

# Plain Language Clinical Study Summary

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 vaccine 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 Studied:** Comirnaty® (also known as PF-07302048 or BNT162b2)

**Protocol Number:** C4591054 (Substudy B)

**Dates of Study:** 23 August 2023 to 22 March 2024

**Title of this Study:** A Study to Learn About New COVID-19 RNA Vaccine Candidates for New Variants in Healthy Individuals (Substudy B)

[A Phase 2/3 Protocol to Investigate the Safety, Tolerability, and Immunogenicity of BNT162b2 RNA-Based Vaccine Candidates for SARS-CoV-2 New Variants in Healthy Individuals]

**Date of this Report:** 06 August 2025

– Thank You –

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



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

## Why was this study done?

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### 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 symptoms such as fever, chills, cough, loss of taste or smell, muscle pain, sore throat, vomiting, diarrhea, or trouble breathing.

All viruses, including the COVID-19 virus, are expected to change over time. These changes or mutations from the original virus are called different “variants” (or strains). One of the strains of SARS-CoV-2 is **Omicron** (also called **Omi**).

Compared to the original COVID-19 virus, the Omi strain spreads more easily between people.

Over the past few years, there have been many different versions of the Omi strain. These Omi strains are being closely watched to see which may cause more severe illness for people and if they are being targeted by current vaccines.

Health authorities continue to track new COVID-19 strains and recommend that scientists update the COVID-19 vaccines depending on the currently circulating strains.

Health authorities recommend people to stay up to date with COVID-19 vaccinations, especially before the fall and winter months when COVID-19 infections are expected to rise. Vaccination can help protect people from illnesses caused by new COVID-19 virus strains.

## What are BNT162b2 and BNT162b2 (Omi XBB.1.5) vaccines?

These injectable vaccines may help the body's immune system to defend against COVID-19.

**BNT162b2** is the original monovalent COVID-19 vaccine designed to target the original strain of the COVID-19 virus. A monovalent COVID-19 vaccine can target 1 strain of the COVID-19 virus.

- 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 produce antibodies to fight against COVID-19.

In 2021, health agencies approved BNT162b2 (original formulation) for use in people 16 years of age and older.

In this study, participants got an updated version of BNT162b2 called **BNT162b2 (Omi XBB.1.5)**. BNT162b2 (Omi XBB.1.5) was designed to help protect against the **Omi XBB.1.5** strain. Omi XBB.1.5 strain was the most widespread COVID-19 virus strain worldwide at the start of this study.

During this study, in 2023, health agencies in the United States (US) and other countries authorized or approved BNT162b2 (Omi XBB.1.5) for use in people 6 months of age and older.

Comirnaty® is the brand name for the BNT162b2 COVID-19 vaccines, including both the original formulation and updated versions such as BNT162b2 (Omi XBB.1.5).



## What was the purpose of this study?

The study was divided into 3 substudies: Substudy A, Substudy B, and Substudy C, each with their own group of participants. This report only includes what happened in **Substudy B**. Results of Substudy A and Substudy C are discussed in separate reports.

The main purpose of Substudy B was to learn if BNT162b2 (Omi XBB.1.5) given to healthy people who had COVID-19 in the past and had not gotten any COVID-19 vaccine is safe and may produce immune responses against the COVID-19 strains circulating at the time of this study.



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 off germs that cause disease.

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### Researchers wanted to know:

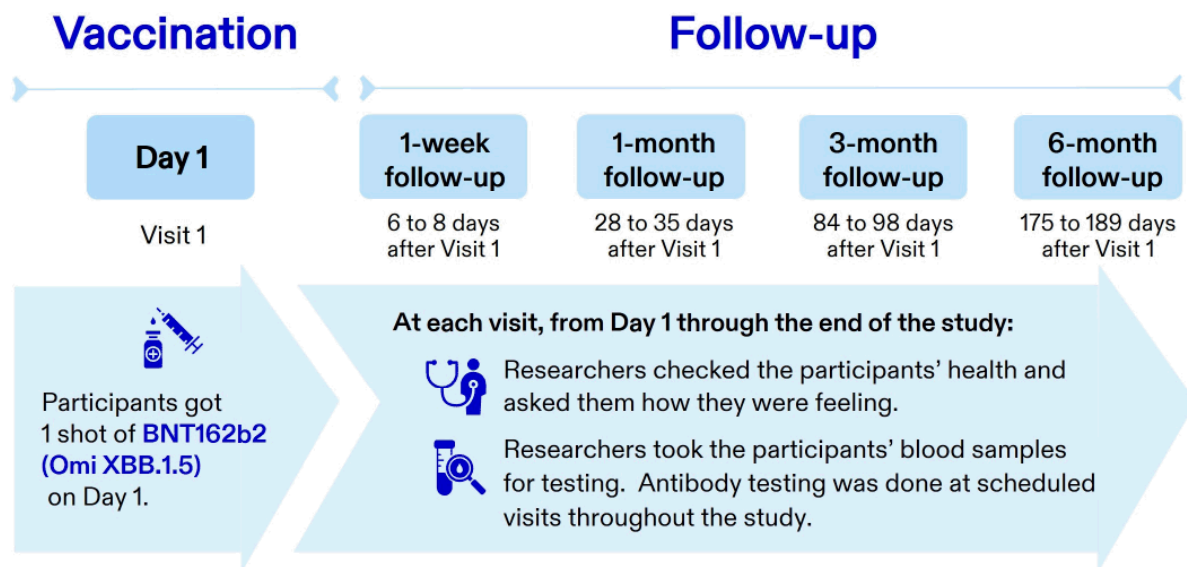
- **Does BNT162b2 (Omi XBB.1.5) vaccine produce immune responses when given to participants who had COVID-19 in the past and had not gotten any COVID-19 vaccine?**
  - **What medical problems did participants have during the study?**
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# What happened during the study?

## How was the study done?

Participants got 1 shot of BNT162b2 (Omi XBB.1.5) 30 micrograms (mcg) in this study. Figure 1 shows how the study was done.

Figure 1. Study plan



This study was “open-label”, which means that the participants, their parents/guardians (for participants 12 to 17 years of age), and researchers knew that all participants got BNT162b2 (Omi XBB.1.5) in this study.

## Where did this study take place?

The Sponsor ran this study in the US.

## When did this study take place?

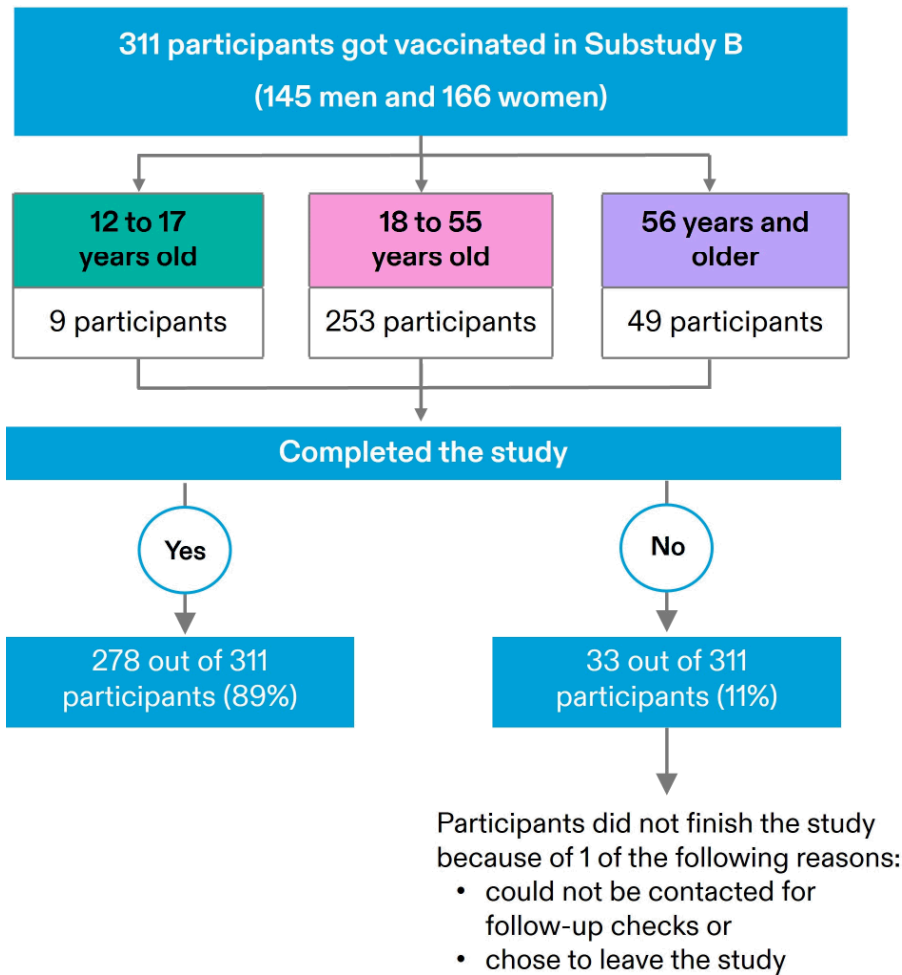
Substudy B began on 23 August 2023 and ended on 22 March 2024.

## Who participated in this study?

The study included participants at least 12 years old who were considered healthy by the researchers. Before joining the study, they must have had COVID-19 in the past and had not gotten any COVID-19 vaccine.

Figure 2 shows how many participants joined the study.

**Figure 2. How many participants joined Substudy B?**



## How long did the study last?

Substudy B participants were in the study for about 6 months. Substudy B took about 7 months to complete. It was completed as planned.

When Substudy B ended in March 2024, the Sponsor agent began reviewing the information collected. The Sponsor agent then created a report of the results. This is a summary of that report.

## What were the results of the study?

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### Does BNT162b2 (Omi XBB.1.5) vaccine produce immune responses when given to participants who had COVID-19 in the past and had not gotten any COVID-19 vaccine?

To answer the question:



Researchers measured the participants' **antibody levels** against Omi XBB.1.5 strain of the COVID-19 virus **before** and 1 month **after** **BNT162b2 (Omi XBB.1.5)** vaccination.



Researchers also checked how many participants had **strong immune responses** against Omi XBB.1.5. In this study, a strong immune response means the antibody levels were at least **4 times higher** at 1 month **after** vaccination compared to **before** vaccination.

Researchers then compared the results of participants in Substudy B to the results of selected participants in Substudy A of this same study.

**Substudy A** included participants at least 12 years old who were considered healthy by the researchers. Substudy A participants previously got COVID-

19 vaccinations before joining the study and also got **BNT162b2 (Omi XBB.1.5) 30 mcg** during this study.

Researchers found that at 1 month after BNT162b2 (Omi XBB.1.5) vaccination:

- The **antibody levels** against Omi XBB.1.5 strain of Substudy B participants were **not worse** than those seen in Substudy A participants.
- The percentage of Substudy B participants with **strong immune responses** against Omi XBB.1.5 strain was **not worse** than that of Substudy A participants.

Researchers found that these results are not likely due to chance.



Overall, study results showed that 1 shot of BNT162b2 (Omi XBB.1.5) given to healthy participants at least 12 years of age who had COVID-19 in the past and had not gotten any COVID-19 vaccine produced **similar** immune responses against COVID-19 compared to participants who had previous shots of COVID-19 vaccine.

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?

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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 unknown underlying disease or by chance).

Or, medical problems could also have been caused by a study vaccine or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many vaccine groups in many studies, doctors try to understand what effects a study vaccine might have on a participant.

### How many participants had any local reaction and systemic event within 7 days after vaccination?

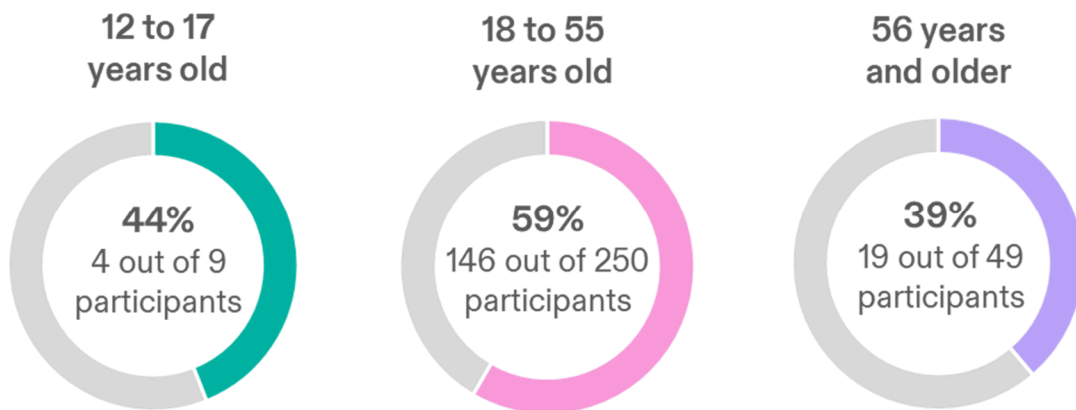
“**Local reactions**” include pain, redness, and swelling at the injection site (area on the arm where the vaccine was injected).

“**Systemic events**” are reactions that affect the whole body like fever, chills, diarrhea, vomiting, headache, tiredness, muscle pain, and joint pain.

To answer the question, researchers checked the electronic diary records of participants in this study.

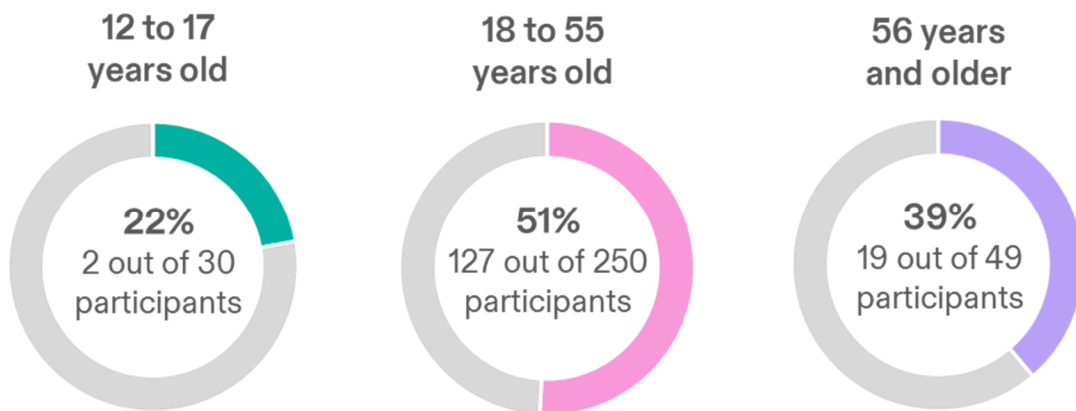
Figure 3 and Figure 4 show the answer to the question.

**Figure 3. Number of participants with any local reaction within 7 days after vaccination – by age group**



The most common local reaction in all age groups was **pain at the injection site**. Most local reactions were mild or moderate in severity and lasted for 1 to 5 days.

**Figure 4. Number of participants with any systemic event within 7 days after vaccination**

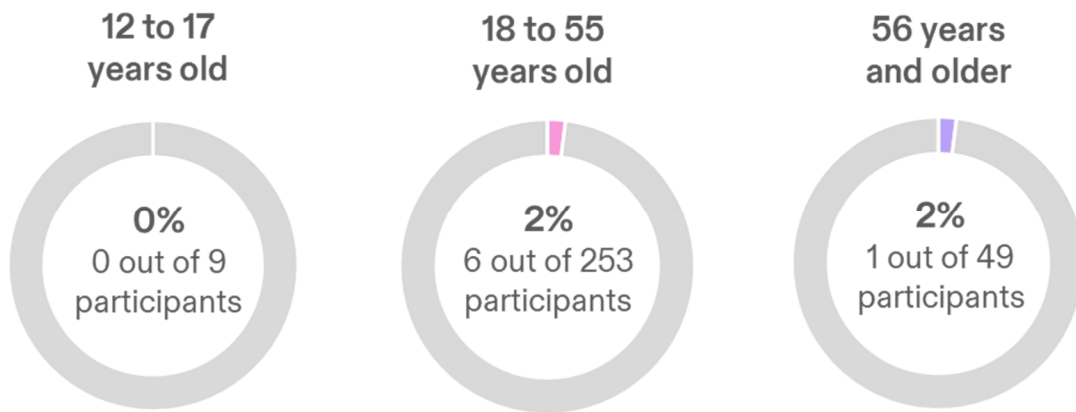


The most common systemic event in all age groups was **tiredness**. Most systemic events were mild or moderate in severity and lasted for 1 to 4 and a half days.

### How many participants had any medical problem within 1 month after vaccination?

Figure 5 shows that, across the 3 age groups, a total of 7 out of 311 participants (2%) had at least 1 medical problem within 1 month after vaccination.

**Figure 5. Number of participants with any medical problem within 1 month after vaccination – by age group**



All of the medical problems within 1 month after vaccination were mild or moderate in severity. None of the medical problems reported within 1 month after vaccination happened in more than 2 participants.

## **Did study participants have any serious medical problems?**

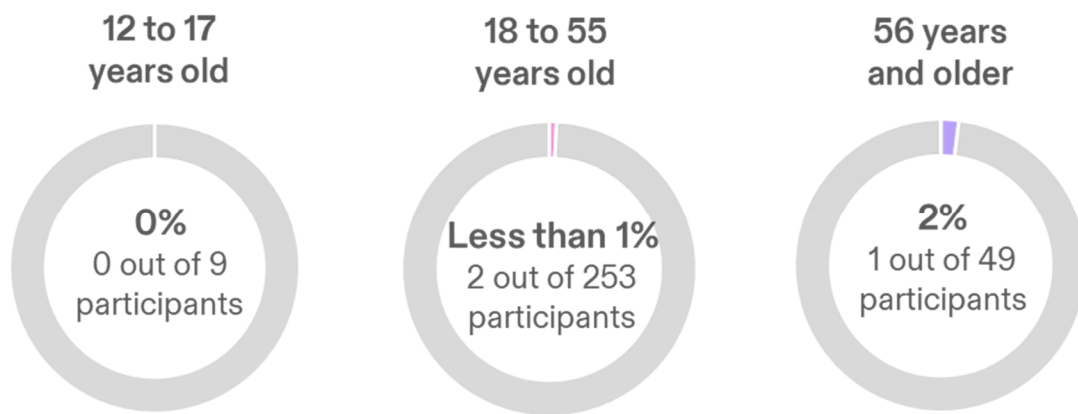
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A medical problem is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems.

### **How many participants had any serious medical problem within 6 months after vaccination?**

Figure 6 shows that, across the 3 age groups, a total of 3 out of 311 participants (1%) had serious medical problems within 6 months after vaccination.

**Figure 6. Number of participants with any serious medical problem within 6 months after vaccination – by age group**



These 3 participants had a total of 3 serious medical problems that researchers believe were not caused by BNT162b2 (Omi XBB.1.5).

None of the participants died during Substudy B.

## Where can I learn more about this study?

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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](http://www.pfizer.com/research/research_clinical_trials/trial_results) Use the protocol number **C4591054 (Substudy B)**

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

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) Use the study identifier **NCT05997290**

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

Again, if you or your child 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!

