visit 2	15SEP2020 (24)	15SEP2020 (24)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 29OCT2020 (68)/ 28OCT2020 (67)/ 27DEC2020 (127)	NO		Tachypnoea
	NO		Salivary hypersecretion
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED COUGH	
	NO		Headache
	YES	FEVER	
	YES	DIARRHEA	
	NO		Asthenia

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	29OCT2020 (68)	COVID-19 and Bilateral pneumonia	02NOV2020 (72)	4	COVID-19 pneumonia

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	29OCT2020 (68)	29OCT2020 (68)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	29OCT2020 (68)	29OCT2020 (68)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	29OCT2020 (68)	01NOV2020 (71)	SWABBED MATERIAL	NASOPHARYNX
3	COVID Illness Visit 1	29OCT2020 (68)	19NOV2020 (89)	SWABBED MATERIAL	

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	POSITIVE	swab performed at the san camilo clinic	OTHER	NALT unknown
3	NEGATIVE		OTHER	NALT unknown

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	29OCT2020 (68)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details					
Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	29OCT2020 (68)	HOSPITALIZATION STATUS	ICU	01NOV2020 (71)	23NOV2020 (93)
COVID Illness Visit 1	29OCT2020 (68)	HOSPITALIZATION STATUS	HOSPITAL	01NOV2020 (71)	23NOV2020 (93)
COVID Illness Visit 1	29OCT2020 (68)	HOSPITALIZATION STATUS	ICU	06NOV2020 (76)	19NOV2020 (89)

Respiratory Treatment						
Visit	Visit Date (Study Day)	Treatment Identifier	Prespecified Concomitant Nondrug Treatment	Treatment	Start Date (Study Day)	End Date or Ongoing (Study Day)
COVID Illness Visit 1	29OCT2020 (68)	1	YES	MECHANICAL VENTILATION	06NOV2020 (76)	16NOV2020 (86)

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry							
Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	29OCT2020 (68)	06NOV2020 (76)	Alkaline Phosphatase	1.12	ukat/L	0.63	2.1
			Alanine Aminotransferase	1.76702	ukat/L	0.25005	0.75015
			Aspartate Aminotransferase	0.8335	ukat/L	0.08335	0.6668
			Bilirubin	12	umol/L	3.4	20.5
			Creatinine	70.7	umol/L	53	110.5
			C Reactive Protein	149.89	mg/L	0.1	10
			Urea Nitrogen	12.14	mmol/L	5	16.07
		07NOV2020 (77)	Alkaline Phosphatase	0.95	ukat/L	0.63	2.1
			Alanine Aminotransferase	1.26692	ukat/L	0.25005	0.75015
			Aspartate Aminotransferase	0.5001	ukat/L	0.08335	0.6668
			Bilirubin	10.3	umol/L	3.4	20.5
			Creatinine	70.7	umol/L	53	110.5
			C Reactive Protein	149.89	mg/L	0.1	10
			Urea Nitrogen	14.28	mmol/L	5	16.07
		10NOV2020 (80)	Alkaline Phosphatase	1.15	ukat/L	0.63	2.1
			Alanine Aminotransferase	3.95079	ukat/L	0.25005	0.75015
			Aspartate Aminotransferase	1.56698	ukat/L	0.08335	0.6668
			Bilirubin	5.1	umol/L	3.4	20.5
			Creatinine	53	umol/L	53	106.1
			Urea Nitrogen	16.43	mmol/L	5	16.07
		17NOV2020 (87)	Alkaline Phosphatase	4.43	ukat/L	0.63	2.1
			Alanine Aminotransferase	13.08595	ukat/L	0.25005	0.75015
			Aspartate Aminotransferase	1.96706	ukat/L	0.08335	0.6668
			Bilirubin	17.1	umol/L	3.4	20.5
			Creatinine	53	umol/L	53	110.5

Laboratory Results - Clinical Chemistry							
Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
			Urea Nitrogen	12.86	mmol/L	5	16.07
		19NOV2020 (89)	Alkaline Phosphatase	2.93	ukat/L	0.63	2.1
			Alanine Aminotransferase	7.58485	ukat/L	0.25005	0.75015
			Aspartate Aminotransferase	1.23358	ukat/L	0.08335	0.6668
			Bilirubin	10.3	umol/L	3.4	20.5
			Creatinine	53	umol/L	53	110.5
			Urea Nitrogen	12.86	mmol/L	5	16.07

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	29OCT2020 (68)	06NOV2020 (76)	Basophils	0	10^9/L	0	0.2
			Eosinophils	0	10^9/L	0	0.7
			Hematocrit	0.41	L/L	0.4	0.54
			Hemoglobin	144	g/L	126	161
			Lymphocytes	695	10^9/L	0.6	2.6
			Monocytes	2	10^9/L	0	0.9
			Neutrophils	7246	10^9/L	1.7	7.6
			Platelets	262	10^9/L	150	400
		07NOV2020 (77)	Basophils	52	10^9/L	0	0.2
			Eosinophils	3	10^9/L	0	0.7
			Hematocrit	0.33	L/L	0.4	0.54
			Hemoglobin	117	g/L	126	161
			Lymphocytes	327	10^9/L	0.6	2.6
			Monocytes	225	10^9/L	0	0.9
			Neutrophils	5265	10^9/L	1.7	7.6
			Platelets	238	10^9/L	150	400
			Erythrocytes	4.01	10^12/L	4.25	5.9
		10NOV2020 (80)	Basophils	37	10^9/L	0	0.2
			Eosinophils	25	10^9/L	0	0.7
			Hematocrit	0.33	L/L	0.4	0.54
			Hemoglobin	111	g/L	126	161
			Lymphocytes	1012	10^9/L	0.6	2.6
			Monocytes	232	10^9/L	0	0.9
			Neutrophils	3672	10^9/L	1.7	7.6
			Platelets	306	10^9/L	150	400

Laboratory Results - Hematology							
Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
			Erythrocytes	3.94	10^12/L	4.25	5.9
		17NOV2020 (87)	Basophils	34	10^9/L	0	0.2
			Eosinophils	168	10^9/L	0	0.7
			Hematocrit	0.36	L/L	0.4	0.54
			Hemoglobin	128	g/L	126	161
			Lymphocytes	990	10^9/L	0.6	2.6
			Monocytes	346	10^9/L	0	0.9
			Neutrophils	5164	10^9/L	1.7	7.6
			Platelets	290	10^9/L	150	400
			Erythrocytes	4.12	10^12/L	4.25	5.9
		19NOV2020 (89)	Basophils	92	10^9/L	0	0.2
			Eosinophils	184	10^9/L	0	0.7
			Hematocrit	0.35	L/L	0.4	0.54
			Hemoglobin	114	g/L	126	161
			Lymphocytes	948	10^9/L	0.6	2.6
			Monocytes	440	10^9/L	0	0.9
			Neutrophils	3794	10^9/L	1.7	7.6
			Platelets	256	10^9/L	150	400
			Erythrocytes	4.05	10^12/L	4.25	5.9

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters				
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Arterial Blood Gases PaO2 (mmHg)	FiO2 (Fraction of Inhaled Oxygen)
COVID Illness Visit 1	29OCT2020 (68)	07NOV2020 (77)	103	0.5
COVID Illness Visit 1	29OCT2020 (68)	09NOV2020 (79)	250	0.4
COVID Illness Visit 1	29OCT2020 (68)	11NOV2020 (81)	390	

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging						
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam
1	COVID Illness Visit 1	29OCT2020 (68)	01NOV2020	CHEST		CT SCAN
2	COVID Illness Visit 1	29OCT2020 (68)	06NOV2020	CHEST		X-RAY
3	COVID Illness Visit 1	29OCT2020 (68)	07NOV2020	CHEST		X-RAY
4	COVID Illness Visit 1	29OCT2020 (68)	10NOV2020	CHEST		X-RAY

Imaging						
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam
5	COVID Illness Visit 1	29OCT2020 (68)	17NOV2020	CHEST		X-RAY
6	COVID Illness Visit 1	29OCT2020 (68)	19NOV2020	CHEST		X-RAY

Imaging			
Assessment Number	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	NA	ABNORMAL	bilateral peripheral pneumonic infiltrate
2	NA	ABNORMAL	Bilateral cottony infiltrates are observed with effacement of the right phrenic cost sinus
3	NA	ABNORMAL	bilateral cottony infiltrate
4	NA	ABNORMAL	Bilateral pulmonary parenchymal infiltrate with imaging improvement with respect to previous ones
5	NA	ABNORMAL	Bilateral interstitial infiltrates unchanged from previous images
6	NA	ABNORMAL	Bilateral interstitial infiltrate

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	23AUG2020	
Completed	VACCINATION	14OCT2020	
Completed	REPEAT SCREENING 1	29JAN2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313422, a 34-year-old white male with a height of 172 cm, a weight of 88 kg, and a BMI of 29.7 kg/m^2, received Dose 1 on 23 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 24). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 02 Nov 2020 (Day 72), the subject was diagnosed with severe COVID-19 pneumonia and reported tachypnea, salivary hypersecretion, new or increased shortness of breath, new or increased cough, headache, fever, diarrhea, and asthenia, with the first symptom starting on 28 Oct 2020, 43 days after receiving Dose 2, and the last symptom resolved on 27 Dec 2020. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 68) was positive. The local laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on 29 Oct 2020 (Day 68) and 19 Nov 2020 (Day 89) were negative and on 01 Nov 2020 (Day 71) the result was positive. The subject did not have any contact with nonstudy healthcare personnel. The subject was hospitalized on 01 Nov 2020 (Day 71) for 23 days and was discharged on 23 Nov 2020 (Day 93). The subject was in the intensive care unit (ICU) from 06 Nov 2020 (Day 76) to 19 Nov 2020 (Day 89). On 01 Nov 2020 (Day 71), a computed tomography scan of the chest showed bilateral peripheral pneumonic infiltrates. On 06 Nov 2020 (Day 76), the subject's laboratory test results showed elevated alanine aminotransferase (ALT) of 1.76702 µkat/L (normal range [NR]: 0.25005-0.75015 µkat/L), aspartate aminotransferase (AST) of 0.8335 µkat/L (NR: 0.08335-0.6668 µkat/L), and C-reactive protein of 149.89 mg/L (NR: 0.1-10 mg/L); alkaline phosphatase (ALP), bilirubin, creatinine, blood urea nitrogen (BUN), basophils, eosinophils, hematocrit, hemoglobin, lymphocytes, monocytes, neutrophils, and platelet count were within normal limits. A chest radiography showed bilateral cottony infiltrates with effacement of the right costophrenic sinus. On the same day (Day 76), the subject required mechanical ventilation until 16 Nov 2020 (Day 86). On 07 Nov 2020 (Day 77), the subject's laboratory test results showed elevated ALT of 1.26692 µkat/L and C-reactive protein of 149.89 mg/L; low hematocrit of 33% (NR: 40%-54%), hemoglobin of 11.7 g/dL (NR: 12.6-16.1 g/dL), lymphocytes of 0.327×10^9/L (NR: 0.6-2.6 $\times 10^9$/L), and erythrocytes of 4.01×10^{12}/L (NR: 4.25-5.9 $\times 10^{12}$/L); ALP, AST, bilirubin, creatinine, BUN, basophils, eosinophils, monocytes, neutrophils, and platelet count were within normal limits. A measurement of arterial blood gases revealed that the partial pressure of oxygen (PaO_2) was 103 mmHg; and measurement of the fraction of inspired oxygen (FiO_2) was 0.5. On 07 Nov 2020 (Day 77), a chest radiography showed bilateral cottony infiltrates. On 09 Nov 2020 (Day 79), the measurement of arterial blood gases revealed that the PaO_2 was 250 mmHg and measurement of the FiO_2 was 0.4.

Narrative Comment
On 10 Nov 2020 (Day 80), the subject's laboratory test results showed elevated ALT of 3.95079 µkat/L, AST of 1.56698 µkat/L, and BUN of 16.43 mmol/L (NR: 5-16.07 mmol/L); and low hematocrit of 33%, hemoglobin of 11.1 g/dL, and erythrocytes of 3.94×10^{12}/L; ALP, bilirubin, creatinine, basophils, eosinophils, lymphocytes, monocytes, neutrophils, and platelet count were within normal limits. A chest radiography showed bilateral pulmonary parenchymal infiltrate with imaging improvement compared to the previous ones. On 11 Nov 2020 (Day 81), the measurement of arterial blood gases revealed that the PaO_2 was 390 mmHg. On 17 Nov 2020 (Day 87), the subject's laboratory test results showed elevated ALP of 4.43 µkat/L (NR: 0.63-2.1 µkat/L), ALT of 13.08595 µkat/L, and AST of 1.96706 µkat/L; low hematocrit of 36% and erythrocytes of 4.12×10^{12}/L; bilirubin, creatinine, BUN, basophils, eosinophils, hemoglobin, lymphocytes, monocytes, neutrophils, and platelet count were within normal limits. A chest radiography showed bilateral interstitial infiltrates unchanged from previous images. On 19 Nov 2020 (Day 89), the subject's laboratory test results showed elevated ALP of 2.93 µkat/L, ALT of 7.58485 µkat/L, and AST of 1.23358 µkat/L; low bilirubin of 0.6 U/L (NR: 38-126 U/L), hematocrit of 35%, hemoglobin of 11.4 g/dL, and erythrocytes of 4.05×10^{12}/L; creatinine, bilirubin, BUN, basophils, eosinophils, lymphocytes, monocytes, neutrophils, and platelet count were within normal limits. A chest radiography showed bilateral interstitial infiltrates. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19, admission to an ICU, and requirement for mechanical ventilation). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 29 Jan 2021 (Day 160) and 18 Feb 2021 (Day 180), respectively, and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	29	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	72.9 kg	25.2 kg/m2	23AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23AUG2020 (1)	16:05
3	BNT162b2	24FEB2021 (186)	15:24

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	23AUG2020 (1)	23AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	23AUG2020 (1)	23AUG2020 (1)	SERUM	NEGATIVE
Visit 2	09OCT2020 (48)	09OCT2020 (48)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No
COVID Illness Visit 2	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 05SEP2020 (14)/ 04SEP2020 (13)/ 07SEP2020 (16)	YES	NEW OR INCREASED COUGH	
	YES	FEVER	
	NO		Asthenia
COVID Illness Visit 2 / 14NOV2020 (84)/ 30OCT2020 (69)/ 12NOV2020 (82)	YES	DIARRHEA	
COVID Illness Visit 3 / 28DEC2020 (128)/ 22DEC2020 (122)/ 02JAN2021 (133)	YES	NEW OR INCREASED SORE THROAT	
	YES	DIARRHEA	

Diagnosis of Potential COVID-19 Illness

Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	05SEP2020 (14)	COVID-19	05SEP2020 (14)	1	COVID-19
COVID Illness Visit 2	14NOV2020 (84)	Gastroenteritis	13NOV2020 (83)	1	Gastroenteritis
COVID Illness Visit 3	28DEC2020 (128)	pharyngitis	27DEC2020 (127)	2	Pharyngitis

SARS-COV-2 Test - Central Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	05SEP2020 (14)	05SEP2020 (14)	NASAL_SWAB	POSITIVE
2	COVID Illness Visit 2	14NOV2020 (84)	14NOV2020 (84)	NASAL_SWAB	POSITIVE
3	COVID Illness Visit 3	28DEC2020 (128)	28DEC2020 (128)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Test - Local Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	05SEP2020 (14)	05SEP2020 (14)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
2	COVID Illness Visit 2	14NOV2020 (84)	14NOV2020 (84)	SWABBED MATERIAL	NASOPHARYNX
3	COVID Illness Visit 3	28DEC2020 (128)	28DEC2020 (128)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
3	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	05SEP2020 (14)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 2	14NOV2020 (84)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 3	28DEC2020 (128)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	23AUG2020	
Withdrawn	VACCINATION	09OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
Completed	REPEAT SCREENING 1	24FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313510, a 29-year-old white female with a height of 170 cm, a weight of 72.9 kg, and a BMI of 25.2 kg/m2, received Dose 1 on 23 Aug 2020. The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and positive at Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject experienced 2 protocol-defined COVID-19 illnesses. On 05 Sep 2020 (Day 14), the subject was diagnosed with COVID-19 for the first time and reported new or increased cough, fever, and asthenia, with the first symptom starting on 04 Sep 2020, 12 days after receiving Dose 1, and the last symptom resolved on 07 Sep 2020. The subject was discontinued from the study intervention on 09 Oct 2020 since she no longer met the eligibility criteria. On 13 Nov 2020 (Day 83), the subject experienced a second COVID-19 illness and was diagnosed with gastroenteritis and reported diarrhea, starting on 30 Oct 2020, 68 days after receiving Dose 1, and resolved on 12 Nov 2020. The central laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illnesses on 05 Sep 2020 (Day 14) and 14 Nov 2020 (Day 84) were positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 05 Sep 2020 (Day 14) was positive and on 14 Nov 2020 (Day 84) the result was negative. The subject did not have any contact with nonstudy healthcare personnel at the time of the COVID-19 illnesses. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 24 Feb 2021 (Day 186) and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	82 kg	32 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Postpartum pulmonary thromboembolism	Pulmonary embolism	01SEP1994	Past
Type 2 diabetes	Type 2 diabetes mellitus	01JUN2000	Present
Arterial hypertension	Hypertension	01JUN2010	Present
Anxiety disorder	Anxiety disorder	01JUN2014	Present
Hypercholesterolemia	Hypercholesterolaemia	01JUN2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	10:05
2	Placebo	16SEP2020 (20)	14:20

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Myoclonus	chin myoclonus	05SEP2020 (9)	09:00	09NOV2020 (74)	12:00	66

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (09NOV2020)	NOT RELATED/OTHER: unknown	1	9	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	28AUG2020 (1)	28AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	28AUG2020 (1)	28AUG2020 (1)	SERUM	NEGATIVE
Visit 2	16SEP2020 (20)	16SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 2	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 11NOV2020 (76)/ 09NOV2020 (74)/ 13NOV2020 (78)	YES	NEW OR INCREASED SORE THROAT	
	YES	DIARRHEA	
COVID Illness Visit 2 / 29DEC2020 (124)/ 28DEC2020 (123)/ 28DEC2020 (123)	YES	NEW OR INCREASED SORE THROAT	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED COUGH	
	NO		Headache
	YES	FEVER	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 2	29DEC2020 (124)	bilateral pneumonia due to Covid-19	03JAN2021 (129)	3	COVID-19 pneumonia

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	11NOV2020 (76)	11NOV2020 (76)	NASAL_SWAB	NEGATIVE
2	COVID Illness Visit 2	29DEC2020 (124)	29DEC2020 (124)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	11NOV2020 (76)	11NOV2020 (76)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 2	29DEC2020 (124)	29DEC2020 (124)	SWABBED MATERIAL	NASOPHARYNX
3	COVID Illness Visit 2	29DEC2020 (124)	01JAN2021 (127)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
3	POSITIVE		OTHER	NALT unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	11NOV2020 (76)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 2	29DEC2020 (124)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	2	NA
		TELEPHONE CONSULTATION	YES	3	NA

Hospitalization Details					
Visit	**Visit Date (Study Day)**	**Hospitalization Category**	**Hospitalization Term**	**Admission Date (Study Day)**	**Discharge Date or Ongoing (Study Day)**
COVID Illness Visit 2	29DEC2020 (124)	HOSPITALIZATION STATUS	HOSPITAL	03JAN2021 (129)	13JAN2021 (139)

Respiratory Treatment

Visit	Visit Date (Study Day)	Treatment Identifier	Prespecified Concomitant Nondrug Treatment	Treatment	Start Date (Study Day)	End Date or Ongoing (Study Day)
COVID Illness Visit 2	29DEC2020 (124)	1	YES	HIGH FLOW OXYGEN THERAPY	03JAN2021 (129)	12JAN2021 (138)

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 2	29DEC2020 (124)	03JAN2021 (129)	Alkaline Phosphatase	1.33	ukat/L	0.5	2
			Alanine Aminotransferase	0.36674	ukat/L	0	0.58345
			Aspartate Aminotransferase	0.31673	ukat/L	0	0.58345
			Bilirubin	9.2	umol/L	5.1	20.5
			Creatinine	70.7	umol/L	53	106.1
			C Reactive Protein	16.8	mg/L	0	5
			Urea Nitrogen	9.28	mmol/L	6.07	17.5

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 2	29DEC2020 (124)	03JAN2021 (129)	Basophils	0.02	10^9/L	0	0.05
			Eosinophils	0.06	10^9/L	0	0.35
			Hematocrit	0.45	L/L	0.36	0.46
			Hemoglobin	152	g/L	118	148
			Lymphocytes	2	10^9/L	1	2.3
			Monocytes	0.57	10^9/L	0.2	0.5
			Neutrophils	2.35	10^9/L	2.15	3.55
			Platelets	178	10^9/L	150	440
			Erythrocytes	5.16	10^12/L	4	5.2
			Leukocytes	5	10^9/L	3.6	11

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 2	29DEC2020 (124)	03JAN2021 (129)	1	130 mmHg	80 mmHg	18 breaths/min	75 beats/min	96 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging								
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment
1	COVID Illness Visit 2	29DEC2020 (124)	01JAN2021	CHEST		CT SCAN	NA	ABNORMAL
2	COVID Illness Visit 2	29DEC2020 (124)	03JAN2021	CHEST		CT SCAN	NA	ABNORMAL

Imaging	
Assessment Number	If Abnormal, Specify Findings
1	Adenomegaly in both axillary hollows. 5mm nodular image of subpleural location in the right diaphragmatic dome. 2mm subpleural nodule at the level of the external basal segment of the left lower lobe
2	Axillary adenomegaly persists. Increase in the number and size of central and peripheral ground glass areas that affect both lung fields.

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	19OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12314681, a 66-year-old white female with a height of 160 cm, a weight of 82 kg, and a BMI of 32 kg/m2, received Dose 1 on 28 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 20). The subject had a reported medical history of pulmonary embolism (on 01 Sep 1994), type 2 diabetes mellitus (since 01 Jun 2000), hypertension (since 01 Jun 2010), and anxiety disorder and hypercholesterolemia (both since 01 Jun 2014). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 03 Jan 2021 (Day 129), the subject was diagnosed with severe COVID-19 pneumonia and reported new or increased sore throat, new or increased shortness of breath, new or increased cough, headache, and fever, with the first symptom starting on 28 Dec 2020, 103 days after receiving Dose 2, and the last symptom resolved on 28 Dec 2020. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Dec 2020 (Day 124) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Dec 2020 (Day 124) was negative and on 01 Jan 2021 (Day 127) the result was positive. The subject had a telephone consultation (3 times) and went to the emergency room (twice). On 01 Jan 2021 (Day 127), a computed tomography scan of the chest showed adenomegaly in both axillary hollows; a nodule measuring 5 mm was located in the subpleural area of the right diaphragmatic dome and subpleural nodule measuring 2 mm at the level of the external basal segment of the left lower lobe. On 03 Jan 2021 (Day 129), a computed tomography scan of the chest showed axillary adenomegaly with an increase in the number and size of central and peripheral ground-glass areas that affected both lung fields. On 03 Jan 2021 (Day 129), the subject's laboratory test results showed elevated C-reactive protein of 16.8 mg/L (normal range [NR]: 0-5 mg/L), hemoglobin of 152 g/L (NR: 118-148 g/L), and monocytes of 0.57 × 109/L (NR: 0.2-0.5 × 109/L); alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, bilirubin, creatinine, blood urea nitrogen, basophils, eosinophils, hematocrit, lymphocytes, neutrophils, platelets, erythrocytes, and leukocytes were within normal limits. The subject was hospitalized on 03 Jan 2021 (Day 129) for 11 days and discharged on 13 Jan 2021 (Day 139). On 03 Jan 2021 (Day 129), the subject had a heart rate of 75 beats/min, blood pressure of 130/80 mmHg, respiratory rate of 18 breaths/min, and oxygen saturation of 96%. The subject required high-flow oxygen therapy from 03 Jan 2021 (Day 129) to 12 Jan 2021 (Day 138). The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and requirement for high-flow oxygen therapy).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	71.65 kg	29.1 kg/m2	29AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	29AUG2020 (1)	17:53
2	Placebo	18SEP2020 (21)	09:21

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	COVID-19	Severe Covid-19 illness	25DEC2020 (119)	19:00	31JAN2021 (156)	20:30	38	4
2	INFEC	Septic shock	Septic shock	25DEC2020 (119)	19:00	31JAN2021 (156)	20:30	38	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Fatal (31JAN2021)	NOT RELATED/OTHER: COVID-19 infection	2	99	Y
2	TC/TCN/W	Y	Fatal (31JAN2021)	NOT RELATED/OTHER: Severe Covid Disease	2	99	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	29AUG2020 (1)	29AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	29AUG2020 (1)	29AUG2020 (1)	SERUM	NEGATIVE
Visit 2	18SEP2020 (21)	18SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26DEC2020 (120)/ 25DEC2020 (119)/ 31JAN2021 (156)	YES	NEW OR INCREASED COUGH	
	NO		Headache
	NO		Fatigue
	YES	FEVER	
	YES	CHILLS	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	26DEC2020 (120)	COVID-19	15JAN2021 (140)	5	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	26DEC2020 (120)	26DEC2020 (120)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	26DEC2020 (120)	26DEC2020 (120)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	26DEC2020 (120)	02JAN2021 (127)	SWABBED MATERIAL	NASOPHARYNX
3	COVID Illness Visit 1	26DEC2020 (120)	15JAN2021 (140)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
3	POSITIVE		OTHER	NALT unknown

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	26DEC2020 (120)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	3	NA

Hospitalization Details					
Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	26DEC2020 (120)	HOSPITALIZATION STATUS	HOSPITAL	05JAN2021 (130)	ONGOING
COVID Illness Visit 1	26DEC2020 (120)	HOSPITALIZATION STATUS	ICU	14JAN2021 (139)	31JAN2021 (156)
COVID Illness Visit 1	26DEC2020 (120)	HOSPITALIZATION STATUS	ICU	05JAN2021 (130)	ONGOING

Respiratory Treatment						
Visit	**Visit Date (Study Day)**	**Treatment Identifier**	**Prespecified Concomitant Nondrug Treatment**	**Treatment**	**Start Date (Study Day)**	**End Date or Ongoing (Study Day)**
COVID Illness Visit 1	26DEC2020 (120)	1	YES	MECHANICAL VENTILATION	16JAN2021 (141)	ONGOING

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction							
Visit	**Visit Date (Study Day)**	**Subcategory of Clinical Event**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**End Date or Ongoing**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	26DEC2020 (120)	SIGNIFICANT ACUTE RENAL DYSFUNCTION	Acute Kidney Failure	14JAN2021 (139)	31JAN2021 (156)	5	Acute kidney injury

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	26DEC2020 (120)	22JAN2021 (147)	Alkaline Phosphatase	4.08	ukat/L	1.08	5
			Alanine Aminotransferase	2.40048	ukat/L	0.08335	0.68347
			Aspartate Aminotransferase	1.28359	ukat/L	0.08335	0.58345
			Bilirubin	20.3	umol/L	8.6	20.5
			Creatinine	602	umol/L	61.9	123.8
			Urea Nitrogen	87.13	mmol/L	3.57	17.86
		31JAN2021 (156)	Alkaline Phosphatase	9.09	ukat/L	1.08	5
			Alanine Aminotransferase	3.70074	ukat/L	0.08335	0.68347
			Aspartate Aminotransferase	5.48443	ukat/L	0.08335	0.58345
			Bilirubin	66.2	umol/L	8.6	20.5
			Creatinine	308.5	umol/L	61.9	123.8
			Urea Nitrogen	47.14	mmol/L	3.57	17.86

Laboratory Results - Hematology							
Visit	**Visit Date (Study Day)**	**Date of Test (Study Day)**	**Laboratory Test**	**Result**	**Units**	**Lower Limit Range**	**Upper Limit Range**
COVID Illness Visit 1	26DEC2020 (120)	22JAN2021 (147)	Hematocrit	0.2	L/L	0.37	0.54
			Hemoglobin	65	g/L	110	160
			Platelets	101	10^9/L	130	450
			Erythrocytes	2.12	10^12/L	3.5	5.5
			Leukocytes	22.9	10^9/L	4	10
		31JAN2021 (156)	Hematocrit	0.25	L/L	0.37	0.54
			Hemoglobin	84	g/L	110	160
			Platelets	16	10^9/L	130	450
			Erythrocytes	2.81	10^12/L	3.5	5.5
			Leukocytes	6	10^9/L	4	10

Vital Signs - COVID-19								
Visit	**Visit Date (Study Day)**	**Date Collected (Study Day)**	**Record Identifier**	**Systolic Blood Pressure**	**Diastolic Blood Pressure**	**Respiratory Rate**	**Heart Rate**	**Oxygen Saturation**
COVID Illness Visit 1	26DEC2020 (120)		1	100 mmHg	60 mmHg	19 breaths/min	92 beats/min	83 %
			2					90 %

Oxygenation Parameters				
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Arterial Blood Gases PaO2 (mmHg)	FiO2 (Fraction of Inhaled Oxygen)
COVID Illness Visit 1	26DEC2020 (120)			0.8

Concomitant Medications - Vasopressors									
Medication Identifier	Concomitant Medications Pre-Specified	Name Of Medications	Dose	Dose Unit	Dose Frequency	Route	Start Date (Study Day)	End Date or Ongoing (Study Day)	Standardized Medication Name
1		Norepinephrine							NOREPINEPHRINE

Imaging									
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 1	26DEC2020 (120)	05JAN2021	CHEST		CT SCAN	NA	ABNORMAL	bilateral pneumonia
2	COVID Illness Visit 1	26DEC2020 (120)	13JAN2021	CHEST		CT SCAN	NA	ABNORMAL	viral pneumonia

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	22OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	31JAN2021	DEATH

Narrative Comment

Subject C4591001 1231 12315324, a 58-year-old white female with a height of 157 cm, a weight of 71.65 kg, and a BMI of 29.1 kg/m^2, received Dose 1 on 29 Aug 2020 and Dose 2 on 18 Sep 2020 (Day 21).

The subject had no reported medical history.

The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1.

On 25 Dec 2020 (Day 119), the subject experienced septic shock with probable COVID-19 illness. On 15 Jan 2021 (Day 140), she was diagnosed with severe COVID-19 pneumonia and reported new or increased cough, headache, fatigue, fever (maximum temperature of 38.4°C), and chills, with the first symptom starting on 25 Dec 2020, 98 days after receiving Dose 2, and the last symptom resolved on 31 Jan 2021.

The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 26 Dec 2020 (Day 120) was positive.

The local laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on 26 Dec 2020 (Day 120) and 02 Jan 2021 (Day 127) were negative and on 15 Jan 2021 (Day 140) the result was positive.

The subject went to the emergency room (3 times).

On 26 Dec 2020 (Day 120), the subject had a heart rate of 92 beats/min, blood pressure of 100/60 mmHg, respiratory rate of 19 breaths/min, and oxygen saturation of 83% and 90%.

Narrative Comment
On 26 Dec 2020 (Day 120), the measurement of the fraction of inspired oxygen was 0.8. On 05 Jan 2021 (Day 130), a computed tomography (CT) scan of the chest was suggestive of bilateral pneumonia with extensive bilateral patchy foci of ground-glass interstitial infiltrates, dense tracts, and bronchiectatic-like images in both lower lobes, and the subject was hospitalized on the same day. On 13 Jan 2021 (Day 138), a CT scan of the chest was suggestive of viral pneumonia, with mediastinum slightly retracted to the left, without evidence of adenomegaly, and extensive, mixed (predominantly consolidated), bilateral parenchymal infiltrates were observed. The subject was diagnosed with significant acute renal dysfunction (multiple organ dysfunction syndrome) on 14 Jan 2021 (Day 139). On 14 Jan 2021 (Day 139), she was moved to the intensive care unit (ICU) and required a mechanical ventilator from 16 Jan 2021 (Day 141) because of respiratory failure. On 22 Jan 2021 (Day 147), the subject's laboratory results showed elevated alanine aminotransferase (ALT) of 2.40048 µkat/L (normal range [NR]: 0.08335-0.68347 µkat/L), aspartate aminotransferase (AST) of 1.28359 µkat/L (NR: 0.08335-0.58345 µkat/L), creatinine of 602 µmol/L (NR: 61.9-123.8 µmol/L), blood urea nitrogen (BUN) of 87.13 mmol/L (NR: 3.57-17.86 mmol/L), and leukocytes of 22.9 × 10^9/L (NR: 4-10 × 10^9/L); low hematocrit of 20% (NR: 37%-54%), hemoglobin of 6.5 g/dL (NR: 11.0-16.0 g/dL), platelet count of 101 × 10^9/L (NR: 130-450 × 10^9/L), and erythrocytes of 2.12 × 10^9/L (NR: 3.5-5.5 × 10^9/L); alkaline phosphatase (ALP) and bilirubin were within normal limits. On 31 Jan 2021 (Day 156), the subject's laboratory results showed elevated ALP of 9.09 µkat/L (NR: 1.08-5 µkat/L), ALT of 3.70074 µkat/L, AST of 5.48443 µkat/L, bilirubin of 66.2 µmol/L (NR: 8.6-20.5 µmol/L), creatinine of 308.5 µmol/L, and BUN of 47.14 mmol/L; low hematocrit of 25%, hemoglobin of 8.4 g/dL, platelet count of 16 × 10^9/L, and erythrocytes of 2. 81 × 10^{12}/L; the leukocyte count was within normal limits. Laboratory results on an unknown date showed prothrombin time of 14.5 seconds, activated partial thromboplastin time of greater than 1 minute, Quick test result of 66%, lactate dehydrogenase of 4367 U/L, direct bilirubin of 2.9 mg/dL, total bilirubin of 3.8 mg/dL, AST of 329 IU/L, ALT of 222 IU/L, ALP of 545 IU/L, albumin of 2.8 g/dL, pH of 7.06, partial pressure of carbon dioxide (pCO_2) of 72 mmHg, partial pressure of oxygen (pO_2) of 37 mmHg, and bicarbonate (HCO_3) of 20 mmol/L (normal ranges not provided). On 31 Jan 2021 (Day 156), the subject developed severe bradycardia, followed by cardiac arrest. She required vasopressor support with norepinephrine (dose unknown) and she received advanced resuscitation maneuvers (according to American Heart Association [AHA] protocol) for 30 minutes, without response. On 31 Jan 2021 (Day 156), she died because of septic shock in the context of a severe COVID-19 illness. She had developed metabolic acidosis, acute renal failure with dialysis criteria, and marked cytopenias (anemia and thrombocytopenia). The causes of death reported in the death certificate were acute respiratory failure, multiorgan failure, and multilobar pneumonia. An autopsy was not performed. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19, admission to an ICU, presented a respiratory failure, significant acute renal dysfunction, oxygen saturation ≤93%, requirement for mechanical ventilation, respiratory treatment, and death).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	109.09 kg	33.5 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	2010	Present
Hypertension	Hypertension	2010	Present
Allergic Rhinitis	Rhinitis allergic	2010	Present
Dyslipidemia	Dyslipidaemia	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14SEP2020 (1)	09:50
3	BNT162b2	18DEC2020 (96)	09:48
4	BNT162b2	08JAN2021 (117)	10:46

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	14SEP2020 (1)	14SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	14SEP2020 (1)	14SEP2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 22SEP2020 (9)/ 21SEP2020 (8)/ 25SEP2020 (12)	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED COUGH	
	YES	FEVER	
	YES	CHILLS	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	22SEP2020 (9)	COVID-19 ILLNESS	22SEP2020 (9)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	22SEP2020 (9)	22SEP2020 (9)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	22SEP2020 (9)	22SEP2020 (9)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	LSU EVT Lab- PCR analysis-CLIA-certified lab

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	22SEP2020 (9)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details					
Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	22SEP2020 (9)	HOSPITALIZATION STATUS	ICU	22SEP2020 (9)	26SEP2020 (13)

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	22SEP2020 (9)	22SEP2020 (9)	Alkaline Phosphatase	1.15	ukat/L	0.92	2.25
			Alanine Aminotransferase	1.61699	ukat/L	0.1667	0.73348
			Aspartate Aminotransferase	0.73348	ukat/L	0.1667	0.6668
			Bilirubin	8.6	umol/L	1.7	17.1
			Creatinine	88.4	umol/L	44.2	123.8
			C Reactive Protein	13.5	mg/L	0	9
			Urea Nitrogen	4.64	mmol/L	2.14	7.14
		23SEP2020 (10)	Alkaline Phosphatase	1.1	ukat/L	0.92	2.25
			Alanine Aminotransferase	1.56698	ukat/L	0.1667	0.73348
			Aspartate Aminotransferase	0.8335	ukat/L	0.1667	0.6668
			Bilirubin	6.8	umol/L	1.7	17.1
			Creatinine	70.7	umol/L	44.2	123.8
			C Reactive Protein	17.7	mg/L	0	9
			Urea Nitrogen	4.29	mmol/L	2.14	7.14
		24SEP2020 (11)	Alkaline Phosphatase	0.97	ukat/L	0.92	2.25
			Alanine Aminotransferase	1.30026	ukat/L	0.1667	0.73348
			Aspartate Aminotransferase	0.6668	ukat/L	0.1667	0.6668
			Bilirubin	6.8	umol/L	1.7	17.1
			Creatinine	68.1	umol/L	44.2	123.8
			C Reactive Protein	0.78	mg/L	0	0.9
			Urea Nitrogen	3.21	mmol/L	2.14	7.14
		25SEP2020 (12)	Alkaline Phosphatase	1.03	ukat/L	0.92	2.25
			Alanine Aminotransferase	1.35027	ukat/L	0.1667	0.73348
			Aspartate Aminotransferase	0.65013	ukat/L	0.1667	0.6668
			Bilirubin	5.1	umol/L	1.7	17.1

Laboratory Results - Clinical Chemistry							
Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
			Creatinine	64.5	umol/L	44.2	123.8
			Urea Nitrogen	4.29	mmol/L	2.14	7.14
		26SEP2020 (13)	Alkaline Phosphatase	1	ukat/L	0.92	2.25
			Alanine Aminotransferase	1.1669	ukat/L	0.1667	0.73348
			Aspartate Aminotransferase	0.46676	ukat/L	0.1667	0.6668
			Bilirubin	5.1	umol/L	1.7	17.1
			Creatinine	70.7	umol/L	44.2	123.8
			Urea Nitrogen	4.29	mmol/L	2.14	7.14

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	22SEP2020 (9)	23SEP2020 (10)	Basophils	0.03	10^9/L	0	0.2
			Eosinophils	0	10^9/L	0	0.5
			Hematocrit	0.41	L/L	0.37	0.47
			Hemoglobin	138	g/L	125	163
			Lymphocytes	1.4	10^9/L	1	4.8
			Monocytes	1.1	10^9/L	0.3	1
			Neutrophils	2.4	10^9/L	1.8	7.7
			Platelets	224	10^9/L	150	350
			Erythrocytes	4.2	10^12/L	4.6	6.2
			Leukocytes	5.03	10^9/L	3.9	12.7
		24SEP2020 (11)	Basophils	0.02	10^9/L	0	0.2
			Eosinophils	0.1	10^9/L	0	0.5
			Hematocrit	0.39	L/L	0.37	0.47
			Hemoglobin	131	g/L	125	163
			Lymphocytes	1.7	10^9/L	1	4.8
			Monocytes	0.8	10^9/L	0.3	1
			Neutrophils	1.4	10^9/L	1.8	7.7
			Platelets	199	10^9/L	150	350
			Erythrocytes	4.07	10^12/L	4.6	6.2
			Leukocytes	4.01	10^9/L	3.9	12.7
		25SEP2020 (12)	Basophils	0.02	10^9/L	0	0.2
			Eosinophils	0.1	10^9/L	0	0.5
			Hematocrit	0.42	L/L	0.37	0.47
			Hemoglobin	143	g/L	125	163
			Lymphocytes	2.3	10^9/L	1	4.8

Laboratory Results - Hematology							
Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
			Monocytes	0.6	10^9/L	0.3	1
			Neutrophils	1.1	10^9/L	1.8	7.7
			Platelets	217	10^9/L	150	350
			Erythrocytes	4.4	10^12/L	4.6	6.2
			Leukocytes	4.11	10^9/L	3.9	12.7
		26SEP2020 (13)	Basophils	0.02	10^9/L	0	0.2
			Eosinophils	0.1	10^9/L	0	0.5
			Hematocrit	0.41	L/L	0.37	0.47
			Hemoglobin	140	g/L	125	163
			Lymphocytes	2.3	10^9/L	1	4.8
			Monocytes	0.6	10^9/L	0.3	1
			Neutrophils	1.3	10^9/L	1.8	7.7
			Platelets	211	10^9/L	150	350
			Erythrocytes	4.33	10^12/L	4.6	6.2
			Leukocytes	4.42	10^9/L	3.9	12.7

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	22SEP2020 (9)	22SEP2020 (9)	1	131 mmHg	95 mmHg	26 breaths/min	111 beats/min	96 %
		23SEP2020 (10)	2	145 mmHg	94 mmHg	11 breaths/min	70 beats/min	95 %
		24SEP2020 (11)	3	120 mmHg	80 mmHg	20 breaths/min	83 beats/min	93 %
		25SEP2020 (12)	4	182 mmHg	72 mmHg	15 breaths/min	90 beats/min	97 %
		26SEP2020 (13)	5	118 mmHg	79 mmHg	16 breaths/min	80 beats/min	96 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging									
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 1	22SEP2020 (9)	22SEP2020	CHEST		X-RAY	NA	ABNORMAL	Minimal bibasilar infiltrates

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14SEP2020	
Withdrawn	VACCINATION	22SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
Completed	REPEAT SCREENING 1	18DEC2020	
Completed	OPEN LABEL TREATMENT	05FEB2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1235 12351071, a 50-year-old white male with a height of 180.34 cm, a weight of 109.09 kg, and a BMI of 33.5 kg/m2, received Dose 1 on 14 Sep 2020. The subject had a reported medical history of asthma, hypertension, and allergic rhinitis (all since 2010); and dyslipidemia (since 2015). The central laboratory SARS-CoV-2 NAAT result was negative at Visit 1. The central laboratory N-binding antibody result was negative at Visit 1. On 22 Sep 2020 (Day 9), the subject was symptomatic of possible COVID-19 illness and was diagnosed with severe COVID-19, and reported new or increased shortness of breath, new or increased cough, fever, chills, new or increased muscle pain, and new or increased sore throat, with the first symptom starting on 21 Sep 2020, 7 days after receiving Dose 1, and the last symptom resolved on 25 Sep 2020. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 22 Sep 2020 (Day 9) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 22 Sep 2020 (Day 9) was positive. The subject had a telephone consultation (once). The subject was admitted to the intensive care unit (ICU) on 22 Sep 2020 (Day 9) and was discharged on 26 Sep 2020 (Day 13). On 22 Sep 2020 (Day 9), the subject had a heart rate of 111 beats/min, blood pressure (BP) of 131/95 mmHg, respiratory rate of 26 breaths/min, and oxygen saturation of 96%. On 23 Sep 2020 (Day 10), the subject had a heart rate of 70 beats/min, BP of 145/94 mmHg, respiratory rate of 11 breaths/min, and oxygen saturation of 95%. On 24 Sep 2020 (Day 11), the subject had a heart rate of 83 beats/min, BP of 120/80 mmHg, respiratory rate of 20 breaths/min, and oxygen saturation of 93%. On 25 Sep 2020 (Day 12), the subject had a heart rate of 90 beats/min, BP of 182/72 mmHg, respiratory rate of 15 breaths/min, and oxygen saturation of 97%. On 26 Sep 2020 (Day 13), the subject had a heart rate of 80 beats/min, BP of 118/79 mmHg, respiratory rate of 16 breaths/min, and oxygen saturation of 96%. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19, admission to an ICU, and oxygen saturation of ⩽93%). On 22 Sep 2020 (Day 9), the chest x-ray showed minimal bibasilar infiltrates. On 22 Sep 2020 (Day 9), the subject's laboratory results showed elevated alanine aminotransferase (ALT) of 1.61699 µkat/L (normal range [NR]: 0.1667-0.73348 µkat/L), aspartate aminotransferase (AST) of 0.73348 µkat/L (NR: 0.1667-0.6668 µkat/L), and C-reactive protein (CRP) of 13.5 mg/L (NR: 0-9 mg/L). On 23 Sep 2020 (Day 10), the subject's laboratory results showed elevated ALT of 1.56698 µkat/L, AST of 0.8335 µkat/L, CRP of 17.7 mg/L, and monocytes of 1.1 × 109/L (NR: 0.3-1.0 × 109/L); and low erythrocytes of 4.2 × 1012/L (NR: 4.6-6.2 × 1012/L). On 24 Sep 2020 (Day 11), the subject's ALT was elevated at 1.30026 µkat/L; and neutrophils and erythrocytes were decreased at 1.4 × 109/L (NR: 1.8-7.7 × 109/L) and 4.07 × 1012/L, respectively; and the subject's CRP and AST returned to normal. On 25 Sep 2020 (Day 12), the subject's ALT was elevated at 1.35027 µkat/L; neutrophils and erythrocytes were decreased at 1.1 × 109/L and 4.4 × 1012/L, respectively. On 26 Sep 2020 (Day 13), the subject's ALT was elevated at 1.1669 µkat/L; neutrophils and erythrocytes were decreased at 1.3 × 109/L and 4.33 × 1012/L, respectively. The subject was discontinued from the study intervention on 22 Sep 2020 since he no longer met the eligibility criteria. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 18 Dec 2020 (Day 96) and 08 Jan 2021 (Day 117), respectively, and remains in the study.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 2001	19	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
184.25 cm	90.65 kg	26.7 kg/m2	07OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	07OCT2020 (1)	14:55
2	Placebo	28OCT2020 (22)	09:00

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	07OCT2020 (1)	07OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	07OCT2020 (1)	07OCT2020 (1)	SERUM	NEGATIVE
Visit 2	28OCT2020 (22)	28OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 06JAN2021 (92)/ 03JAN2021 (89)/ 27JAN2021 (113)	YES	NEW LOSS OF TASTE OR SMELL	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	06JAN2021 (92)	Sars-Cov-2 positive	07JAN2021 (93)	2	SARS-CoV-2 test positive

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	06JAN2021 (92)	06JAN2021 (92)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	06JAN2021 (92)	06JAN2021 (92)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	Local lab Ampath ISO15189 accredited

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	06JAN2021 (92)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	06JAN2021 (92)	06JAN2021 (92)	1	104 mmHg	58 mmHg	20 breaths/min	84 beats/min	98 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07OCT2020	
Completed	VACCINATION	25NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1246 12461110, a 19-year-old white male with a height of 184.25 cm, a weight of 90.65 kg, and a BMI of 26.7 kg/m2, received Dose 1 on 07 Oct 2020 and Dose 2 on 28 Oct 2020 (Day 22). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 07 Jan 2021 (Day 93), the subject was diagnosed with severe COVID-19 illness and reported new loss of taste or smell, with the symptom starting on 03 Jan 2021, 67 days after receiving Dose 2, and resolved on 27 Jan 2021. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Jan 2021 (Day 92) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Jan 2021 (Day 92) was positive. The subject did not have any contact with nonstudy healthcare personnel. On 06 Jan 2021 (Day 92), the subject had a heart rate of 84 beats/min, blood pressure of 104/58 mmHg, respiratory rate of 20 breaths/min, and oxygen saturation of 98% on room air. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and presented evidence of shock: diastolic blood pressure <60 mmHg).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	95 kg	37.1 kg/m2	28SEP2020 (-1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bilateral tubal ligation	Female sterilisation	1997	Past
Post Menopausal	Postmenopause	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	29SEP2020 (1)	08:56

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	28SEP2020 (-1)	28SEP2020 (-1)	NASAL_SWAB	NEGATIVE
Visit 1	28SEP2020 (-1)	28SEP2020 (-1)	SERUM	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 16OCT2020 (18)/ 15OCT2020 (17)/ 27OCT2020 (29)	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	16OCT2020 (18)	COVID-19	23OCT2020 (25)	3	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	16OCT2020 (18)	16OCT2020 (18)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location	Test Result
1	COVID Illness Visit 1	16OCT2020 (18)	23OCT2020 (25)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	Covid Illness confirmed by positive SARS_CoV_2 PCR test done at the National Health Laboratory Services in Cape Town South Africa	OTHER	CLIA-certified lab

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	16OCT2020 (18)	OTHER	NO		NA
		SPECIALIST	NO		NA
		EMERGENCY ROOM	YES	1	NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		URGENT CARE	YES	1	NA
		TELEPHONE CONSULTATION	YES	7	NA

Hospitalization Details					
Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	16OCT2020 (18)	HOSPITALIZATION STATUS	HOSPITAL	23OCT2020 (25)	26OCT2020 (28)

Respiratory Treatment						
Visit	Visit Date (Study Day)	Treatment Identifier	Prespecified Concomitant Nondrug Treatment	Treatment	Start Date (Study Day)	End Date or Ongoing (Study Day)
COVID Illness Visit 1	16OCT2020 (18)	1	YES	HIGH FLOW OXYGEN THERAPY	23OCT2020 (25)	24OCT2020 (26)

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging									
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 1	16OCT2020 (18)	22OCT2020	CHEST		X-RAY	NA	UNKNOWN	

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28SEP2020	
Withdrawn	VACCINATION	15OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1247 12471066, a 58-year-old black or African American female with a height of 160 cm, a weight of 95 kg, and a BMI of 37.1 kg/m2, received Dose 1 on 29 Sep 2020. The subject had a reported medical history of female sterilization (in 1997) and postmenopause (since 2019). The central laboratory SARS-CoV-2 NAAT result was negative at Visit 1. The central laboratory N-binding antibody result was negative at Visit 1. On 23 Oct 2020 (Day 25), the subject was diagnosed with severe COVID-19 and reported new or increased shortness of breath and new or increased cough, with the first symptom starting on 15 Oct 2020, 16 days after receiving Dose 1, and the last symptom resolved on 27 Oct 2020. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 16 Oct 2020 (Day 18) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 23 Oct 2020 (Day 25) was positive. The subject had a telephone consultation (7 times), had an urgent care visit (once), went to her primary care physician (once), and went to the emergency room (once). On 22 Oct 2020 (Day 24), a chest radiograph revealed unknown results. The subject was hospitalized on 23 Oct 2020 (Day 25) for 4 days and discharged on 26 Oct 2020 (Day 28). She required high-flow oxygen therapy from 23 Oct 2020 (Day 25) to 24 Oct 2020 (Day 26). The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and requirement for high-flow oxygen therapy). The subject was discontinued from the study intervention on 15 Oct 2020 since she no longer met the eligibility criteria and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1983	37	Multiple	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
167 cm	99 kg	35.5 kg/m2	29SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	29SEP2020 (1)	09:49
2	Placebo	29OCT2020 (31)	12:07

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
3	BNT162b2	04FEB2021 (129)	11:19
4	BNT162b2	25FEB2021 (150)	14:54

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Escherichia urinary tract infection	Acute E.coli UTI	18OCT2020 (20)		25OCT2020 (27)		8

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Resolved (25OCT2020)	NOT RELATED/OTHER: E.coli	1	20	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	29SEP2020 (1)	29SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	29SEP2020 (1)	29SEP2020 (1)	SERUM	NEGATIVE
Visit 2	20OCT2020 (22)	29OCT2020 (31)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 23DEC2020 (86)/ 16DEC2020 (79)/ 06JAN2021 (100)	YES	NEW OR INCREASED SORE THROAT	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED COUGH	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	CHILLS	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	23DEC2020 (86)	Covid-19	28DEC2020 (91)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	23DEC2020 (86)	23DEC2020 (86)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	23DEC2020 (86)	28DEC2020 (91)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT Unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	23DEC2020 (86)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	23DEC2020 (86)	HOSPITALIZATION STATUS	HOSPITAL	02JAN2021 (96)	ONGOING
COVID Illness Visit 1	23DEC2020 (86)	HOSPITALIZATION STATUS	ICU	02JAN2021 (96)	ONGOING

Respiratory Treatment						
Visit	Visit Date (Study Day)	Treatment Identifier	Prespecified Concomitant Nondrug Treatment	Treatment	Start Date (Study Day)	End Date or Ongoing (Study Day)
COVID Illness Visit 1	23DEC2020 (86)	1	YES	HIGH FLOW OXYGEN THERAPY	01JAN2021 (95)	03JAN2021 (97)

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry							
Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	23DEC2020 (86)	01JAN2021 (95)	Alkaline Phosphatase	3.17	ukat/L	0.67	2
			Alanine Aminotransferase	7.96826	ukat/L	0.1667	0.6668
			Aspartate Aminotransferase	2.61719	ukat/L	0.25005	0.6668
			Bilirubin	19	umol/L	5	21
			Creatinine	84	umol/L	63.6	104.3
			C Reactive Protein	205	mg/L	0	10

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	23DEC2020 (86)	01JAN2021 (95)	Basophils	0.03	10^9/L	0	0.1
			Eosinophils	0.07	10^9/L	0	0.95
			Hematocrit	0.42	L/L	0.4	0.5
			Hemoglobin	138	g/L	130	170
			Lymphocytes	1.27	10^9/L	1.4	4.2
			Monocytes	0.38	10^9/L	0.3	0.8
			Neutrophils	9.36	10^9/L	1.6	6.98
			Platelets	405	10^9/L	171	388

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	23DEC2020 (86)	01JAN2021 (95)	1	158 mmHg	100 mmHg	32 breaths/min	97 beats/min	

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging									
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 1	23DEC2020 (86)	01JAN2021	CHEST		X-RAY	NA	ABNORMAL	Bilateral patchy ground glass infiltrates

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	29SEP2020	
Completed	VACCINATION	26NOV2020	
Completed	REPEAT SCREENING 1	04FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1247 12471092, a 37-year-old multiracial male, with a height of 167 cm, a weight of 99 kg, and a BMI of 35.5 kg/m2, received Dose 1 on 29 Sep 2020 and Dose 2 on 29 Oct 2020 (Day 31). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 28 Dec 2020 (Day 91), the subject was diagnosed with severe COVID-19 and reported new or increased sore throat, new or increased shortness of breath, new or increased muscle pain, new or increased cough, new loss of taste or smell, and chills, with the first symptom starting on 16 Dec 2020, 48 days after receiving Dose 2, and the last symptom resolved on 06 Jan 2021. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 23 Dec 2020 (Day 86) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 28 Dec 2020 (Day 91) was positive. The subject went to his primary care physician (once). On 01 Jan 2021 (Day 95), the subject had a heart rate of 97 beats/min, blood pressure of 158/100 mmHg, and respiratory rate of 32 breaths/min. On 01 Jan 2021 (Day 95), a chest radiograph revealed bilateral patchy ground-glass infiltrates. On 01 Jan 2021 (Day 95), the subject began receiving high-flow oxygen therapy, which he continued until 03 Jan 2021 (Day 97). On 01 Jan 2021 (Day 95), the subject's laboratory test results showed elevated alkaline phosphatase of 3.17 µkat/L (normal range [NR]: 0.67-2.0 µkat/L), alanine aminotransferase of 7.96826 µkat/L (NR: 0.1667-0.6668 µkat/L), aspartate aminotransferase of 2.61719 µkat/L (NR: 0.25005-0.6668 µkat/L), C-reactive protein of 205 mg/L (NR: 0-10 mg/L), neutrophils of 9.36 × 109/L (NR: 1.6-6.98 × 109/L), and platelets of 405 × 109/L (NR: 171-388 × 109/L); and decreased lymphocytes of 1.27 × 109/L (NR: 1.4-4.2 × 109/L); bilirubin, creatinine, basophils, eosinophils, hematocrit, hemoglobin, and monocytes were within normal limits. The subject was hospitalized on 02 Jan 2021 (Day 96) and remained hospitalized at the time of the last available report. The subject was in the intensive care unit (ICU). The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19, admission to an ICU, and requirement for high-flow oxygen therapy). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 04 Feb 2021 (Day 129) and 25 Feb 2021 (Day 150), respectively, and remains in the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	94 kg	32.9 kg/m2	27SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	01NOV2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27SEP2020 (1)	17:30

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
2	Placebo	15OCT2020 (19)	14:13
3	BNT162b2	25FEB2021 (152)	14:22

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	METAB	Hyperglycaemia	hyperglycemia	29OCT2020 (33)	12:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	TC	N	Yes	NOT RELATED/OTHER: unknown	2	15	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	27SEP2020 (1)	27SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	27SEP2020 (1)	27SEP2020 (1)	SERUM	NEGATIVE
Visit 2	15OCT2020 (19)	15OCT2020 (19)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 27OCT2020 (31)/ 26OCT2020 (30)/ 11NOV2020 (46)	YES	NEW OR INCREASED SORE THROAT	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW LOSS OF TASTE OR SMELL	
	NO		Asthenia

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	27OCT2020 (31)	COVID-19 illness	27OCT2020 (31)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	27OCT2020 (31)	27OCT2020 (31)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	27OCT2020 (31)	27OCT2020 (31)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	27OCT2020 (31)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	27OCT2020 (31)	27OCT2020 (31)	1	140 mmHg	80 mmHg	20 breaths/min	125 beats/min	

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27SEP2020	
Completed	VACCINATION	12NOV2020	
Completed	REPEAT SCREENING 1	25FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 4444 44442304, a 49-year-old white male with a height of 169 cm, a weight of 94 kg, and a BMI of 32.9 kg/m2, received Dose 1 on 27 Sep 2020 and Dose 2 on 15 Oct 2020 (Day 19). The subject had a reported medical history of obesity (since 01 Nov 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 27 Oct 2020 (Day 31), the subject was diagnosed with severe COVID-19 and reported new or increased sore throat, new or increased muscle pain, new loss of taste or smell, and asthenia, with the first symptom starting on 26 Oct 2020, 11 days after receiving Dose 2, and the last symptom resolved on 11 Nov 2020. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 27 Oct 2020 (Day 31) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 27 Oct 2020 (Day 31) was positive. The subject did not have any contact with nonstudy healthcare personnel. On 27 Oct 2020 (Day 31), the subject had a heart rate of 125 beats/min, blood pressure of 140/80 mmHg, and respiratory rate of 20 breaths/min. The subject therefore had a severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and heart rate ⩾125 beats/min). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first dose of BNT162b2 on 25 Feb 2021 (Day 152) and remains in the study.