Clinical Study Results

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medication works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: BioNTech SE

Sponsor Agent: Pfizer Inc.

Vaccine(s) Studied: PF-07302048 (BNT162b2)/Comirnaty®

Protocol Number: C4591024

Dates of Study: 15 October 2021 to 23 July 2023

Title of this Study: A Study to Evaluate the Safety, Tolerability, and Immunogenicity of Vaccine Candidate BNT162b2 in Immunocompromised Participants

[A Phase 2b, Open-Label Study to Evaluate the Safety, Tolerability, and Immunogenicity of Vaccine Candidate BNT162b2 in Immunocompromised Participants ≥ 2 Years of Age]

Date(s) of this Report: 24 June 2024

– Thank You –

If you or your child participated in this study, Pfizer, the Sponsor, would like to thank you for your participation.

This summary will describe the study results. If you have any questions about the study or the results, please contact the doctor or staff at your study site.

Why was this study done?

What is COVID-19?

“Coronavirus disease 2019” (or COVID-19) is caused by a virus called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

COVID-19 spreads easily from person to person and can cause mild to severe illness. People with COVID-19 can have fever, chills, cough, loss of taste or smell, or trouble breathing.

What is BNT162b2 COVID-19 vaccine?

BNT162b2, referred to as BNT in this summary (also called Comirnaty® pronounced as “Koe-mir’-na-tee”) is an injectable vaccine that can help the body’s immune system to defend against the original strain of COVID-19.

- It does not contain a whole virus or any part of the virus that can cause COVID-19.
- It is made up of a part of the virus’s genetic code, surrounded by fatty particles called lipids. It uses the body’s own cells to produce a spike protein, which may help the body to produce antibodies to fight against COVID-19.

BNT is now approved for use in many countries worldwide.

What was the purpose of this study?

The main purpose of this study was:

1. To determine the “immune response” to BNT vaccine when given to participants who had low immunity due to various underlying conditions and were at least 2 years of age.

When a person first gets a vaccine, a protective immune response is triggered in the body. This means that the body’s immune system is

activated to make antibodies. Antibodies are proteins that can fight off infections and help prevent disease.

An **immune response** is the body's ability to find and fight germs that cause diseases.

2. To determine whether BNT vaccine was safe and tolerable.

Researchers wanted to know:

- **What was the immune response to BNT vaccine in participants 1 month after Dose 3 and Dose 4?**
- **How many participants had redness, swelling, or pain at the injection site (local reactions) within 7 days after each vaccination?**
- **How many participants had fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain (systemic events) within 7 days after each vaccination?**
- **How many participants had a medical problem within 1 month after each vaccination?**
- **How many participants had a serious medical problem during the study?**

What happened during the study?

How was the study done?

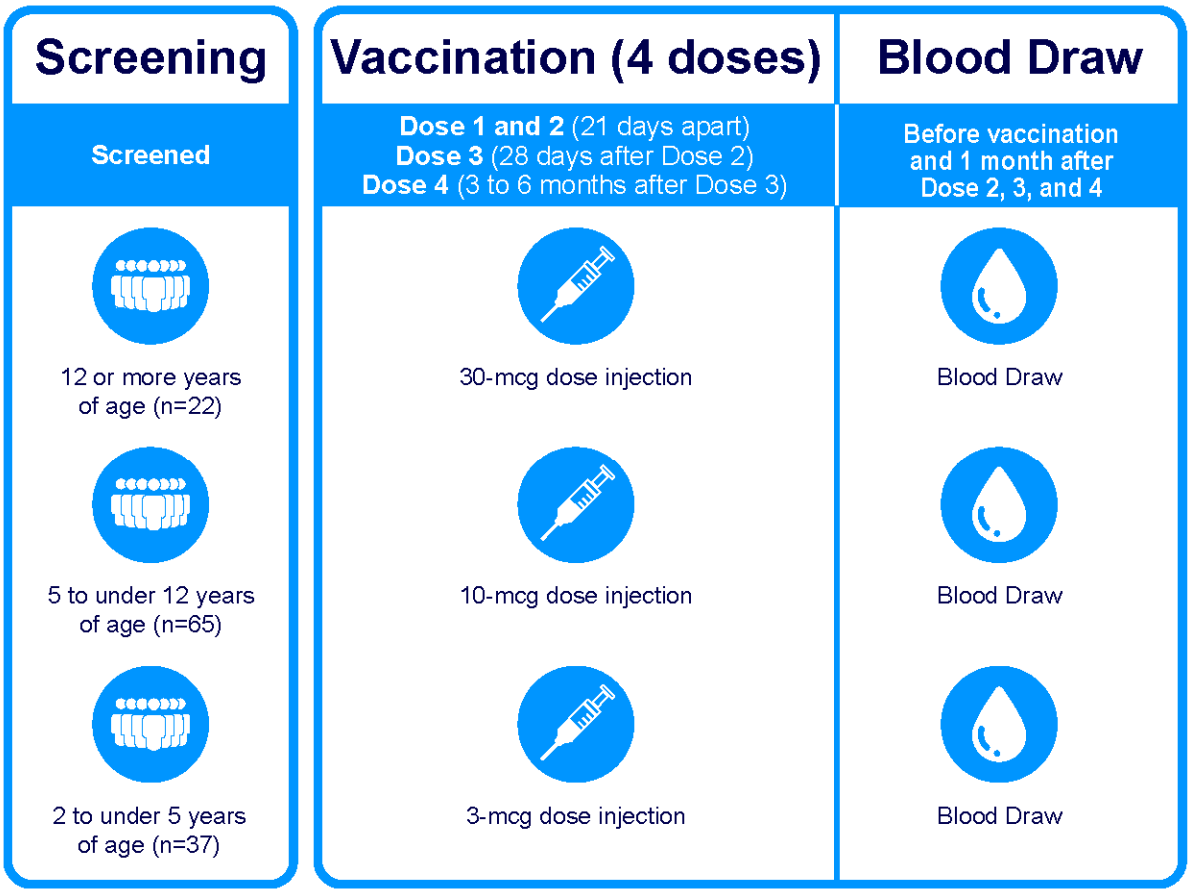
This study included participants who were “immunocompromised” which means the participants had low immunity levels due to previous other diseases such as cancers or organ transplants amongst other disorders. Participants at least 18 years of age were immunocompromised either due to suffering from cancers, or end-stage kidney disease, or diseases that affect their immune system for which they are taking medicines that reduce their immunity. Participants 2 to under 18 years of age were immunocompromised as a result of taking medicines that reduce immunity due to receiving new organs or stem cells, or bone marrow from donors.

In this study, participants were given 4 doses of BNT vaccine as an injection. The first 2 doses were 21-days apart. The third dose was given 28 days after the second dose and the fourth dose was given 3-6 months after the third dose.

The dose for each of the 4 vaccinations depended upon the age of the participant at the time of vaccination as shown below and in Figure 1.

- Participants who were at least 12 years of age on the day of vaccination received 30 micrograms (mcg) dose.
- Participants who were at least 5 to 12 years of age on the day of vaccination received 10-mcg dose
- Participants who were 2 to under 5 years of age on the day of vaccination received 3-mcg dose

Figure 1. How was the Study done?



n = number of participants *mcg = micrograms*

This was an "open-label" study; which means the participants and the investigators knew what vaccine the participants were receiving.

The immune response of the participants was determined by measuring the amount of BNT antibodies in their blood in response to the vaccine.

Where did this study take place?

The Sponsor ran this study at 18 locations in Brazil, Germany, Mexico, and United States.

When did this study take place?

It began 15 October 2021 and ended 23 July 2023.

Who participated in this study?

The study included participants who were immunocompromised, who were at least 2 years of age or older and met other inclusion/exclusion criteria as required.

- Participants 2 to under 5 years of age: 22 boys and 15 girls
- Participants 5 to under 12 years of age: 39 boys and 26 girls
- Participants 12 to under 18 years of age: 8 boys and 7 girls
- Participants 18 years or more of age: 4 men and 3 women

Of the 37 participants 2 to under 5 years of age who started the study, 25 participants finished the study.

Of the 65 participants 5 to under 12 years of age who started the study, 54 participants finished the study.

Of the 15 participants 12 to under 18 years of age who started the study, 8 participants finished the study.

Of the 7 participants 18 years or more of age who started the study, 4 participants finished the study.

Participants withdrew from the study mainly due to withdrawal by the parent/guardian for children and by their own choice for adults.

How long did the study last?

Most of the participants were in the study for about 13 months. The entire study took approximately 21 months to complete.

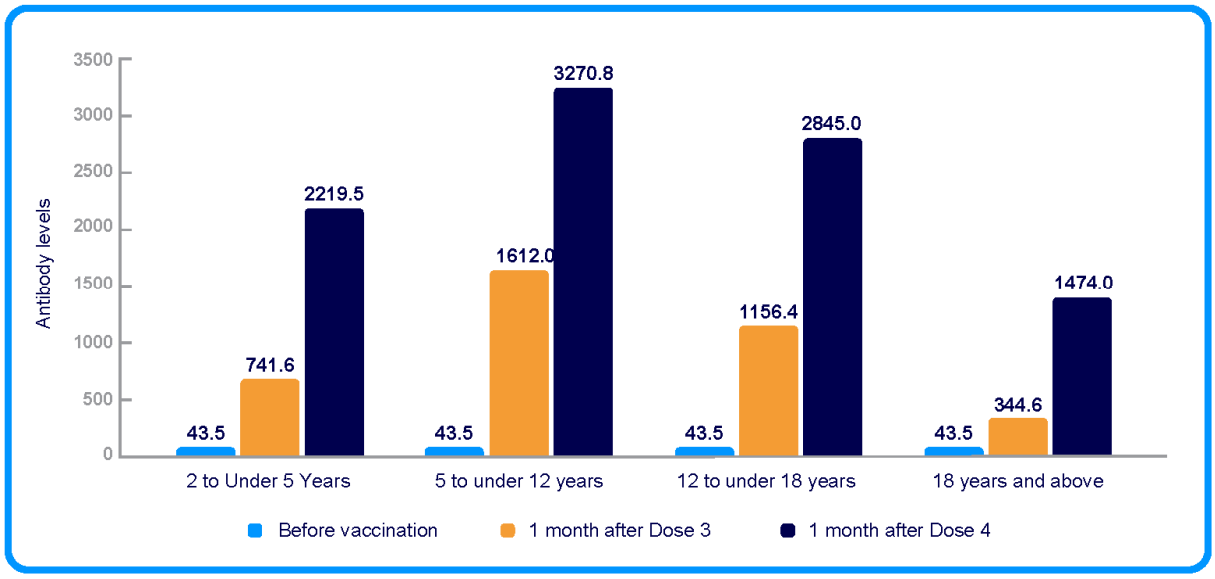
Data gathered from the study were analysed and then summarized to create this report.

What were the results of the study?

- **What was the immune response to BNT vaccine in participants 1 month after Dose 3 and Dose 4?**

Immune response (antibodies to the vaccine against COVID-19 virus) for participants without previous COVID infection up to 1 month after Dose 3 or 1 month after Dose 4 in the various age groups was as shown in Figure 2. In general, antibody levels were higher 1 month after Dose 3 and 1 month after Dose 4 compared to levels before vaccination in all age groups.

Figure 2. Immune Response



- **How many participants had redness, swelling, or pain at the injection site (local reactions) within 7 days after each vaccination?**

Among the participants 2 to under 5 years of age, 18.9% after Dose 1, 14.3% after Dose 2, 14.3% after Dose 3, and 21.1% after Dose 4 reported local reactions within 7 days after the dose.

Among the participants 5 to under 12 years of age, 66.2% after Dose 1, 63.1% after Dose 2, 52.5% after Dose 3, and 54.3 % after Dose 4 reported local reactions within 7 days after the dose.

Among the participants 12 to under 18 years of age, 80.0% after Dose 1, 80.0% after Dose 2, 71.4% after Dose 3, and 75.0 % after Dose 4 reported local reactions within 7 days after the dose.

Among the participants 18 years or more of age, 85.7% after Dose 1, 71.4% after Dose 2, 60.0% after Dose 3, and 75.0% after Dose 4 reported local reactions within 7 days after the dose.

Across all age groups, reactions at the injection site such as redness, swelling and pain within 7 days after injection were mild to moderate in severity.

- **How many participants had fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain (systemic events) within 7 days after each vaccination?**

The following participants had at least 1 symptom of fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain within 7 days after each vaccination:

Among the participants 2 to under 5 years of age, 27.0% after Dose 1, 23.5% after Dose 2, 8.6% after Dose 3 and 26.3% after Dose 4 reported systemic events within 7 days after the dose.

Among the participants 5 to under 12 years of age, 46.2% after Dose 1, 60.0% after Dose 2, 55.7% after Dose 3, and 52.2% after Dose 4 reported systemic reactions within 7 days after the dose.

Among the participants 12 to under 18 years of age, 73.3% after Dose 1, 78.6% after Dose 2, 85.7% after Dose 3, and 62.5% after Dose 4 reported systemic reactions within 7 days after the dose.

Among the participants 18 years or more of age, 85.7% after Dose 1, 71.4% after Dose 2, 60.0% after Dose 3, and 50.0% after Dose 4 reported systemic reactions within 7 days after the dose.

Tiredness was the most commonly reported systemic event.

Across all age groups, the majority of systemic events were mild or moderate in severity.

This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

What medical problems did participants have during the study?

The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused

by the vaccination or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what effects the vaccination might have on a participant.

Participants that reported at least 1 medical problem from the vaccination from Dose 1 to 1 month after Dose 2:

- 14 out of 37 (37.8%) participants in the 2 to under 5 years group,
- 15 out of 65 (23.1%) participants in the 5 to under 12 years group,
- 2 out of 15 (13.3%) participants in the 12 to under 18 years group, and
- 1 out of 7 (14.3%) participants in the 18 years or more group

Participants that reported at least 1 medical problem from the vaccination from Dose 3 to 1 month after Dose 3:

- 9 out of 35 (25.7%) participants in the 2 to under 5 years group,
- 8 out of 62 (12.9%) participants in the 5 to under 12 years group,
- 2 out of 14 (14.3%) participants in the 12 to under 18 years group, and
- Zero participants out of the 7 in the 18 years or more group

Participants that reported at least 1 medical problem from the vaccination from Dose 4 to 1 month after Dose 4:

- 2 out of 19 (10.5%) participants in the 2 to under 5 years group,
- 7 out of 46 (15.2%) participants in the 5 to under 12 years group,
- Zero participants out of 8 in the 12 to under 18 years group, and
- 1 participant out of 4 (25.0%) in the 18 years or more group

No participants left the study because of medical problems. The most common medical problems – those reported by at least 5% of participants in any age group are described below.

Below are instructions on how to read Table 1 and the same instructions apply to Table 2 and Table 3.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were commonly reported during the study. All medical problems reported by at least 5% of participants in any age group are listed.
- The **2nd** column tells how many of the 37 participants in the 2 to under 5 years group reported each medical problem. Below this number is the percentage of the 37 participants who reported the medical problem.
- The **3rd** column tells how many of the 65 participants in the 5 to under 12 years group reported each medical problem. Below this number is the percentage of the 65 participants who reported the medical problem.
- The **4th** column tells how many of the 15 participants in the 12 to under 18 years group reported each medical problem. Below this number is the percentage of the 15 participants who reported the medical problem.
- The **5th** column tells how many of the 7 participants in the 18 years or more group reported each medical problem. Below this number is the percentage of the 7 participants who reported the medical problem.

Using these instructions, you can see how many participants reported injection site pain,

- 2 out of the 37 (5.4%) participants in the 2 to under 5 years group
- 2 out of the 65 (3.1%) participants in the 5 to under 12 years group,
- 1 out of 15 (6.7%) participants in the 12 to under 18 years group, and
- None of the participants in the at least 18 years group reported injection site pain.

Table 1. Medical problems reported by at least 5% of the study participants from Dose 1 to 1 month after Dose 2

Medical Problem	2 to under 5 years (37 Participants)	5 to under 12 years (65 Participants)	12 to under 18 years (15 Participants)	18 years or more (7 Participants)
Injection site pain	2 out of 37 participants (5.4%)	2 out of 65 participants (3.1%)	1 out of 15 participants (6.7%)	0
Fever	2 out of 37 participants (5.4%)	0	1 out of 15 participants (6.7%)	0

Table 1. Medical problems reported by at least 5% of the study participants from Dose 1 to 1 month after Dose 2

Medical Problem	2 to under 5 years (37 Participants)	5 to under 12 years (65 Participants)	12 to under 18 years (15 Participants)	18 years or more (7 Participants)
Chills	0	0	1 out of 15 participants (6.7%)	0
Urinary tract infection	1 out of 37 participants (2.7%)	1 out of 65 participants (1.5%)	1 out of 15 participants (6.7%)	1 out of 7 participants (14.3%)
Dizziness	0	0	1 out of 15 participants (6.7%)	0
Headache	0	1 out of 65 participants (1.5%)	1 out of 15 participants (6.7%)	0
Swelling of vagina	0	0	0	1 out of 7 participants (14.3%)

Table 2. Medical problems reported by at least 5% of the study participants from Dose 3 to 1 month after Dose 3

Medical Problem	2 to under 5 years (35 Participants)	5 to under 12 years (62 Participants)	12 to under 18 years (14 Participants)	18 years or more (7 Participants)
Urinary tract infection	0	1 out of 62 participants (1.6%)	1 out of 14 participants (7.1%)	0
Headache	0	0	1 out of 14 participants (7.1%)	0

Table 3. Medical problems reported by at least 5% of the study participants from Dose 4 to 1 month after Dose 4

Medical Problem	2 to under 5 years (19 Participants)	5 to under 12 years (46 Participants)	12 to under 18 years (8 Participants)	18 years or more (4 Participants)
Pink eye	1 out of 19 participants (5.3%)	0	0	0
Urinary tract infection	1 out of 19 participants (5.3%)	1 out of 46 participants (2.2%)	0	0

Table 3. Medical problems reported by at least 5% of the study participants from Dose 4 to 1 month after Dose 4				
Medical Problem	2 to under 5 years (19 Participants)	5 to under 12 years (46 Participants)	12 to under 18 years (8 Participants)	18 years or more (4 Participants)
Swelling of joints	1 out of 19 participants (5.3%)	0	0	0
Spread of cancer to the bone	0	0	0	1 out of 4 participants (25.0%)
External ear infection	0	3 out of 46 participants (6.5%)	0	0

Did study participants have any serious medical problems?

A medical problem is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems.

Among the participants 2 to under 5 years of age, 11 participants (29.7%) reported at least 1 serious medical problem. Most of these were infections and infestations. None of these were thought to be related to the vaccine.

Among the participants 5 to under 12 years of age, 11 participants (16.9%) reported at least 1 serious medical problem. Most of these were infections and infestations. None of these were thought to be related to the vaccine.

In the younger age groups of 2 to under 5 years and 5 to under 12 years, participants who had solid organ transplants had the most number of serious medical problems, most of which were infections.

Among the participants 12 to under 18 years of age, no participant reported serious medical problems.

Among the participants 18 years or older, 2 participants (28.6%) reported at least 1 serious medical problem. One participant reported severe pain due to urinary stones. One participant had black tarry stools (melaena), tissue damage due to infection (gangrene), and high levels of body waste compounds in blood due to kidneys not functioning properly (azotaemia). None of these were thought to be related to the vaccine.

No participants died during the study.

Where can I learn more about this study?

If you have questions about the results of your study, please speak with the doctor or staff at your study site.

For more details on your study protocol, please visit:

www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number C4591024

The full scientific report of this study is available online at:

www.clinicaltrials.gov	Use the study identifier **NCT04895982**
www.clinicaltrialsregister.eu	Use the study identifier 2021-001290-23

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients.

Again, if you participated in this study, **thank you** for volunteering. We do research to try to find the best ways to help patients, and you helped us to do that!