		Vaccine Group (as Administered)								
		BNT162b2 (30 μg)				Placebo				
System Organ Class Preferred Term	12-15 Years (Na=1131)			5 Years =536)	12-15 Years (Na=1129)			5 Years a=561)		
	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)		
Any event	66 (5.8)	(4.5, 7.4)	57 (10.6)	(8.2, 13.6)	66 (5.8)	(4.5, 7.4)	45 (8.0)	(5.9, 10.6)		
BLOOD AND LYMPHATIC SYSTEM DISORDERS	9 (0.8)	(0.4, 1.5)	1 (0.2)	(0.0, 1.0)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)		
Lymphadenopathy	9 (0.8)	(0.4, 1.5)	1 (0.2)	(0.0, 1.0)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)		
CARDIAC DISORDERS	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)		
Tachycardia	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)		
EAR AND LABYRINTH DISORDERS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)		
Ear pain	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)		
Cerumen impaction	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)		
EYE DISORDERS	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)		
Eye pain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)		
Eyelid rash	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)		
Ocular hyperaemia	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)		
Retinal haemorrhage	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)		
GASTROINTESTINAL DISORDERS	14 (1.2)	(0.7, 2.1)	4 (0.7)	(0.2, 1.9)	3 (0.3)	(0.1, 0.8)	5 (0.9)	(0.3, 2.1)		
Nausea	5 (0.4)	(0.1, 1.0)	2 (0.4)	(0.0, 1.3)	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)		
Diarrhoea	3 (0.3)	(0.1, 0.8)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)		
Abdominal pain	2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)		
Aphthous ulcer	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)		

	Vaccine Group (as Administered)							
		BNT162	b2 (30 μg))	Placebo			
	12-15 Years (Na=1131)			5 Years a=536)	12-15 Years (Na=1129)		16-25 Years (N ^a =561)	
System Organ Class Preferred Term	n ^b (%)	(95% CI°)	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)
Lip swelling	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Vomiting	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Gastritis	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Mouth swelling	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Oral mucosal blistering	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Rectal prolapse	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Toothache	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	16 (1.4)	(0.8, 2.3)	21 (3.9)	(2.4, 5.9)	11 (1.0)	(0.5, 1.7)	10 (1.8)	(0.9, 3.3)
Injection site pain	7 (0.6)	(0.2, 1.3)	10 (1.9)	(0.9, 3.4)	7 (0.6)	(0.2, 1.3)	2 (0.4)	(0.0, 1.3)
Fatigue	7 (0.6)	(0.2, 1.3)	7 (1.3)	(0.5, 2.7)	4 (0.4)	(0.1, 0.9)	3 (0.5)	(0.1, 1.6)
Pyrexia	5 (0.4)	(0.1, 1.0)	7 (1.3)	(0.5, 2.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Chills	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Injection site erythema	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)
Injection site swelling	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	0	(0.0, 0.7)
Oedema peripheral	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)
Pain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Chest pain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Injection site bruising	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Injection site discomfort	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)

			Vacc	ine Group (a	s Admin	istered)					
		BNT162b2 (30 μg)					Placebo				
		12-15 Years (Na=1131)		5 Years 2=536)	12-15 Years (Na=1129)			5 Years =561)			
System Organ Class Preferred Term	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)			
Injection site hyperaesthesia	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)			
Nodule	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)			
Peripheral swelling	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)			
Vessel puncture site pain	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)			
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)			
Food allergy	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)			
INFECTIONS AND INFESTATIONS	7 (0.6)	(0.2, 1.3)	4 (0.7)	(0.2, 1.9)	6 (0.5)	(0.2, 1.2)	12 (2.1)	(1.1, 3.7)			
Ear infection	3 (0.3)	(0.1, 0.8)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)			
Conjunctivitis	0	(0.0, 0.3)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)			
Otitis externa	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)			
Otitis media	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)			
Sinusitis	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)			
Tonsillitis	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)			
Vulvovaginal mycotic infection	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)			
Body tinea	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)			
Candida infection	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)			
Cellulitis	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)			
Cystitis	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)			
Folliculitis	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)			

	Vaccine Group (as Administered)								
		BNT162	b2 (30 μg)		Placebo				
			5 Years =536)				5 Years a=561)		
System Organ Class Preferred Term	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	
Genital herpes	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	
Genital herpes simplex	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Impetigo	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	
Infectious mononucleosis	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
Oral fungal infection	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	
Pharyngitis streptococcal	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	
Pilonidal cyst	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
Subcutaneous abscess	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
Tinea capitis	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Tinea infection	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	
Urinary tract infection	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Vulval abscess	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	8 (0.7)	(0.3, 1.4)	3 (0.6)	(0.1, 1.6)	10 (0.9)	(0.4, 1.6)	6 (1.1)	(0.4, 2.3)	
Ligament sprain	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	2 (0.4)	(0.0, 1.3)	
Concussion	3 (0.3)	(0.1, 0.8)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Accident	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
Clavicle fracture	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
Contusion	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
Exposure during pregnancy	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)	

			Vacc	ine Group (a	s Admin	istered)			
		BNT162b2 (30 μg)				Placebo			
		12-15 Years (N ^a =1131)		5 Years a=536)	12-15 Years (Na=1129)			5 Years a=561)	
System Organ Class Preferred Term	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI°)	
Fall	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	
Muscle strain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
Procedural pain	0	(0.0, 0.3)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	
Tooth fracture	0	(0.0, 0.3)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	
Fibula fracture	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	
Foot fracture	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
Hand fracture	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Humerus fracture	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
Joint dislocation	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Lip injury	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
Meniscus injury	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Patella fracture	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
Radius fracture	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Road traffic accident	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	
INVESTIGATIONS	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Electrocardiogram QT prolonged	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)	
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Decreased appetite	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	0	(0.0, 0.7)	

	Vaccine Group (as Administered)								
		BNT162b2 (30 μg)				Placebo			
		12-15 Years (Na=1131)		5 Years =536)	12-15 Years (Na=1129)		16-25 Years (Na=561)		
System Organ Class Preferred Term	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	9 (0.8)	(0.4, 1.5)	12 (2.2)	(1.2, 3.9)	8 (0.7)	(0.3, 1.4)	8 (1.4)	(0.6, 2.8)	
Arthralgia	2 (0.2)	(0.0, 0.6)	3 (0.6)	(0.1, 1.6)	3 (0.3)	(0.1, 0.8)	4 (0.7)	(0.2, 1.8)	
Myalgia	3 (0.3)	(0.1, 0.8)	6 (1.1)	(0.4, 2.4)	2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)	
Back pain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	
Pain in extremity	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Arthropathy	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	
Joint swelling	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
Limb mass	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Mobility decreased	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Musculoskeletal chest pain	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
Musculoskeletal discomfort	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Neck pain	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
Osteochondrosis	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Plantar fasciitis	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	
Spinal disorder	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	
Torticollis	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.3)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	
Fibroadenoma of breast	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	

	Vaccine Group (as Administered)								
		BNT162b2 (30 μg)				Placebo			
		5 Years =1131)		5 Years =536)		5 Years =1129)		5 Years a=561)	
System Organ Class Preferred Term	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	
Skin papilloma	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
NERVOUS SYSTEM DISORDERS	11 (1.0)	(0.5, 1.7)	13 (2.4)	(1.3, 4.1)	7 (0.6)	(0.2, 1.3)	7 (1.2)	(0.5, 2.6)	
Headache	5 (0.4)	(0.1, 1.0)	11 (2.1)	(1.0, 3.6)	4 (0.4)	(0.1, 0.9)	5 (0.9)	(0.3, 2.1)	
Dizziness	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)	
Migraine	2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Presyncope	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	
Burning sensation	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Paraesthesia	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)	
PSYCHIATRIC DISORDERS	4 (0.4)	(0.1, 0.9)	5 (0.9)	(0.3, 2.2)	5 (0.4)	(0.1, 1.0)	1 (0.2)	(0.0, 1.0)	
Anxiety	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)	
Depression	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	
Attention deficit hyperactivity disorder	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
Depressed mood	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	
Disorientation	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Generalised anxiety disorder	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Sleep terror	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Tic	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Cervical dysplasia	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)	

	Vaccine Group (as Administered)								
		BNT162b2 (30 μg)					Placebo		
	12-15 Years (Na=1131)			16-25 Years (N ^a =536)		12-15 Years (Na=1129)		5 Years =561)	
System Organ Class Preferred Term	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)	4 (0.4)	(0.1, 0.9)	4 (0.7)	(0.2, 1.8)	
Rhinorrhoea	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	4 (0.4)	(0.1, 0.9)	0	(0.0, 0.7)	
Oropharyngeal pain	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	3 (0.5)	(0.1, 1.6)	
Asthma	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Nasal congestion	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Reflux laryngitis	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	6 (0.5)	(0.2, 1.2)	5 (0.9)	(0.3, 2.2)	13 (1.2)	(0.6, 2.0)	2 (0.4)	(0.0, 1.3)	
Rash	2 (0.2)	(0.0, 0.6)	3 (0.6)	(0.1, 1.6)	4 (0.4)	(0.1, 0.9)	0	(0.0, 0.7)	
Urticaria	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	4 (0.4)	(0.1, 0.9)	0	(0.0, 0.7)	
Acne	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	
Dermatitis contact	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
Macule	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	
Pityriasis rosea	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
Rash erythematous	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Rash maculo-papular	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	
Seborrhoeic dermatitis	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	
Sclerotherapy	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)	
Tooth extraction	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	

Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) - Safety Population

			Vacc	ine Group (a	s Admin	istered)		
		BNT162b2 (30 μg)				Plac	ebo	
	=	12-15 Years 16-25 Years (N ^a =1131) (N ^a =536)			12-15 Years (Na=1129)		16-25 Years (N ^a =561)	
System Organ Class Preferred Term	n^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)
Wisdom teeth removal	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)

Note: MedDRA (v23.1) coding dictionary applied.

Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.

Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years of age who received an electronic diary (e-diary).

- a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
- b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," <math>n = number of subjects reporting at least 1 occurrence of any event.
- c. Exact 2-sided CI based on the Clopper and Pearson method.

PFIZER CONFIDENTIAL SDTM Creation: . (.) Source Data: adae Table Generation: 04APR2021 (13:23)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA RR/adae s130 1md2 soc nsae ped saf