16.1.3.1 LIST OF INDEPENDENT ETHICS COMMITTEE (IEC) OR INSTITUTIONAL REVIEW BOARD (IRB)

UNITED STATES

Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1005	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1006	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1007	Cincinnati Children's Hospital Medical Center IRB 3333 Burnet Ave, MLC 5020 Cincinnati, OH 45229 UNITED STATES
1008	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1009	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES

Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1013	Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1016	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1039	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1044	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1057	Copernicus Group Institutional Review Board 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1066	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES

Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1077	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1084	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1091	Copernicus Group Institutional Review Board 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1123	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1124	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1125	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1126	Kaiser Permanente Northern California Institutional Review Board 1800 Harrison St, 10th Fl Oakland, CA 94612 UNITED STATES

Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1131	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1139	WESTERN INSTITUTIONAL REVIEW BOARD 1019 39th Ave SE, Ste 120 Puyallup, WASHINGTON 98374-2115 UNITED STATES
1140	WESTERN INSTITUTIONAL REVIEW BOARD 1019 39th Ave S.E, Ste 120 Puyallup, WA 98374 UNITED STATES
1142	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1147	Western Institutional Review Board 1019 39th Ave Se, Ste 120 Puyallup, WASHINGTON 98374 UNITED STATES
1150	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1152	Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES

Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1156	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1223	Yale University Human Research Protection Program (Human Investigation Committee) 25 Science Park, 3rd Fl, 150 Munson St New Haven, CT 06520 UNITED STATES
1235	Western Institutional Review Board 1019 39th Ave. SE, Ste 120 Puyallup, WA 98374 UNITED STATES
1270	Kaiser Permanente Northern California Institutional Review Board 1800 Harrison St, 10th Fl Oakland, CA 94612 UNITED STATES

INFORMED CONSENT AND /OR ASSENT ADDENDUM FOR A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS

Protocol Number: C4591001

You have already signed a consent form to allow your child to participate in the research study mentioned above. This addendum is part of the consent procedure. It has been written to provide you with additional information on your child's new schedule of study visits, tests, and procedures and reimbursement to cover any reasonable expenses (for example, parking, meals, travel) associated with these new visits. It also provides the latest information on BNT162b2 vaccine risks that you will want to know. All other information in the main consent form not addressed in this addendum still applies.

Administration of BNT162b2 to Participants Originally Assigned to Placebo

You were asked by the study site whether you would consider your child receiving BNT162b2 vaccine (active study vaccine) if they received placebo during the earlier part of the study. Since it is confirmed that they received placebo, and have expressed willingness to receive the BNT162b2 vaccine, you are now being asked to read, sign and date this consent document before commencing any new set of study-related procedures.

After signing this consent addendum, the study doctor will check if your child meets all the requirements to receive BNT162b2 vaccine. If they do not meet the requirements, they will not be able to receive the vaccine and the study doctor will explain why this is the case.

Once the study doctor has confirmed your child meet the study requirements to receive BNT162b2 vaccine, they will receive 2 injections, approximately 3 weeks apart. The injection will be given into the muscle in their upper arm and will be asked to wait at the study site for at least 30 minutes for observation after receiving the vaccine.

Overview of Study Procedures and Assessments:

The table below lists the tests and procedures or assessments that your child will have done for the remaining duration of the study. In addition to the visits listed, your study doctor may ask your child to come in for extra visit(s) if necessary, to protect their well-being.

Your child may have blood taken once and this will be used to test if they already had antibodies against coronavirus that causes COVID-19. About 20mL of blood (about 4 teaspoons) will be collected from their arm using a needle at Visit 101.

For placebo participants receiving BNT162b2, the study doctor or nurse will:

Visit Number	101	102	103	104	105
Visit Description	**BNT162b2 Vaccine 1**	**BNT162b2 Vaccine 2**	**1-Month Telephone Visit**	**6-Month Telephone Visit**	**18-Month Telephone Visit**
Obtain urine pregnancy test (if appropriate)	X	X			
Check contraceptives (if appropriate)	X	X			
Ask about medicines your child is currently taking	X	X	X	X	X
Record latest CD4 count and viral load (for HIV positive participants only)	X		X	X	X
Check your child meets all the study requirements	X	X			
Collect blood sample to test antibody levels[a]	~20 mL				
Take a nasal swab	X	X			
Administer the study injection, followed by a 30minutes observation period	X	X			
COVID-19 illness e-diary completion	X	X	X	X	X
Ask how your child is feeling generally	X	X	X	X	
Request to return the e-diary or assist to delete the app					X

a. Only if the sample was not taken as part of the study in last 7days

In addition to the above:

- you will remember that your child has been asked to attend an extra visit (i.e. convalescent visit) to the study site about a month after their potential COVID-19 illness visit. Now, that the study team has obtained enough clinical data in the study from these convalescent visits, it is no longer a requirement for your child to attend this extra visit after their potential COVID-19 illness.
- You will also remember that you and/or your child have been asked to tell the study doctor immediately if your child or their partner become pregnant during the study, up until 6 months after their last study injection. However, the reporting duration has now been revised to 28days after their last study injection.

Study Vaccine Risks

Up until the June 2021, the safety of BNT162b2 has been studied in clinical trials that have included about 28,500 people who have received at least one dose of the vaccine. In addition, since the vaccine has been approved for emergency use or received a conditional marketing authorization in many countries, by the end of April 2021 about 400 million doses have been distributed.

Based on the clinical study results, and information gathered during general use, the following risks have been determined to be caused by BNT162b2 vaccine:

Very common (occurring in more than 1 in 10 people): injection site pain, injection site swelling, fatigue (tiredness), increased body temperature (fever, more common after the second dose), chills, headache, diarrhea, joint aches, and muscle aches.

Common (between 1 in 10 and 1 in 100 people): feeling sick (nausea), being sick (vomiting), and injection site redness.

Uncommon (between 1 in 100 and 1 in 1,000 people): enlarged lymph glands, allergic reactions (symptoms may include rash, itching, hives), decreased appetite, lethargy, sweating and night sweats, pain in arm, and feeling weak or unwell.

Rare (between 1 in 1,000 and 1 in 10,000 people): swelling of the face or lips.

Frequency that cannot be estimated from available data: severe allergic reaction (anaphylaxis).

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received BNT162b2. Cases have mainly been reported in males under 30 years of age and following the

second vaccination, however, there have been some cases reported in older males and females as well as following the first vaccination. The chance of having this occur is very low and, in most of these people, symptoms began within a few days to a week following vaccination. As a precaution, your child should seek medical attention right away if they have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Please also notify study staff, when appropriate, if your child has any of these symptoms.

Whilst some severe cases have been reported, most cases have been associated with full resolution of symptoms in the short term, however, long-term follow-up is limited. It is not known whether the risk of myocarditis or pericarditis is increased following additional doses of the vaccine, e.g. following a booster dose.

If your child has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart) previously, please tell your child's study doctor.

The part of this study that included 2,260 12-15 year olds (1131 of whom received BNT162b2) demonstrated similar risks in this age group. There were no confirmed cases of myocarditis or pericarditis in the data from this part of the study, however as mentioned above there is a very low chance that this may occur after vaccination.

As in all research studies, the COVID-19 vaccine may involve risks that might be expected based on results from studies of similar vaccines, as well as risks that are currently unknown.

Therefore, it is important that you/your child report all symptoms and side effects that your child experiences as soon as they occur, whether or not you think they are caused by the study vaccine.

Due to the way in which the study vaccines are made, they cannot cause COVID-19 disease.

<u>If my child catches COVID-19 disease, could the vaccine make it worse?</u>

For some other vaccines tested in animals against similar viruses (but not the coronavirus that causes COVID-19), there have been reports of the illness being more severe in the animals that received the vaccine than in those that did not. So far this has

not been seen with BNT162b2. It remains important for you/your child to contact your child's study doctor if your child develop symptoms that might be caused by COVID-19 (for example, fever, cough, shortness of breath).

Key Reminders

- Vaccination with BNT162b2 has been shown to be effective in preventing COVID-19 but your child still needs to follow local recommendations about how to avoid COVID-19 (for example, social distancing and mask use).
- It is also very important that you continue to complete the COVID-19 Illness e-Diary regularly on your child's behalf as instructed. If you do not, your study doctor or nurse will contact you or your child to check how they are.

Will my child be paid for receiving the active study vaccine and for the additional visits to the study site??

Your child will not receive any payment for receiving the active study vaccine. However, you will be reimbursed $XX.XX by the study site for the onsite visit(s) you/your child complete as part of their new study schedule to cover out-of-pocket expenses, such as travel and parking.

Please take as much time as you need to ask questions from the research study team before you agree for your child to receive the active vaccine. If after receiving this information you agree for your child to receive the active study vaccine, please sign below.

SIGNATURES:

- I have read the information in this addendum to the informed consent document.
- I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction.
- I have been given enough time to decide whether or not I want my child to receive the active vaccine.
- I voluntarily agree for my child to receive the active vaccine.
- I do not give up any of my or my child's legal rights by signing this addendum to the informed consent document.
- I have been told that I will receive a signed and dated copy of this addendum.

SIGNATURE LINE(S) TO BE COMPLETED FOR A CHILD PARTICIPANT:

As the consenting adult providing permission for this child to participate in the study, I acknowledge that (Please check one of the following):

☐ I am the biological or adoptive parent of the child.

☐ I am the legal guardian or legally acceptable representative of the child.

I also acknowledge that (Please check one of the following):

☐ I have sole legal responsibility for the care and custody of the child.

☐ The other adult(s) with whom I share legal responsibility for the care and custody of the child (for example, biological parent, adoptive parent, or legal guardian or representative) is (1) aware of and agrees with my granting permission for this child to participate in the study OR (2) deceased, unknown, incompetent, or not reasonably available (someone is "not reasonably available" when he/she cannot be reached by phone/mail/email because, for example, he/she is on active military duty or is incarcerated).

_____

Printed Name of Parent / Guardian / Legally Acceptable Representative

_____ _____

Signature of Parent / Guardian / Legally Acceptable Representative Date of signature§

Consent of Second Parent/Guardian/Legally Acceptable Representative:

As the consenting adult providing permission for this child to participate in the study, I acknowledge that (Please check one of the following):

☐ I am the biological or adoptive parent of the child.

☐ I am the legal guardian or legally acceptable representative of the child.

_____ _____

Printed Name of Parent / Guardian / Legally Acceptable Representative

Relationship to study participant

_____ _____

Signature of Parent / Guardian / Date of signature§

Legally Acceptable Representative

PERSON OBTAINING CONSENT

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Conducting the Consent Discussion † Date of signature

§Participant/parent/guardian/legally acceptable representative must personally date their signature

†The investigator, or an appropriately qualified and trained person designated by the investigator to conduct the informed consent process, must sign and date the consent document during the same interview when the participant/parent/guardian/legally acceptable representative signs the addendum.

OLDER CHILDREN ASSENT ADDENDUM FOR A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS

Protocol Number: C4591001

You have already signed the assent form to participate in the research study mentioned above. This addendum is part of the assent procedure. It has been written to provide you with additional information on your new schedule of study visits, tests, and procedures. It also provides the latest information on study vaccine risks that you will want to know. All other information in the main assent form not addressed in this addendum still applies.

Administration of BNT162b2 to Participants Originally Assigned to Placebo

You were asked by the study site whether you would consider receiving BNT162b2 vaccine (will be referred as 'active vaccine' or 'active study vaccine') if you received placebo during the earlier part of the study. Since it is confirmed that you received placebo, and expressed your willingness to receive the active vaccine, you are now being asked to read and sign this assent form before conducting any new set of study-related procedures. Your parent(s) or your guardian(s) will be asked to sign another form.

After signing this assent document, the study doctor will check if you meet all the requirements to receive the active vaccine. If you do not meet the requirements, you will not be able to receive the vaccine and the study doctor will explain why this is the case.

Once the study doctor has confirmed you meet the study requirements to receive active vaccine, you will receive 2 injections, approximately 3 weeks apart. The injection will be given into the muscle in your upper arm, just like how you received previous study injections. After that, you, along with your parent (s) or guardian (s) will be asked to wait at the study site for at least 30 minutes for observation after receiving the vaccine.

Overview of Study Procedures and Assessments:

The table below lists the tests and procedures or assessments that you will have done for the remaining duration of the study. In addition to the visits listed, your study doctor may ask you to come in for extra visit(s) if necessary, to protect your well-being.

You may have blood taken once and this will be used to test if you already had antibodies against coronavirus that causes COVID-19. About 20mL of blood (about 4 teaspoons) will be collected from your arm using a needle at Visit 101.

For placebo participants receiving active vaccine, the study doctor or nurse will:

Visit Number	101	102	103	104	105
Visit Description	**BNT162b2 Vaccine 1**	**BNT162b2 Vaccine 2**	**1-Month Telephone Visit**	**6-Month Telephone Visit**	**18-Month Telephone Visit**
Obtain urine pregnancy test (if appropriate)	X	X			
Check contraceptives (if appropriate)	X	X			
Ask about medicines you are currently taking	X	X	X	X	X
Record latest CD4 count and viral load (for HIV positive participants only)	X		X	X	X
Check you meet all the study requirements	X	X			
Collect blood sample to test antibody levels[a]	~20 mL				
Take a nasal swab	X	X			
Administer the study injection, followed by a 30minutes observation period	X	X			
COVID-19 illness e-diary completion	X	X	X	X	X
Ask how you are feeling generally	X	X	X	X	
Request to return the e-diary or assist to delete the app					X

a. Only if the sample was not taken as part of the study in last 7days

In addition to the above:

- you will remember that you have been asked to attend an extra visit to the study site about a month after your potential COVID-19 illness visit. Now, that the study team has obtained enough clinical data in the study from these visits, it is no longer a requirement for you to attend this extra visit after the potential COVID-19 illness.
- You will also remember that you have been asked to tell the study doctor immediately if you or your partner become pregnant during the study, up until 6 months after your last study injection. However, the reporting duration has now been revised to 28days after your last study injection.

Study Vaccine Risks

The injection could cause pain, swelling, and redness where it is given.

Other side effects could include: fatigue (tiredness), increased body temperature (fever), chills, headache, diarrhea, joint aches, muscle aches, feeling sick (nausea), being sick (vomiting), enlarged lymph glands, allergic reaction (symptoms may include rash, itching, hives, and swelling of the face or lips), decreased appetite, lethargy, sweating and night sweats, pain in arm, feeling weak or unwell, and severe allergic reaction (anaphylaxis).

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received BNT162b2. Cases have mainly been reported in males under 30 years of age and following the second vaccination, however, there have been some cases reported in older males and females as well as following the first vaccination. The chance of having this occur is very low and in most of these people, symptoms began within a few days to a week following vaccination. As a precaution, you should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Please also notify study staff, when appropriate, if you have any of these symptoms.

Whilst some severe cases have been reported, most cases have been associated with full resolution of symptoms in the short term, however, long-term follow-up is limited. It is not known whether the risk of myocarditis or pericarditis is increased following additional doses of the vaccine, e.g. following a booster dose.

If you have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart) previously, please tell your study doctor.

The study team will monitor you for risks or discomforts during the study. However, the study team does not know all the effects that the vaccine, or your participation in this study, may have on you.

Therefore, it is important that you report all symptoms and side effects that you experience as soon as they occur, whether or not you think they are caused by the study vaccine. Due to the way in which the study vaccines are made, they cannot cause COVID-19 disease.

Please take as much time as you need to ask questions from the research study team before agreeing to receive the active vaccine. You can circle or highlight things on this paper you want to know more about. If you don't understand something, just ask us. It is okay to ask questions now and anytime later that you think of them.

Please check one box below to show whether or not you want to receive the active study vaccine.

☐ Yes, I want to receive the active study vaccine.

☐ No, I do not want to receive the active study vaccine.

_____

Printed Name of Child/Young Person

_____ _____ _____

Child/Young Person Signature Date Time

Statement of person conducting assent discussion:

1. I have explained all aspects of transition from placebo to active vaccine to the participant to the best of his or her ability to understand.
2. I have answered all questions of the participant relating to this transition from placebo to active vaccine.
3. I believe the participant's decision to receive or not receive active vaccine is voluntary.

4. If the participant decides to receive active vaccine, the study doctor and study staff agree to respect the participant's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

Printed Name of Person Obtaining Assent: _____

Signature of Person Obtaining Assent: _____ Date: _____ Time: _____

Table of Contents

This Table of Contents describes the different sections of this consent document. Be sure to read through all sections of this consent document before making your decision about whether or not to participate in this study.

1. Key Study Information and Contact Information

The study team will address any questions, concerns or complaints you or your child may have before, during and after your child complete the study. The study team includes the study doctor, nurses, and others who work with the study doctor.

Phone numbers for the study team are listed below under "Study Site Contact Information." **You also will be given a card with important emergency contact information, including a 24-hour number.** Show this card to any doctor, nurse or other health care provider if your child seeks emergency care while taking part in this study. This card includes information about the study that will help them treat your child.

If you have any general questions about your child's rights as a study participant, or would like to obtain information from, offer suggestions to, or speak with someone not directly involved in the study, you may contact **[**For the site-level ICD, include as appropriate: the Institutional Review Board ***or*** the Independent Ethics Committee, patient rights advocate, and/or bioethicist**]** listed below.

Name of Study: **A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS**

[Institution] Study Number:

Sponsor Study Number: **C4591001**

Name of Company Sponsoring the Study: **BioNTech. Pfizer is conducting the study for BioNTech**

Name of Principal Investigator (Study Doctor):

Study Site Contact Information:

Contact Person:

Address:

Phone Number (Normal Business Hours):

Phone Number (Off-Hours or Emergency):

[Complete the following entries for the site-level ICD as appropriate.**]**

[Institutional Review Board *or* Independent Ethics Committee] Contact Information:

Contact Person:

Address:

Phone Number:

Patient Rights Advocate:

Contact Person:

Address:

Phone Number:

Bioethicist:

Contact Person:

Address:

Phone Number:

2. Brief Summary of this Study

You are being asked to allow your child to take part in a research study that involves comparing an investigational (study) vaccine against a placebo (injection with no active ingredient) to see if the vaccine can prevent COVID-19. The vaccine is given by injection.

Depending on your child's age, mental status and local laws, the study team **may need to verify your child's agreement (called "assent") to take part in this study**. Your child may give assent verbally, or they may be asked to print or sign their name on an assent document similar to this consent document. They may have an opportunity to meet privately with a member of the study team to ask confidential questions. Your child will also be able to decide not to take part for confidential reasons, which, if they request, would not be shared with you unless required by local law. Also, if your child reaches the legally recognized age of majority (adulthood) during the study, they must separately provide their consent to continue taking part in the study.

You are being asked to allow your child to be in this research study because your child is healthy and over the age of 12.

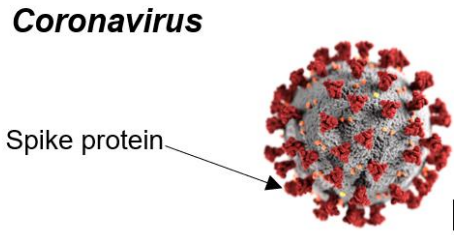
This is a research study involving both Pfizer and BioNTech. Pfizer and BioNTech are separate companies who are cooperating to perform this study. Pfizer is responsible for conducting this study. BioNTech is the regulatory sponsor of this study. Funding for this study is provided by BioNTech and Pfizer and [the study doctor/institution] will be paid to conduct this study.

A new respiratory disease appeared in Wuhan, China in December 2019 and has since rapidly spread to many other countries around the world. In January 2020, the cause of this disease was found to be a new Coronavirus; and the disease it causes was named COVID-19 (Coronavirus disease 2019). Since then, many companies around the World have quickly started to look for treatments and ways to prevent COVID-19.

Vaccines help your body to produce antibodies to help you to fight off a disease. This research study involves 2 investigational vaccines to prevent COVID-19, that will be

given to volunteers. The vaccines are given by injection. The vaccines are slightly different but work in the same way. The study will also test each of these vaccines at different dose levels (amounts of vaccine).

These vaccines do not contain the whole virus, or the parts of the virus that can make your child ill, instead the vaccines are made up of part of the virus's genetic code, surrounded by fatty particles called lipids. They use a persons cells' protein making machinery to produce some, or all, of the spike protein seen on the outside of the virus. This spike protein, made by your child's body, may help your child's body to produce antibodies to fight against COVID-19. We will check how many antibodies your child makes by taking blood samples and testing them.



This study is different from your child's regular medical care. The purpose of regular medical care is to improve or otherwise manage your child's health, but the purpose of research is to gather information to advance science and medicine and does not replace your child's regular medical care. If your child needs medical care during their time in the study, you should contact your regular provider and inform the study team, as described later in this document.

Allowing your child to taking part in this study is voluntary (your choice). There is no penalty or change to you or your child's regular medical care if you decide not to allow your child to participate. You can choose to let your child take part in the study now, and then change your mind later at any time without losing any benefits or medical care to which you or your child are entitled. We encourage you to have conversations with your family, friends, doctors, and study team about this study and whether it is right for your child. The study team will work with you to answer any questions that you may have about the study.

You will receive a signed copy of this consent document for your records. Please keep this consent document for your reference.

3. What is the purpose of this study?

The World Health Organization (WHO) has declared COVID-19 to be a pandemic (a disease that has spread all over the world and is affecting lots of people); finding a vaccine to prevent COVID-19 is an urgent need. To test this investigational vaccine as

quickly as possible, this study has been separated into 2 phases. In both the phases we will try to see if the vaccine works to prevent COVID-19, as well as:

- **Phase 1** where we choose which vaccines at which dose levels are safest and make the most antibodies.
- **Phase 2/3** where we look at one vaccine at one dose level in lots of people to collect even more information about the safety of the vaccines and the amounts of antibodies they produce.

Your child is being asked to take part in **Phase 2/3.**

The study will compare the results of the people who receive the study vaccine (BNT162b2) with those who receive a placebo (a placebo does not contain any active ingredients). In this study the placebo will be salt-water, also known as normal saline. Everyone in Phase 2/3 of the study will receive 2 injections of either:

- Study vaccine followed by study vaccine
- Placebo followed by placebo

In Phase 2/3 everyone who receives the study vaccine will receive the same vaccine at the same dose, that was chosen based on the results from Phase 1.

The study doctor will determine whether your child is eligible for the study. This study will require your child to visit the study doctor to undergo study procedures and to provide information about their health. You/your child will also be required to contact the study doctor if your child experience any of the COVID-19 symptoms (explained later in this document).

4. How long will my child participate in this study?

Your child could be in this study for up to about 26 months and will need to visit the study site 6 or 7 planned times during the study. Your child will also need to visit the study site if they experience COVID-19 symptoms.

5. How many adults and children will take part in this study?

Approximately 44,193 volunteers could take part in the 2 phases of this study.

In Phase 2/3 of the study up to 43,998 volunteers will take part, in which approximately 2000 will be of 12 to 15 years of age and the remaining will be above the age of 16 years.

6. What will happen during this study?

Before any study procedures begin, or before your child begins preparing for the study, you will be asked to read and sign this consent document. We may also ask your child to read and sign a similar document.

After signing this consent document, the study doctor will check if your child meets all of the requirements to take part in this study. If your child does not meet the requirements, they will not be able to take part in the study and the study doctor will explain why this is the case.

Study Vaccines

Once the study doctor has confirmed your child meets the study requirements, your child will be randomly assigned (like flipping a coin) to receive the study vaccine or placebo. For every 1 volunteer who receives the study vaccine, 1 volunteer will receive the placebo. No one (including you, your child, your child's personal doctor or the study team) can choose this assignment.

This is an 'observer-blind study', which means that you, your child and the study doctor will not know whether your child will receive the study vaccine or placebo. The person who gives your child the vaccine will know because the vaccine and placebo do not look the same. The syringe will be covered with a label so the contents are not visible and the person that gives your child the vaccine will not be able to talk about it. In case of urgent need, the study doctor can learn quickly whether your child received study vaccine or placebo.

The study vaccine or placebo will be given to your child through an injection into the muscle of the upper arm. All volunteers will receive 2 injections, approximately 3 weeks apart. On the days your child receives the study vaccine or placebo, you and your child will be asked to wait at the study site for at least 30 minutes for observation.

Overview of Study Procedures and Assessments

The table below lists the tests and procedures or assessments that will be done in this research study. In addition to the visits listed, the study doctor may ask your child to come in for extra visit(s) if necessary, to protect their well-being.

For people taking part in Phase 2/3, the study doctor or nurse will:

Visit Number	1	2	3	4	5	6
Visit Description	Study Vaccine 1	Study Vaccine 2	1-Month Visit	6-Month Visit	12-Month Visit	24-Month Visit
Ask about Medical history as well as date of birth, sex, race and ethnicity	X					
Ask about medicines your child is currently taking	X	X	X	X	X	X
Perform clinical assessment	X					
Record latest CD4 count and viral load (for HIV positive volunteers only)	X		X	X	X	X
Measure body temperature	X	X				
Measure height and weight	X					
If your child is female and started her periods, she will be asked to provide a urine sample for a pregnancy test.	X	X				
Ask about other vaccinations your child has had	X	X	X	X		
Check your child meets all the study requirements	X	X				
If needed, we will discuss with your child about appropriate birth control	X	X	X			
Collect blood sample to test antibody levels[a]	~20 mL/ ~10 mL		~20 mL/ ~10 mL	~20mL/ ~10 mL	~20 mL/ ~10 mL	~20 mL/ ~10 mL
Take a nasal swab	X	X				
Get the study injection, followed by a 30mins observations period	X	X				
Give you/your child an e-diary or help you/your child download one	X					
Vaccination e-diary completion for 7 days (if your child is part of a chosen group to report potential side effects daily for 7 days following vaccination)	X	X				

For people taking part in Phase 2/3, the study doctor or nurse will:

Visit Number	1	2	3	4	5	6
Visit Description	Study Vaccine 1	Study Vaccine 2	1-Month Visit	6-Month Visit	12-Month Visit	24-Month Visit
COVID-19 illness e-diary completion	X	X	X	X	X	X
Ask how your child is feeling generally	X	X	X	X	X	X

Abbreviations: HIV = human immunodeficiency virus; e-diary = electronic diary.

a. 20 mL is to be collected from participants ⩾16 years of age; 10 mL is to be collected from participants 12 to 15 years of age.

Blood samples for antibody testing

Your child will have blood taken 5 times during the planned visits of the study. This will be used to test if they already had antibodies against the coronavirus that causes COVID-19 when they enrolled in the study and may be used to test their antibody levels after vaccination. If your child is 16 years of age or above, about 20 mL of blood (about 4 teaspoons) will be collected from their arm using a needle at these visits. Alternatively, if your child is between 12 to 15 years of age, about 10 mL of blood (about 2 teaspoons) will be collected from their arm using a needle at the above specified visits.

E-Diary

At Visit 1, the study team will show you or your child how to fill in an electronic diary (or e-Diary). Parent(s)/ legal guardian(s), as appropriate, will be required to complete the e-diary on behalf of younger age group children, whilst children in older age group might not require similar level of support from their parent(s)/ legal guardian(s). Therefore, older age group children (e.g. 16 years or above) are expected to complete the e-diary themselves.

We will either give you/ your child a device (a bit like a mobile phone) or ask to download an application ('app') to smart phone if you or your child has one. The device/app is secure, and your child's confidentiality will be maintained.

There are 2 parts to the e-Diary. Everyone will need to complete the COVID-19 illness part of the e-Diary on the device or app on their smartphone. The COVID-19 illness e-Diary will prompt you/ your child to record any COVID-19 symptoms (see below) every 7 days or at any time your child has COVID-19 symptoms. You or your child may also receive text messages to the device or your/your child's own smartphone, or emails (if you/they provide your/their email address) to remind you/your child to complete the COVID-19 illness part of the e-Diary.

If your child is part of a subset of participants, you/ your child will also be instructed by the study team to complete the vaccination part of the e-Diary for 7 days after each vaccination, once a day in the evening with the first day being the day of the vaccination.

You/ your child will be given a thermometer and a measuring device to take home. You/ your child will use the thermometer to measure temperature under the tongue and will use the measuring device to measure any redness or swelling where the injection was given. You/ your child will need to record these measurements in the vaccination part of the e-Diary.

The vaccination part of the e-Diary will also ask other questions about potential side effects your child may have after the injection. If your child has any severe symptoms

after vaccination, you/ your child should contact your study doctor and the study doctor or nurse may schedule an extra visit.

It is very important that you/ your child, as appropriate, complete the e-Diary regularly as instructed. If this was not completed, your study doctor or nurse will contact you/ your child to check how your child is doing.

Urine pregnancy test

If your child is female and has started her periods, she will be asked to provide a urine sample to check she is not pregnant before given the study injection.

What happens if my child has positive nasal swab test result?

Nasal swabs obtained during the study (at Visits 1 and 2, and at the time of a potential COVID-19 illness – see below) will be tested in a research laboratory. Positive results from the Visit 1 and 2 swabs, and all results from the illness visit swabs, will be provided to your study doctor, but this will take some time so you should not rely on these for your child's medical treatment.

If Your Child Gets COVID-19 Symptoms

If your child gets any of the following you must contact the study doctor straight away. Note that this is not instead of routine medical care. If your child feels unwell enough that you would normally see a healthcare professional, please contact your usual provider, as well as the study doctor.

- **A diagnosis of COVID-19;**
- **Fever;**
- **New or increased cough;**
- **New or increased shortness of breath;**
- **Chills;**
- **New or increased muscle pain;**
- **New loss of taste/smell;**
- **Sore throat;**
- **Diarrhea;**
- **Vomiting.**

The study doctor may ask you/your child to have a telephone conversation, video call or to visit the site to talk about how they are feeling and if they have needed any other medical care. The study team will also ask you to help your child to take a nose swab, or the study team may take a swab to check for the coronavirus. We will give you/your

child separate instructions about how to take a nose swab and how to ship the swab to the laboratory if needed. The result from this swab will be provided to the study doctor once it is available, but this will take some time, and cannot be used to diagnose COVID-19. This is why it is important that you contact your usual provider if your child has COVID-19 symptoms and think your child needs medical care.

If your child is diagnosed with COVID-19, for the purposes of the study, the study doctor will contact your child's usual provider, and any facility where you child is treated, to obtain details and collect medical records: by signing this informed consent document, you agree to this.

After the study

The study vaccine is available only during this study and not after the study is over. If you leave the study before receiving the study vaccine, it may be available to you through an authorized healthcare professional.

7. Are there any special instructions to follow for this study?

It is important you and your child follow all the instructions given by the study nurse or doctor and tell them if:

- You don't understand anything about the study
- You /your child are not able to comply with the study requirements
- There are changes in your child's health
- Your child takes any new medications or receive any other vaccines
- You or your child are going away for a long period
- Your child wishes to take part in another research study

8. What are the possible risks and discomforts of this study?

Any research has some risks, which may include negative effects that could make your child unwell or uncomfortable and even potentially be serious or life-threatening. All research participants taking part in the study will be watched carefully for any negative effects; however, the study team does not know all the effects that the study vaccine may have on your child.

If your child takes part in this study, the most likely risks or discomforts are discussed below.

It is important that you/ your child report to the study team all symptoms and side effects as soon as they occur. Phone numbers for the study team are listed in [Section 1] of this consent document.

Study Vaccine Risks

Up until June 2021, the safety of BNT162b2 has been studied in clinical trials that have included about 28,500 people who have received at least one dose of the vaccine. In addition, since the vaccine has been approved for emergency use or received a conditional marketing authorization in many countries, by the end of April 2021 about 400 million doses have been distributed.

Based on the clinical study results, and information gathered during general use, the following risks have been determined to be caused by BNT162b2 vaccine:

Very common (occurring in more than 1 in 10 people): injection site pain, injection site swelling, fatigue (tiredness), increased body temperature (fever, more common after the second dose), chills, headache, diarrhea, joint aches, and muscle aches.

Common (between 1 in 10 and 1 in 100 people): feeling sick (nausea), being sick (vomiting), and injection site redness.

Uncommon (between 1 in 100 and 1 in 1,000 people): enlarged lymph glands, allergic reactions (symptoms may include rash, itching, hives), decreased appetite, lethargy, sweating and night sweats, pain in arm, and feeling weak or unwell.

Rare (between 1 in 1,000 and 1 in 10,000 people): swelling of the face or lips.

Frequency that cannot be estimated from available data: severe allergic reaction (anaphylaxis).

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received BNT162b2. Cases have mainly been reported in males under 30 years of age and following the second vaccination, however, there have been some cases reported in older males and females as well as following the first vaccination. The chance of having this occur is very low and, in most of these people, symptoms began within a few days to a week following vaccination. As a precaution, your child should seek medical attention right away if your child has any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath

- Feelings of having a fast-beating, fluttering, or pounding heart

Please also notify study staff, when appropriate, if your child has any of these symptoms.

Whilst some severe cases have been reported, most cases have been associated with full resolution of symptoms in the short term, however, long-term follow-up is limited. It is not known whether the risk of myocarditis or pericarditis is increased following additional doses of the vaccine, e.g. following a booster dose.

If your child has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart) previously, please tell their study doctor.

As in all research studies, the COVID-19 vaccine may involve risks that might be expected based on results from studies of similar vaccines, as well as risks that are currently unknown.

Therefore, it is important that you/ your child report all symptoms and side effects that your child experiences as soon as they occur, whether or not you think they are caused by the study vaccine.

Due to the way in which the study vaccines are made, they cannot cause COVID-19 disease.

If my child catches COVID-19 disease, could the vaccine make it worse?

For some other vaccines tested in animals against similar viruses (but not the coronavirus that causes COVID-19), there have been reports of the illness being more severe in the animals that received the vaccine than in those that did not. So far this has not been seen with BNT162b2. It remains important for you/ your child to contact your child's study doctor if your child develop symptoms that might be caused by COVID-19 (for example, fever, cough, shortness of breath).

Placebo Risks

As the placebo injection contains salt-water and no active ingredients, the chances of having the side effects mentioned above are less likely. In other studies, using the same placebo, some volunteers who received the placebo injection reported pain, bruising, swelling and redness at the site of injection.

Risks from Study Procedures

Risks and possible discomforts from the study procedures include:

- **Blood samples:** The risks and possible discomforts involved in taking blood include pain from inserting the needle, or less often, swelling, bruising, or infection around the vein where the blood is collected. Your child may feel dizzy or may faint. If your child has a previous history of feeling dizzy or fainting during blood sample collection, you should talk to the study doctor.
- **Nasal Swabs:** The risks and possible discomforts involved in taking nasal swabs may include pain or general discomfort. Sometimes it may cause the nose to bleed.

Pregnancy-Related Risks; Use of Birth Control

If your child is currently pregnant, plans to become pregnant, or is breastfeeding a child, they should not join this study.

If your child is able to have children and is sexually active, they must use birth control consistently and correctly for at least 28 days after they receive their last injection. This applies to males as well as females who take part in the research study. The study doctor will discuss with your child the methods of birth control that they should use while in this research study. The study doctor will help your child select the method that is appropriate for them. The study doctor will also check that your child understands how to use the birth control method and may review this with them at each of their research study visits.

Birth control methods, even when used properly are not perfect. If your child or their partner becomes pregnant during the research study, or if they want to stop their required birth control during the research study, they should tell the study doctor immediately. Your child may be withdrawn from the research study if they stop using birth control or they become pregnant.

Pregnancy Follow-up

If your child or their your partner become pregnant during the study, up until 28 days after their last study injection, please tell the study doctor **immediately**. Please also tell the doctor who will be taking care of your child/their partner during the pregnancy that your child took part in this study. The study doctor will ask if your child/their partner or their pregnancy doctor is willing to provide updates on the progress of the pregnancy and its outcome. If your child/their partner agree, this information will be provided to BioNTech/Pfizer for safety follow-up.

9. What are possible benefits of this study?

Vaccination with BNT162b2 has been shown to be effective in preventing COVID-19. You child should still follow local recommendations about how to avoid COVID-19 (for example, social distancing and mask use).

10. What will happen to my child's blood and nasal swab samples?

Your child's blood and nasal swab samples will be used only for scientific research. Each sample will be labeled with a code so that the laboratory workers testing the samples will not know who your child is. Some of the samples may be stored for future testing and may be kept for up to 15 years after the study ends, at which time they will be destroyed. In addition to testing for this study, any samples left over after the study is complete may be used for additional research related to the development of products. No testing of your child's DNA will be performed.

You may request that your child's samples, if they can be identified, be destroyed at any time. Any data already collected from those samples will still be used for the study. The samples will remain the property of BioNTech/Pfizer and may be shared with other researchers as long as confidentiality is maintained, and no testing of your child's DNA will be performed. You and your child will not be told of additional tests, nor will you or your child receive results of any of these tests.

11. What other choices do I have if I do not want my child to join this study?

This study is for research purposes only. The only alternative is to not take part in this study.

12. What happens if my child is injured during this study?

For mandatory research injury language, <**click here**> (retain this link in the study-level ICD). The country-specific research injury language must be included verbatim in the country-level ICD.

13. Can I withdraw my child from the study?

Yes. You are free to withdraw your consent for your child and discontinue their participation in the research study at any time. Your decision will not affect your or your child's regular medical care or any benefits to which you/your child is are entitled. Tell the study doctor if you are thinking about stopping or decide to stop so that your child can end participation in the study in the safest way.

While your child is participating, the study team will tell you in a timely manner if new information is learned during the course of the study that could change your mind about

your child continuing in this study. If you decide to withdraw your child from the study, your child may be asked to continue to participate in the study procedures even though they would no longer receive the study vaccine.

If your child continues with the study, information about their health will continue to be collected as described in [Section 6].

If you decide to stop your child participating in this study, you must notify the study doctor. The study team will explain what other procedures or discussions would occur.

Sometimes the study doctor or BioNTech/Pfizer may decide to take your child out of the study (even if you do not agree) if:

- You/your child are unable or unwilling to follow the instructions of the study team;
- The study doctor decides that the study is not in your child's best interest or that they are no longer eligible to participate; or
- The study is stopped by BioNTech/Pfizer, the institutional review board (IRB) or independent ethics committee (IEC) (a group of people who review the study to protect your rights), or by a government or regulatory agency.

The study team will give you a Privacy Supplement, which is considered part of this consent document. It describes what happens to your child's personal information (including biological samples) and how it may be used if you withdraw your child from the study.

14. What will I have to pay for if my child takes part in this study?

You will not need to pay for any of the study vaccines (COVID-19 Vaccine or placebo), study-related procedures, or study visits.

15. Will my child be paid for taking part in this study?

You will not receive any payment for your child taking part in this study. However, for each visit you/your child completes, you will be reimbursed by the study site to cover reasonable expenses (for example, parking, meals, travel) that you have as a result of taking part in this study. You will be reimbursed by [enter, as applicable, method of reimbursement; amounts; and reimbursement schedule; note whether receipts are required].

BioNTech/Pfizer may use information resulting from the study to develop products or processes from which they may make a profit. There are no plans to pay you/your child or provide you/your child with any products developed from this research. BioNTech/Pfizer will own all products or processes that are developed using information from the study.

16. What will happen to my child' personal information?

<**click here**> for language to be inserted into this section. This text must be inserted verbatim. Any requested changes must be approved by Clinical Development Legal. Note that the Privacy Supplement follows this consent document, after the signature section.

17. Where can I find additional information about this study or the study results?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The study results, when available, may also be found on www.pfizer.com and https://www.clinicaltrialsregister.eu/.

In addition, a plain summary of the study results will be made available in the EU database at [insert link to the database]. This information will be provided no matter what the study's outcome. To the extent possible, you will be able to access these summaries in the EU database soon after they become available using the following EU trial number for the study: [insert trial number].

These Web sites are in English only. If you need assistance understanding these Web sites, please ask a member of the study team.

BioNTech/Pfizer will provide the study doctor with information about the study results when all participants have completed the study. At that time, certain of your child's individual study results may be given to you or your child's doctor (if different from the study doctor) in accordance with applicable law, but will not be given to your family, your employer or any insurance company.

If any exploratory research is done, it may not be possible to link any results from that exploratory research to specific individuals, including your child. BioNTech/Pfizer does not plan to return information from any exploratory research to you/your child, the study doctor, or your doctor (if different from the study doctor).

18. Signatures

Agreement to Participate and to Process Data
1. I confirm I have read (or, if I cannot read, a study team member has read to me) and understand this consent document for the study described above and have

had the opportunity to ask questions. I have had enough time to review this consent document. I also have had an opportunity to ask about the details of the study and to decide whether or not to participate.
2. I have read and understand the Privacy Supplement. I understand that taking part in the study will require the processing (including collection, use, transfer, storage, analysis and reporting) of my child's personal information, as explained in the Privacy Supplement. I understand and agree to the processing of my child's personal information within and outside my country of residence for health care, medical research and/or regulatory purposes.
3. I understand that taking part is voluntary and that I am free to stop my child taking part in this study or to withdraw my consent to the processing of my child's personal information at any time. I do not need to give any reason and my child's regular medical care and legal rights will not be affected. However, even if I withdraw my consent to processing, my child's personal information held at that time may be kept to comply with laws and regulations and to maintain the integrity of the study. I also understand that my child's biological samples may not be able to be destroyed because they may no longer be traceable to my child, may have already been used, or may have been given to a third party.
4. I agree to the study team accessing my child's medical history, including information from medical records and test results and any medical treatment my child receive during the course of the study, and if necessary, contacting my child's doctor or any other health care providers treating my child for access to such information.
5. I understand that BioNTech/Pfizer and/or others working with or on behalf of BioNTech/Pfizer, institutional review boards (IRBs) or independent ethics committees (IECs), and regulatory agencies may need access to personal information about my child generated at the study site or collected by the study team for the study and any other research. I agree that they may have access to my child's personal information.
6. I do not give up any of my child's legal rights by signing this consent document. I have been told that I will receive a signed and dated copy of this document.
7. I agree for my child to take part in the study described in this document.

In the section below, the term "legally acceptable representative" should be replaced with the term required per local regulation (country-level).

As the consenting adult providing permission for this child to participate in the study, I acknowledge that (Please check <u>one</u> of the following):

☐ I am the biological or adoptive parent of the child.

☐ I am the legal guardian or legally acceptable representative of the child.

[If neither option below is checked, then the consent of the second parent/guardian/legally acceptable representative must be obtained. If there are two parents/guardians/legally acceptable representatives available to give permission, and they disagree about allowing the child to participate in the study, the child should not be enrolled unless that disagreement can be resolved.**]**

I also acknowledge that (Please check one of the following):

☐ I have sole legal responsibility for the care and custody of the child.

☐ The other adult(s) with whom I share legal responsibility for the care and custody of the child (for example, biological parent, adoptive parent, or legal guardian or representative) is (1) aware of and agrees with my granting permission for this child to participate in the study OR (2) deceased, unknown, incompetent, or not reasonably available (someone is "not reasonably available" when he/she cannot be reached by phone/mail/email because, for example, he/she is on active military duty or is incarcerated).

_____

Printed name of parent/guardian/legally acceptable representative

_____ _____

Signature of parent/guardian/legally acceptable representative Date of signature§

[Include the statements and signature lines below for a second parent/guardian/legally acceptable representative if (1) required by the IRB/IEC; (2) required by local law (*e.g.*, parents are divorced and have shared custody of the child); or (3) the second parent/guardian/legally acceptable representative is (or would like to be) involved in the consent process and there is reason to believe that he/she may disagree with the decision of the first parent/guardian/legally acceptable representative.

Consent of Second Parent/Guardian/Legally Acceptable Representative:

As the consenting adult providing permission for this child to participate in the study, I acknowledge that (Please check one of the following):

☐ I am the biological or adoptive parent of the child.

☐ I am the legal guardian or legally acceptable representative of the child.

_____
Printed name of parent/guardian/legally acceptable representative

_____ _____
Signature of parent/guardian/legally acceptable representative Date of signature[§]]

Person Obtaining Consent:

_____
Printed name of person conducting the consent discussion

_____ _____
Signature of person conducting the consent discussion[†] Date of signature

[§] Participant/parent/guardian/legally acceptable representative must personally date their respective signatures.

[†] The investigator, or an appropriately qualified and trained person designated by the investigator to conduct the informed consent process, must sign and date the consent document during the same discussion when the participant's parent/guardian/legally acceptable representative signs the consent document.

PRIVACY SUPPLEMENT

For mandatory country-specific data privacy language to be inserted in this Privacy Supplement, <**click here**> (retain this link in the study-level ICD). The country-specific data privacy language must be included verbatim in the country-level ICD. Any requested changes must be approved by Clinical Development Legal.

Who will use my child's personal information, how will they use it, and where will it be stored?

[Mandatory study language – retain the below paragraph and delete this green text before finalisation]

Any personal information collected about you/your child during this study will be entered into records, including health records, maintained by the study team at your study site. You/your child's records that include information that directly identifies you/your child may be uploaded to secure systems maintained by a third party engaged by BioNTech/Pfizer so that BioNTech/Pfizer and/or BioNTech/Pfizer representatives can review and verify study data. Some of the uploaded records will be kept for XX years. The remaining records that are uploaded will be temporary and removed from the secure system after the study is over.

- This template is used by informed consent document authors to develop the assent document for 11-year-olds through legal age of adulthood.
- Do not delete the header at the top of this page until the assent is customized at the country/site-level.
- Before sending the assent to the institutional review board (IRB)/independent ethics committee (IEC), remove the header at the top of this page, remove all inapplicable text, remove all instructional green text, and replace all blue text with appropriate language.
- The assent must be filed in the Pfizer Trial Master File.

A RESEARCH STUDY TO SEE IF A VACCINE AGAINST COVID-19 IS SAFE AND WORKS

We are asking if you would like to be in a research study to see if a vaccine to prevent COVID-19 is safe and if it can help prevent children and adults from getting COVID-19. Research studies are the way we find out if test medicines or vaccines are safe and if they work.

The study is being done with healthy children and adults and that is why the study doctor wants to know if you want to take part in the research study.

WHY ARE WE DOING THIS STUDY?

We are doing this study to collect information in children and adults to see if the vaccine is safe and if it can help prevent people from getting COVID-19.

The study doctor and nurses will explain the study and answer any questions that you have. You can circle or highlight things on this paper you want to know more about. If you don't understand something, just ask us. It is okay to ask questions now and anytime later that you think of them.

If you decide to be in this study, you will be asked to sign this form. Your parent(s) or your guardian(s) will sign another form. You can talk to your parent(s) or your guardian(s) and ask to read the information the study doctor gives them.

WHAT WILL HAPPEN TO ME IF I GO INTO THE STUDY?

The study starts with an appointment with the study doctor and some tests to see if you can be in the study. If you decide to take part in the study you will be given an injection in your arm at your first and second visit and will need to give at least 5 blood samples. There will be at least 6 visits to the study clinic over roughly the next 2 years.

If you get ill with COVID-19 like symptoms, the study doctor may ask you to have a telephone conversation, video call or to visit the site to talk about how you are feeling and if you have needed any other medical care.

At your first visit, the study doctor or nurse will give you or your parent(s)/ guardian(s) a device (a bit like a mobile phone) or ask to download an application ('app') to smart phone if you or your parent(s)/ guardian(s) have one. The device/app is secure and your information will be maintained in confidence. The study doctor will show you or your parent(s)/ guardian(s) on how to fill in the electronic diary (also called e-Diary).

There are 2 parts to the electronic diary. Everyone will need to complete the COVID-19 illness part of the e-Diary on the device or app on their smartphone. The COVID-19 illness e-Diary will prompt you or your parent(s)/ guardian(s) to record any COVID-19 symptoms every 7 days or at any time you have COVID-19 symptoms. You or your parent(s)/ guardian(s) may also receive text messages to your/ their device or your/ their own smartphone, or emails (if you or your parent(s)/ guardian(s) provide an email address) to remind you or your parent(s)/ guardian(s) to complete the COVID-19 illness part of the e-Diary.

If you are part of a selected group of participants, you or your parent(s)/ guardian(s) will also be asked to fill in an e-Diary about how you are feeling for 7 days afer your vaccine injections.

If you decide the take part the following will happen:

At your first visit:

- Before you are given your injection, the study doctor or nurse will take your temperature, measure your height and weight, do a physical exam and ask you some questions about your health.
- The study doctor or nurse will take a blood sample from your arm using a needle (this will be either 20mL or 10 mL depending on your age group) and take a sample from your nose using a swab (like a Q-tip).
- You will then be given an injection into the muscle at the top of your arm.
- If you are part of the selected group of participants, you or your parent(s)/ guardian(s) will be asked to complete an electronic diary about how you are feeling for 7 days after the visit.

At your second visit:

- You will be given your second injection, the study doctor or nurse will take your temperature and ask you some questions about your health before they give your injection in your arm.

- If you are part of the selected group of participants, you or your parent(s)/ guardian(s) will be asked to complete an electronic diary about how you are feeling for 7 days after the visit.

It is very important that you or your parent(s)/ guardian(s), as appropriate, complete the e-Diary regularly as instructed. If this was not completed, your study doctor or nurse will contact you or your parent(s)/ guardian(s) to check how you are doing.

At the other 4 visits the study doctor or nurse will ask you some questions about your health and will take a blood sample from your arm using a needle. Each blood sample will be either about 20mL (4 teaspoons) or 10 mL (2 teaspoons) depending on your age group.

When you visit the study doctor, the study doctor will write down information about you. Only people who are working on this study will see your information. They are required to keep your information private.

What are the Study Injections?

There are 2 types of injections in the study. The active study injection and a dummy placebo injection. A dummy placebo is a pretend vaccine that looks just like the test vaccine but has no active ingredients in it.

Once the study doctor has checked that it is OK for you to be in the study a computer will decide if you will get the active study injection or the dummy placebo. **You and your parent(s)/guardian(s) will <u>not</u> be told which injection you will get.**

For every 1 child/young person who receives the study vaccine, 1 child/young person will receive the placebo. No one (including you, your parents, your personal doctor or the study team) can choose which injection you will get.

WHAT ARE THE POSSIBLE BENEFITS TO ME IF I AGREE TO BE IN THIS STUDY?

Vaccination with BNT162b2 (which is active study injection) has been shown to be effective in preventing COVID-19. You should still follow local recommendations about how to avoid COVID-19 (for example, social distancing and mask use).

WHAT ARE THE POSSIBLE UNCOMFORTABLE OR HARMFUL THINGS THAT COULD HAPPEN TO ME IF I AGREE TO BE IN THIS STUDY?

There is a chance that during the study you could feel pain or feel bad or uncomfortable. Please let the study doctor know if you experience any of these things. The study team will monitor you for risks or discomforts during the study. However, the study team does not know all the effects that the vaccine, or your participation in this study, may have on you.

<u>The injection could cause</u> pain, swelling, and redness where it is given.

Other side effects could include fatigue (tiredness), increased body temperature (fever), chills, headache, diarrhea, joint aches, muscle aches, feeling sick (nausea), being sick (vomiting), enlarged lymph glands, allergic reaction (symptoms may include rash, itching, hives, and swelling of the face or lips), decreased appetite, lethargy, sweating and night sweats, pain in arm, feeling weak or unwell, and severe allergic reaction (anaphylaxis).

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the active study vaccine. Cases have mainly been reported in males under 30 years of age and following the second vaccination, however, there have been some cases reported in older males and females as well as following the first vaccination. The chance of having this occur is very low and, in most of these people, symptoms began within a few days to a week following vaccination. As a precaution, you should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Please also notify study staff, when appropriate, if you have any of these symptoms.

Whilst some severe cases have been reported, most cases have been associated with full resolution of symptoms in the short term, however, long-term follow-up is limited. It is not known whether the risk of myocarditis or pericarditis is increased following additional doses of the vaccine, e.g. following a booster dose.

If you have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart) previously, please tell your study doctor.

In addition,

- Taking a blood sample may:
  - hurt when the needle goes into your arm.
  - cause a red spot or bruise on your arm or your arm might feel sore.
  - make you feel dizzy.
  - cause an infection at the place where the needle went into your arm.
- Taking a swab from your nose may:
  - hurt when the sample is taken.
  - Cause your nose to bleed.
- You may feel embarrassed by the questions the study doctor or nurse asks you.

You might also feel other things. Remember to tell your parent(s) or your guardian(s) and the study doctor everything you are feeling while you are in the study including if you feel unwell.

Pregnancy, Contraceptives and Babies (do I need to use birth control?)

If you are a girl:

If you are pregnant, planning to become pregnant or breast feeding a baby, you cannot be in the study.

If you think you are pregnant during the study, you must tell the study doctor immediately. The study doctor may ask for information about the pregnancy and the birth of the baby. The study doctor may share this information with others who are working on this study.

If you have started to have periods, the study doctor or nurse will test your urine to make sure you are not pregnant before you are given your injections. The doctor or nurse will tell you if the test results show you are pregnant. Depending on the laws of your area, the study doctor or nurse may also tell your parent(s) or your guardian(s) about the results of the pregnancy test.

If you are sexually active, you must use birth control consistently and correctly during the study and for at least 28 days after your second injection. Your study doctor or nurse will discuss this with you if it is appropriate to do so.

If you are a boy:

If you are sexually active, you must use birth control (eg a condom) consistently and correctly during the study and for at least 28 days after your second injection. Your study doctor or nurse will discuss this with you if it is appropriate to do so.

If you think that you may have gotten a girl pregnant, you must tell your study doctor immediately. The study doctor may ask for information about the pregnancy and the birth of the baby. The study doctor may share this information with others who are working on this study.

WHAT OTHER OPTIONS ARE THERE?

This study is for research purposes only. Your alternative is to not take part in this study.

Taking part is voluntary and **you do not have to be in the study if you don't want to.**

It is your choice if you want to be in this study or not. No one will be mad if you choose not to take part.

Your doctors or your parent(s) or your guardian(s) cannot make you be in the study if you don't want to be in it. If you say okay now to being in the study and you change your mind about it later, you can stop being in the study. Just tell the study doctor or your parent(s) or your guardian(s) if you want to stop at any time. If you quit the study, you will be asked to come in for one last visit.

WHAT IF I HAVE QUESTIONS?

You can ask questions about the study at any time.

You can call the study doctor any time.

If you want to ask questions about what it means to be in a research study, you or your parent(s) or your guardian(s) can call [insert IRB/IEC name] (a group of people who review the study to protect your rights) at [insert IRB/IEC number].

For you to be in this study, you and your parent(s) or your guardian(s) must agree to you being in it. But it is still up to you if you *want* to do it.

Please check one box below to show whether or not you want to be in this study.

☐ Yes, I want to be in this study.

☐ No, I do not want to be in this study.

_____
Printed Name of Child/Young Person

_____ _____ _____
Child/Young Person Signature Date Time

Statement of person conducting assent discussion:

1. I have explained all aspects of the research to the participant to the best of his or her ability to understand.
2. I have answered all questions of the participant relating to this research.
3. I believe the participant's decision to enroll or not enroll is voluntary.
4. If the participant decides to enroll, the study doctor and study staff agree to respect the participant's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

Printed Name of Person Obtaining Assent: _____

Signature of Person Obtaining Assent: _____ Date: _____ Time: _____

Participant Guide to Using the TrialMax App for Vaccination and COVID-19 Illness Diary

Pfizer

C4591001-*Post-12-July-2020*

TrialMax App

Thank you for participating in the **C4591001-Post-12-July-2020** study.

This clinical study uses the TrialMax App to record important information during the study. The TrialMax App will be used on your personal device or on a provisioned device supplied by the site. This booklet explains how to use the TrialMax App on either device type.

Please note that pictures within this guide will not always appear exactly the same way on your personal device, as every device has different display settings.

Important: The TrialMax App whether on your personal or provisioned device is to gather information to advance science and medicine during this research study and does not replace your regular medical care. For urgent issues, please contact your study clinic staff on the contact number provided.

App Guidelines

Please follow these points when using the TrialMax App for this clinical study.

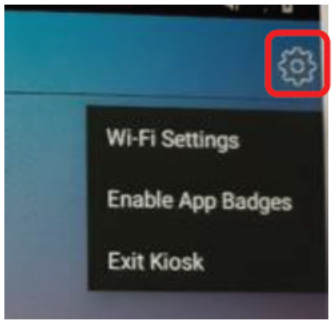
1. Always keep your device **charged**.
2. Always download any updates to the TrialMax App.
3. Do **not** share your PIN code.
4. After entering your diary responses, please ensure they are sent by tapping the 'Save' button.
5. Your device will need a mobile network or Wi-Fi connection to send data. If your device is not connected to a mobile network or Wi-Fi connection, your data will automatically send once your device is connected again.
6. After entering your diary responses, please ensure they are sent by tapping the 'Save' button.

If you have installed the TrialMax App on your personal device, additional guidelines.

7. If prompted when installing or using the TrialMax App, always accept permissions for the TrialMax App to sync with your device's calendar. This will allow the reminder notifications for your diary to display.
8. Do not delete the TrialMax App unless instructed by the study clinic staff.
    - If you accidentally delete the TrialMax App or are planning to change your device, please call the helpdesk (866 402 1154) as soon as possible.

Setting up WiFi on a provisioned device

If you are using a device provided to you for the study, you can configure a WiFi connection by pressing the 'Gear/Setting' symbol in the top right-hand corner of the screen.



Gear/Setting symbol

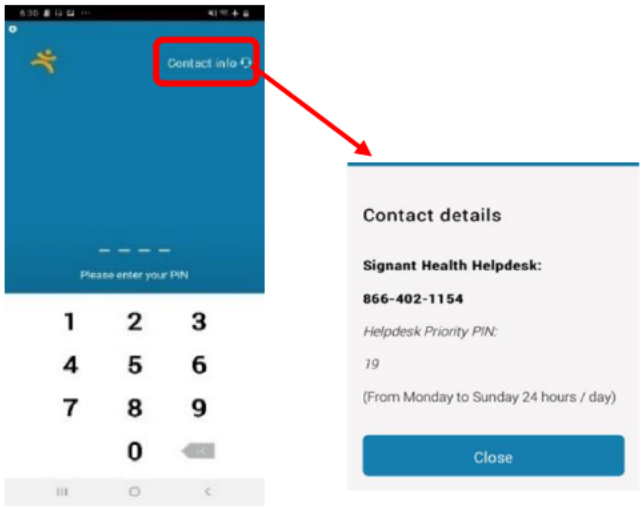
Select 'Wi-Fi Settings'. Select the appropriate network and enter the password if required. Once the connection is authenticated, the Wi-Fi will connect. Once you return to the Home screen, the TrialMax App will automatically open.

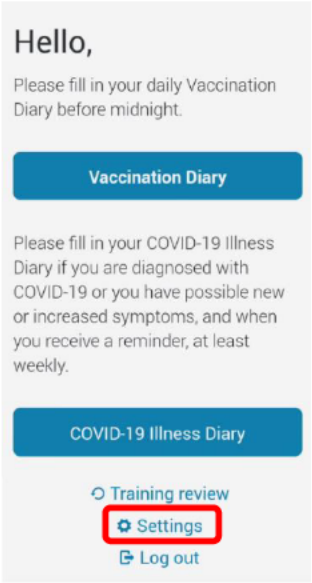
Using the TrialMax App

This Quick Reference Guide will walk you through various functions of the TrialMax App.

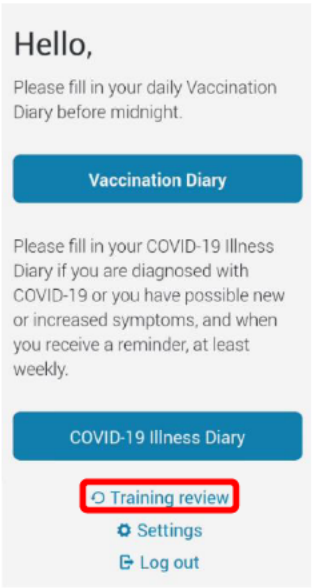
For any technical Issues with the TrialMax App, the helpdesk contact Information is displayed on the log-in screen of the TrialMax App.

Select 'Contact info' to view the helpdesk contact information





Once the Settings button is selected, you will be able to update your diary reminder notifications.



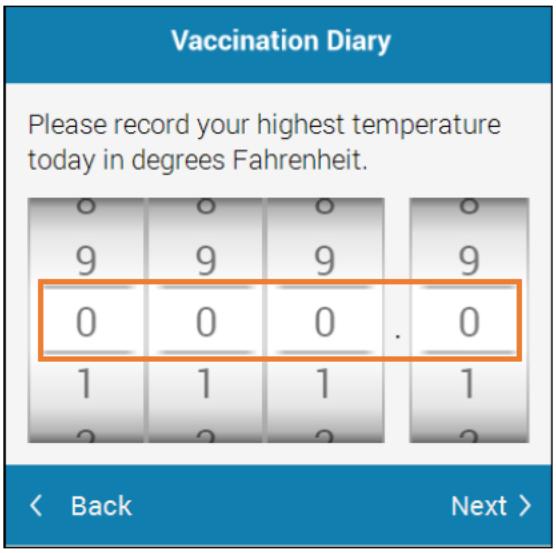
Training on how-to use the TrialMax App including a practice session. The practice session will allow you to practice using the different types of buttons and functions that will be available in the diary.

Types of Questions

The following provide examples of the screens in the study questionnaires on TrialMax App and how to use them.

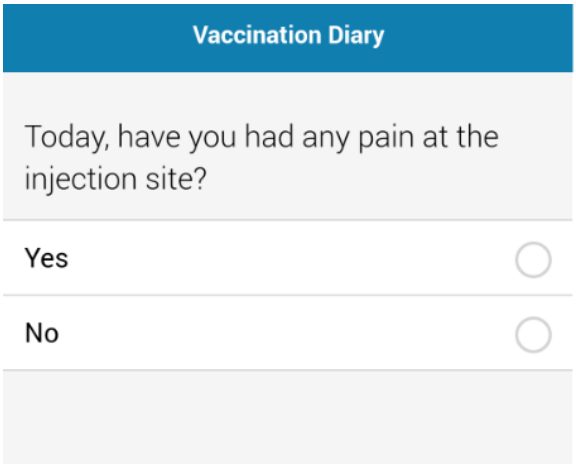
Number Spinner Questions:

- To answer, scroll down or up on each column of numbers until you reach your desired answer.
- Tap your chosen numbers so that they appear within the orange lines.
- When you are ready to move to the next set of question, press 'Next'.
- To go to the previous page, press 'Back' to review or modify your answer



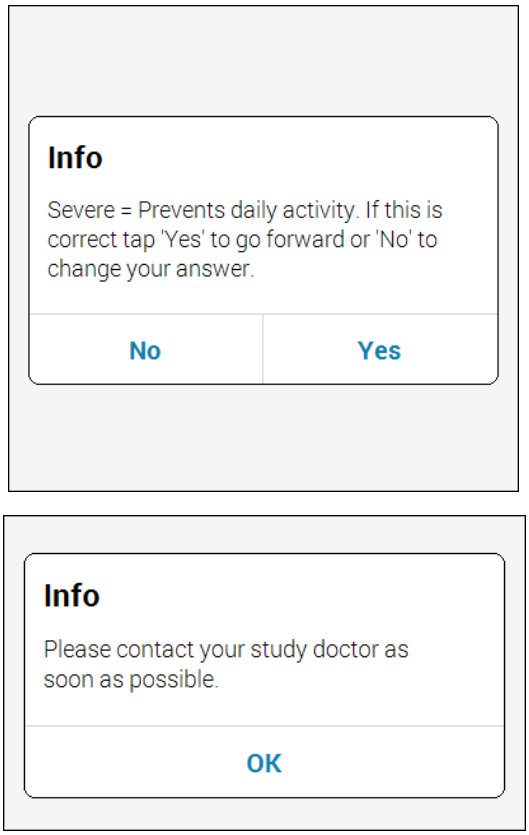
Multiple Choice Questions:

- Select the response that best describes your answer to each question, a black dot will appear in the circular button.
- When you are ready to move to the next set of questions, press 'Next'.
- To go to the previous page, press 'Back' to review or modify your answer

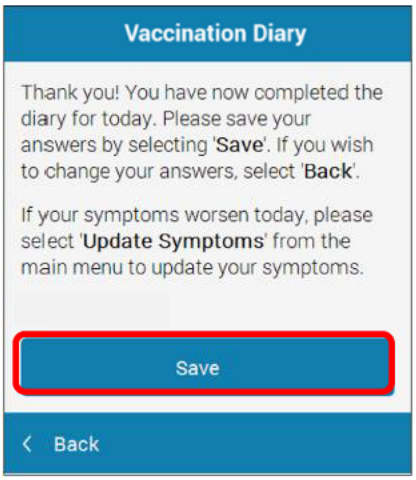


Information Pop-ups

These pop-ups display important information, such as confirming the severity of a symptom, confirming a temperature you have entered or, to contact your study doctor.



Saving Diary Data



For all entries in the TrialMax App:

- ensure you have completed all data requested.
- tap the 'Save' button.

Please note: If your device is left idle for longer than 10 minutes, your session will time out. You will be logged out of the TrialMax App and any unsaved responses will be lost.

Traveling and Changing Time Zones with TrialMax App

Always take your personal or provisioned device with you when traveling in order to complete the TrialMax App away from home.

If traveling via airplane, turn off your device during the flight to avoid any interference.

If you are using a device provided by the site:

- The date and time will update automatically to the new time zone when you turn the device on.

If you are using your own device:

- Make sure your settings allow for automatic update of date and time.

Sending Data

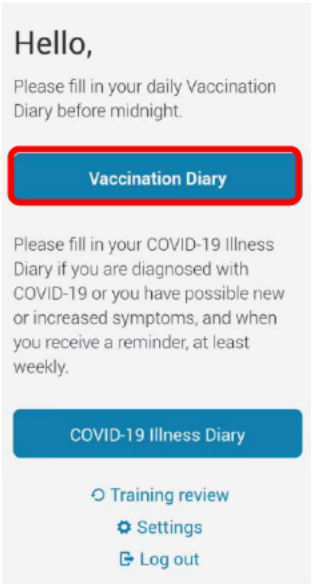
The TrialMax App sends data automatically each time you login or save a diary entry, provided the device is connected to a mobile network or Wi-Fi network.

The TrialMax App can be used offline temporarily; however, remember to log into the TrialMax App when the device is connected to a mobile network or Wi-Fi network as soon as possible to allow data sending to occur.

REMINDER - Keep your device charged

Vaccination Diary

Please note if you are using your own device, allow the TrialMax App to synchronise with your calendar in order to see notifications appropriately.



You should complete the Vaccination Diary every evening for a period of 7 days following vaccination, starting on the day you had your vaccination.

IMPORTANT: Please complete the diary every day between 06:00 PM and 11:59 PM. Answer all questions in one sitting.

Diary Entries started prior to midnight will be allowed to continue through to completion as long as you do not log out of the device.

Diary Entries started prior to midnight and saved after midnight will be counted for the day the questionnaire was started. If device is left for more than 10 minutes, the TrialMax App automatically will lock you out.

Example: Started diary 11:50 PM on 01 Jun 2020 and saved at 12:01 AM on 02 Jun 2020, will count for 01 Jun 2020.

It's important that you complete the "Vaccination Diary" as requested, because you can't go back after midnight to fill in any missed entries.

Notifications are set up to help you remember to complete your diary. Site staff will set the notification alert time when they set-up your TrialMax App activation code. You can change the alert time as needed in the 'Settings' button.

Once you've selected the 'Vaccination Diary' button you will be able to record symptoms, their severity and if those symptoms resulted in a hospitalization/emergency room visit.

General instructions

The study clinic staff will give you a digital thermometer and show you how to use it to measure your temperature under your tongue. Follow these instructions for all temperature measurements you record in the TrialMax App.

NOTE: The provisioned thermometer measures temperature in degrees Fahrenheit (°F). All entries made into the diary should be recorded in degrees Fahrenheit.

- You can record the temperature displayed on the thermometer into the TrialMax App.
- You can keep this thermometer at the end of the study.

Thermometer use

How to take care of the thermometer:

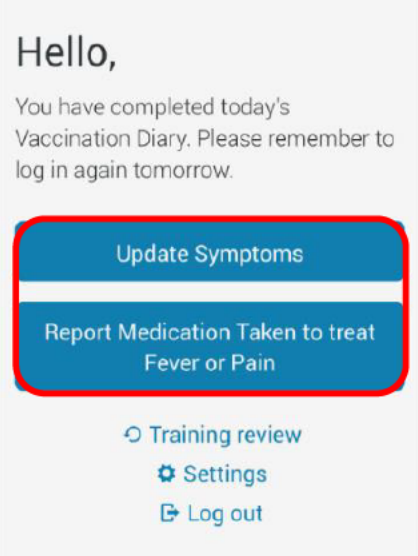
- The thermometer is waterproof.
- To disinfect, you can put it completely in water or wipe it with a tissue dipped in a mild disinfectant.
- Do not put the thermometer in hot water or household bleach products.
- Do not leave the thermometer in direct sunlight or let it fall or be hit, as this could damage it.
- Do not try to open the thermometer.
- Please refer to the instructions in the thermometer box if you need further instructions for use, care, and maintenance instructions.

If you have any problems with measuring your temperature, if thermometer stops working, or if you lose or break the thermometer, please call the study doctor or study clinic staff.

Instructions for taking and entering your temperature after study vaccination

- On the day you had your vaccination and for 6 more days (7 days in total), you will measure your temperature (under your tongue) every evening, and at any time you feel feverish.
- Enter your measured temperature in the TrialMax App between 6:00PM and 11:59PM.
- If your temperature is 102°F or higher, please call the study doctor or nurse to schedule an extra appointment so that they can assess the temperature.
- If you have a fever or a temperature of 102°F or higher on the last day you complete the TrialMax App (day 7), keep measuring your temperature daily until the temperature is below 102°F for at least one day. Make a note of the date and temperature as you will need to give this information to the study doctor or nurse.
- It is also important to let your study doctor or nurse know whether you have been hospitalised/or went to the ER for any of the ongoing symptoms.

Updating symptoms and medication responses



If your temperature increases or symptoms worsen after the vaccination diary is completed for the day, please select 'Update Symptoms' from the main menu to record the increased temperature or worsened severity.

If you have taken medication to treat fever or pain since the vaccination, report this by selecting the 'Report Medication Taken to treat Fever or Pain' button.

These details can be updated until 11:59pm.

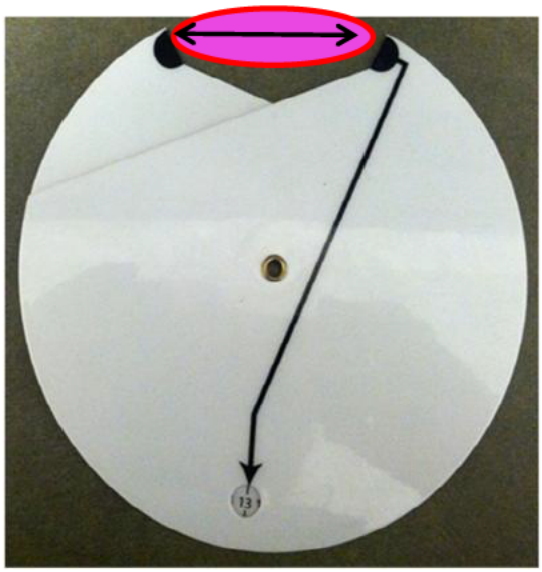
Instructions for measuring any redness or swelling at the injection site:

Please note, that for any questions regarding the use of the measuring device you should contact your study clinic staff and not the Signant Health Helpdesk.

- On the day you had your vaccination and for 6 more days (7 days in total), you will need to examine the arm where you were given the injection (injection site) to see if there is any redness or swelling.
- Record this information in the TrialMax App each day between 6:00PM and 11:59PM.
- If you have any redness or swelling at the injection site on your arm, use the measuring device provided to measure the biggest part of the redness and/or swelling as shown by the study clinic staff.

For example:

Measure this Distance



- The measuring device can be adjusted by sliding the two measuring pointers so that they are closer or further away from each other.
- Once the measuring device is the correct size to measure the biggest part of the redness/swelling, the size is displayed as a number. The number the arrow is pointing to in the window is the number that should be recorded in the TrialMax App.
- If the size is between two numbers, record the larger number in the TrialMax App.
  - For example, if the measurement is between 4 and 5, then 5 should be recorded in the TrialMax App.
- If the size of the redness or swelling is bigger than 21, then 21 should be recorded in the TrialMax App. Please call the study doctor or study clinic staff to discuss or schedule an extra appointment so that they can take a look at the redness/swelling.
  - Note: A pop-up in the TrialMax App will remind you to contact the study doctor if you have reported a value of 21.
- If the redness or swelling at the injection site is ongoing on the last day you complete the TrialMax App (Day 7), you will need to make a note of the date that this resolved. Give this information to the study doctor or study clinic staff.

Instructions for assessing any pain at the injection site:

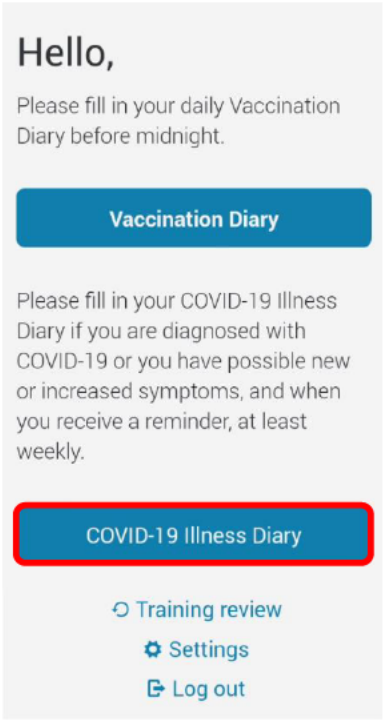
- On the day you had your vaccination and for 6 more days (7 days in total), you will need to examine the arm where you were given the injection (injection site) to see if there is any pain at the injection site.
- Information must be recorded in the TrialMax App each day between 6:00PM and 11:59PM.
- If you have pain at the injection site, you will need to assess if the pain was mild, moderate or severe, and record this information in the TrialMax App.
- Definitions of mild, moderate and severe pain will be displayed to you before this symptom is recorded.
- If the pain at the injection site is severe, please notify the study doctor or study clinic staff to discuss or schedule an extra appointment so that they can assess the pain at the injection site.
  - Note: A pop-up in the TrialMax App will remind you to contact the study doctor if you have reported a severe symptom.
- If the pain at the injection site is ongoing on the last day you complete the TrialMax App (Day 7), you will need to make a note of the date that this resolved. Give this information to the study doctor or study clinic staff.

Instructions for assessing any fatigue (tiredness), headache, vomiting, diarrhea, chills, new and worsened muscle pain, new or worsened joint pain:

- On the day you had your study vaccination and for 6 more days (7 days in total), you will be asked whether you had experienced fatigue (tiredness), headache, vomiting, diarrhea, chills, new or worsened muscle pain and new or worsened joint pain since vaccination. This information must be recorded in the TrialMax App each day between 6:00PM and 11:59PM.
- If you experience any of these symptoms you will need to assess if they were mild, moderate or severe, and record this information in the TrialMax App.
- Definitions of mild, moderate and severe symptoms will be displayed to you before this is recorded.
- If a symptom you are experiencing is severe, please call the study doctor or study clinic staff to schedule an extra appointment so that they can investigate.
  - Note: A pop-up in the TrialMax App will remind you to contact the study doctor if you have reported a severe symptom.
- If you have symptom(s) that continue past the last day you completed the TrialMax App (Day 7), you will need to tell the study doctor or study clinic staff the date that the symptom(s) stopped. Please make a note of the date your symptoms stopped.

Illness Diary

Please note if you are using your own device, allow the TrialMax App to synchronise with your calendar in order to see notifications appropriately.



The Illness Diary will be available for you to complete at all times, starting on your first day of participation. The Illness Diary should be completed at least once every 7 days, if you are diagnosed with COVID-19, or if you have new or worsened symptoms.

IMPORTANT: Diary Entries started prior to midnight will be allowed to continue through to completion as long as you do not log out of the device.

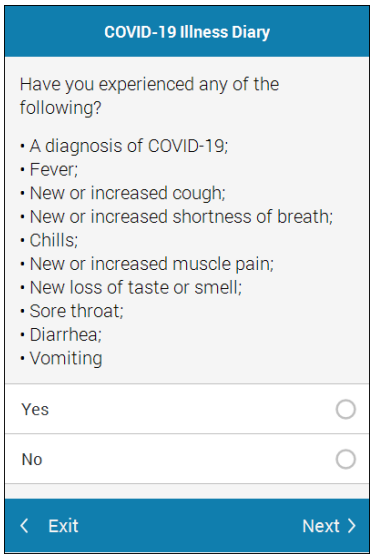
Diary Entries started prior to midnight and saved after midnight will be counted for the day the questionnaire was started. If device is left for more than 10 minutes, the TrialMax App automatically will lock you out.

Example: Started diary 11:50 PM on 01 Jun 2020 and saved at 12:01 AM on 02 Jun 2020, will count for 01 Jun 2020.

Notifications are set up to help you remember to complete your diary. Site staff will set the notification alert time when they set-up your TrialMax App activation code. You will get a reminder to complete the Illness Diary only weekly, if the Illness Diary is not completed before the scheduled notification alert time. You can change the alert time as needed in the 'Settings' button.

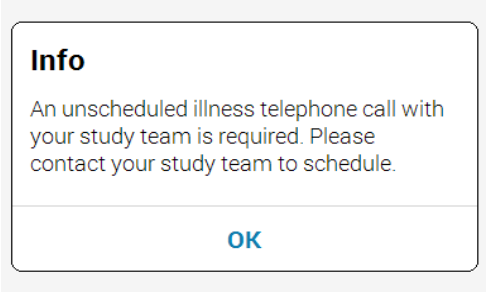
Instructions for assessing symptoms in the COIVID-19 Illness Diary

- Starting on the day your diary is activated you will be asked to note if you experience any of the following symptoms or events: A diagnosis of COVID-19, fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhea, or vomiting. This information can be recorded in the TrialMax App at any time.
- The Illness Diary must be completed a minimum of once every 7 days, even when there are no symptoms or events to report.



Carefully review the symptoms listed in the diary and select "yes" or "no" depending how you are feeling when completing the diary.

If you selected "Yes" to experiencing any of the listed symptoms a pop-up message will appear prompting you to contact your study clinic to schedule an illness check with the study team.



Visits to the Study Clinic

IMPORTANT: Remember to take your personal or provisioned device to every study clinic visit (scheduled or unscheduled).

Speak to study clinic staff if:

- You have any questions about the App or the study
- Your device is lost, stolen or damaged
- You have questions about your health or participation in the study

If you are using your own device, please do not uninstall the Trial Max App during the duration of the study.

[TRIALMAX®]

Helpdesk

Telephone: 866 402 1154

Helpdesk Priority PIN: 19

Available hours: 24 hours per day, 7 days per week.

For when you:

- Forget your PIN code or cannot log into TrialMax App
- Need help with a technical issue
- Have any other questions about using the TrialMax App

When calling the Helpdesk, you will be asked to enter a PIN. Enter the PIN code above to enter the priority queue. The Helpdesk will ask for the following information. This information can be found in this guide or on the sticker supplied by the clinic staff: **Study protocol, Study code, Site number and your Participant number.**

It is important not to provide any information about your health to the Helpdesk. Please contact your study doctor or study clinic staff for health concerns.

QRG APPROVAL

Content for Approval					
Language	English for United States				
QRG – Vaccination + Illness Diary	A-1426-0086-5151QRG-Vaccination+Illness diary-enUS_v2.pdf	**Version**	2	**Date**	19-Jun-2020
QRG - Illness Diary	A-1426-0086-5151QRG-Illness diary-enUS_v2.pdf	**Version**	2	**Date**	19-Jun-2020

CUSTOMER

Approval		
Name and Title: Kimberly Rarrick		Signature: DocuSigned by: Kimberly Rarrick D1ED069CC2B34D9...
Company: Pfizer	Role: Study Manager	Date: 19-Jun-2020 | 13:32 EDT

SIGNANT HEALTH

Approval	
Name: Brittany Hayes	Signature: DocuSigned by: Brittany Hayes C4D49137536548E...
Title: Project Manager II	Date: 19-Jun-2020 | 13:31 EDT