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 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® (Pfizer-BioNTech RNA-based COVID-19 Vaccine), also known as BNT162b2 or PF-07302048
Protocol Number:	C4591031 Substudy D
Dates of Study:	24 January 2022 to 25 May 2023
Title of this Study:	Substudy D: A Study of BNT162b2 COVID-19 Vaccines in Healthy Adults [Substudy D Final Report: A Phase 3 Master Protocol to Evaluate Additional Dose(s) of BNT162b2 in Healthy Individuals Previously Vaccinated With BNT162b2]
Date of this Report:	17 July 2024

– Thank You –

If you participated in this study, Pfizer, the Sponsor Agent, 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 **s**evere **a**cute **r**espiratory **s**yndrome **co**rona**v**irus **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.

All viruses, including the COVID-19 virus, are expected to change over time. These changes or mutations from the original virus are called **variants** (or **strains**). Compared to the original COVID-19 virus, the **Omicron** strain spreads more easily between people.

What are BNT162b2 (BNT) and BNT162b2 Omi (BNT Omi)?

BNT162b2 (**BNT**, also known as Comirnaty®) and **BNT162b2 Omi** (**BNT Omi**) are injectable vaccines that may help the body's immune system to defend against COVID-19.

BNT is the original monovalent COVID-19 vaccine that can target the original strain of the COVID-19 virus.

A **monovalent** vaccine can target 1 strain of a virus.

- BNT does not contain a whole virus or any part of the virus that can cause COVID-19.
- BNT 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.

As of July 2022, **BNT** 30 micrograms (30 mcg) had been widely approved around the world.

BNT Omi is an Omicron-modified form of the original BNT162b2 vaccine. BNT Omi is also a monovalent vaccine that was designed to target the **Omicron BA.1** strain of the COVID-19 virus. Like all variants, this Omicron strain has mutations in the spike protein of the COVID-19 virus that make it different from the original strain.

BNT Omi is an investigational vaccine being tested in this study.

What was the purpose of this study?

The main purpose of this study was to find out if **BNT Omi** (given as 1 or 2 booster doses, or as 2 primary doses) helps to produce immune responses against the COVID-19 virus Omicron BA.1 strain and is safe for healthy adult participants.

Primary or first dose (or series of doses) of a vaccine:

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.

A person's immune protection from their primary dose or doses of a vaccine can fade over time.

Booster dose of a vaccine:

- A **booster shot** is the extra dose of a vaccine given after the first (primary) dose or series of doses.
- A booster shot can help the immune system maintain or **boost** the level of protection against a disease.

Researchers wanted to know:

- **Did participants have immune responses against the COVID-19 virus Omicron BA.1 strain after vaccination?**
- **How many participants had redness, swelling, or pain at the injection site within 7 days after vaccination?**
- **How many participants had fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain within 7 days after vaccination?**
- **What medical problems did participants have during the study?**

What happened during the study?

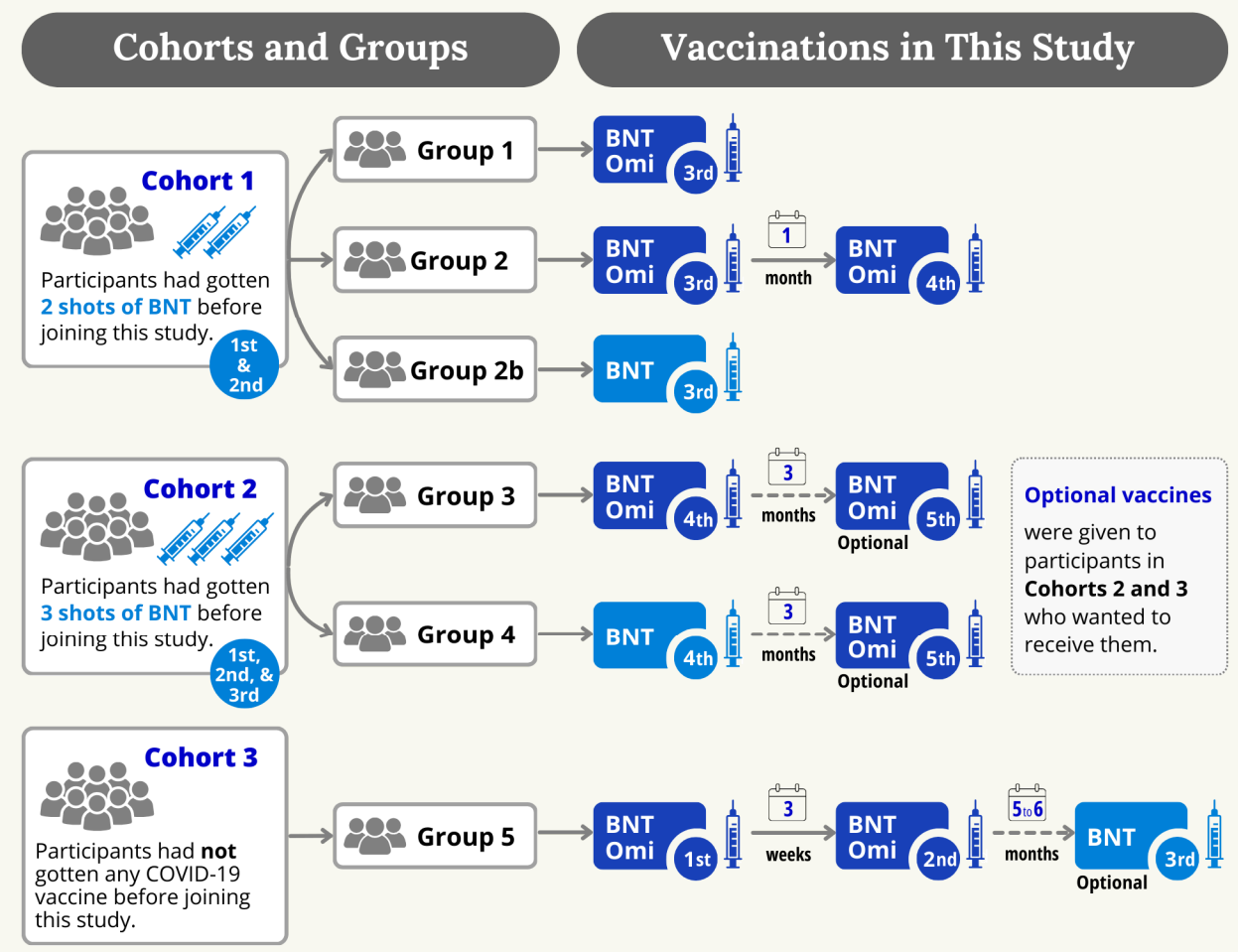
How was the study done?

Participants were divided into 3 large groups called **cohorts**, based on their COVID-19 vaccination status before joining this study.

Then, researchers used a computer program to randomly assign participants within each cohort to a vaccine group.

Figure 1 shows the 6 groups across the 3 cohorts in this study.

Figure 1. Which vaccines were given in this study?



Cohort 1:	
Participants had gotten 2 primary doses of BNT before joining this study.	
Group 1 **BNT Omi 1-dose** group	• Participants got 1 booster dose of **BNT Omi** (their 3rd shot) as Vaccination 1 in this study.
Group 2 **BNT Omi 2-dose** group	• Participants got 2 booster doses of **BNT Omi** (their 3rd and 4th shots) as Vaccinations 1 and 2 given 1 month apart in this study.
Group 2b **BNT 1-dose** group	• Participants got 1 booster dose of **BNT** (their 3rd shot) as Vaccination 1 in this study.

Cohort 2:	
Participants had gotten 2 primary doses and 1 booster dose of BNT before joining this study.	
Group 3 (**BNT Omi** group)	• Participants got 1 booster dose of **BNT Omi** (their 4th shot) as Vaccination 1 in this study. • After 3 months, this dose was followed by 1 booster dose of **BNT Omi** (their 5th shot) as Vaccination 2 if participants wanted to receive it (“optional”).
Group 4 (**BNT** group)	• Participants got 1 booster dose of **BNT** (their 4th shot) as Vaccination 1 in this study. • After 3 months, this dose was followed by 1 booster dose of **BNT Omi** (their 5th shot) as Vaccination 2 if participants wanted to receive it (“optional”).

Cohort 3:	
Participants had not gotten any COVID-19 vaccine before joining this study.	
Group 5 (**BNT Omi** group)**:**	• Participants got 2 primary doses of **BNT Omi** (their first 2 shots) as Vaccinations 1 and 2 given 3 weeks apart in this study. • Then, 5 to 6 months after the 2nd shot of BNT Omi, this dose was followed by 1 booster dose of **BNT** (their 3rd shot) as Vaccination 3 if participants wanted to receive it (“optional”).

For **Cohorts 1** and **2**, only the person giving the injection knew which vaccines the participants got. The participants and researchers did not know.

For **Cohort 3**, participants and researchers knew which vaccines the participants got.

Across the 3 cohorts, study doctors checked each participant’s health and took their blood samples throughout the study. Participants visited the study site for their scheduled vaccinations and follow-up checks.

Where did this study take place?

This study ran at 38 locations in South Africa and the United States.

When did this study take place?

It began on 24 January 2022 and ended on 25 May 2023.

Who participated in this study?

The study included adults who were assessed as healthy by study doctors.

- **Cohort 1** participants must have gotten 2 primary doses of BNT 30 mcg before joining this study, with their 2nd dose being 3 to 8 months before Day 1 of this study.
- **Cohort 2** participants must have gotten 2 primary doses and 1 booster dose of BNT 30 mcg before joining this study, with their 2nd dose being 3 to 6 months before Day 1 of this study.
- **Cohort 3** participants must not have gotten any COVID-19 vaccine before joining this study.

Across the 3 cohorts, participants were 18 to 55 years old.

The table below shows how many participants took part in each cohort.

Table 1. Number of participants in the study

	Cohort 1	Cohort 2	Cohort 3
Started the study	619 participants	640 participants	210 participants
Finished the study	573 of 619 participants (92.6%)	581 of 640 participants (90.8%)	159 of 210 participants (75.7%)
Did not finish the study	44 of 619 participants (7.1%)	59 of 640 participants (9.2%)	51 of 210 participants (24.3%)
Got the assigned dose of Vaccination 1 in the study	617 of 619 participants (99.7%)	638 of 640 participants (99.7%)	All 210 participants (100%)
Number of male and female participants	240 (38.9%) male and 377 (61.1%) female out of 617 participants	330 (51.7%) male and 308 (48.3%) female out of 638 participants	104 (49.5%) male and 106 (50.5%) female out of 210 participants

Among participants in the 3 cohorts that did not finish the study (Table 1), the most common reason was because:

- they chose to leave before the study was over, or
- they could not be contacted for their check-up.

How long did the study last?

Each participant was in the study for about 12 to 13 months. The entire study took 16 months to complete.

When the study ended in May 2023, 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?

Did participants have immune responses against the COVID-19 virus Omicron BA.1 strain after vaccination?

To answer this question, researchers measured the participants' **antibody levels** against the Omicron BA.1 strain **before** and **after** their vaccinations in this study.

- Antibody levels can tell us about the body's immune response (ability to find and fight off germs that cause disease).
- Antibody levels were measured using different tests done at different times for each of the 3 cohorts.

Then, researchers checked how many participants had **strong immune responses** against the Omicron BA.1 strain after vaccination in this study.

- 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** the first dose of study vaccination.
- This can tell us how many people made a lot of antibodies after getting vaccinated.

Overall, study results showed that participants across the 3 cohorts had:

- **high antibody levels** against the Omicron BA.1 strain after vaccinations in this study.

- **strong immune responses** against the Omicron BA.1 strain after vaccinations in this study.

The section below describes these results for each cohort.

Cohort 1

Figure 2. Cohort 1 at 1 month after vaccination in this study – Immune responses against the COVID-19 virus Omicron BA.1 strain

Figure 2-A

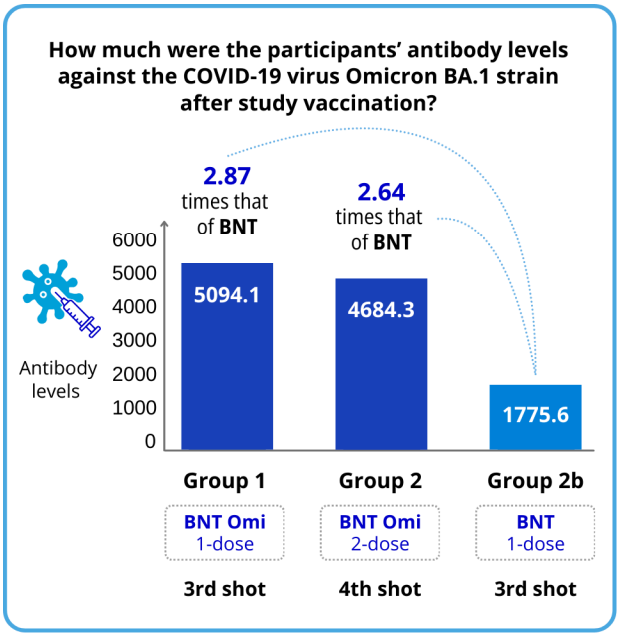
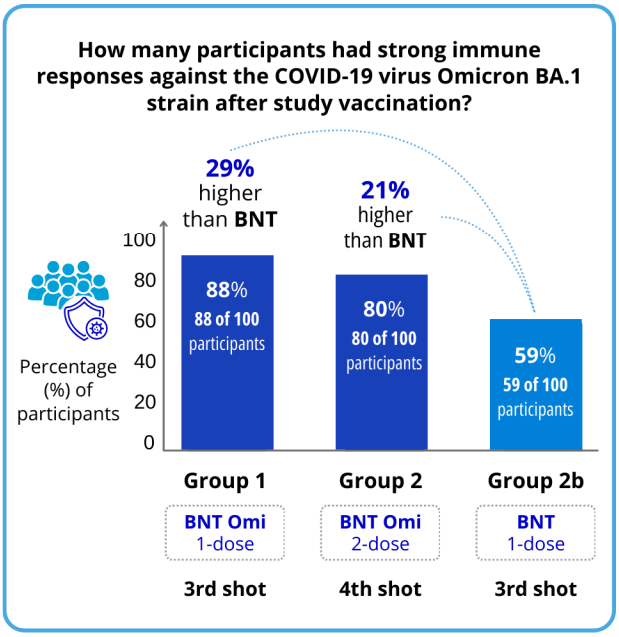


Figure 2-B



Cohort 1: Participants in **Groups 1, 2, and 2b** had gotten **2 shots of BNT** before joining the study

Cohort 1: Healthy adults who had gotten **2 primary doses of BNT** before joining this study

Figure 2-A above shows the antibody levels against the Omicron BA.1 strain at 1 month after participants in each group got their vaccinations in this study.

- The antibodies of **Group 1** at 1 month after getting **1 booster dose** of **BNT Omi** (their 3rd shot) were **2.87 times** that of the antibodies of **Group 2b** at 1 month after getting **1 booster dose** of **BNT** (their 3rd shot).
- The antibodies of **Group 2** at 1 month after getting **2 booster doses** of **BNT Omi** (their 3rd and 4th shots) were **2.64 times** that of the antibodies of **Group 2b** at 1 month after getting **1 booster dose** of **BNT** (their 3rd shot).

Figure 2-B above shows the percentage of participants with strong immune responses to the Omicron BA.1 strain at 1 month after participants in each group got their vaccinations in this study.

- **29% more** participants in **Group 1** had strong immune responses at 1 month after getting **1 booster dose** of **BNT Omi** (their 3rd shot) than **Group 2b** at 1 month after getting **1 booster dose** of **BNT** (their 3rd shot).
- **21% more** participants in **Group 2** had strong immune responses at 1 month after getting **2 booster doses** of **BNT Omi** (their 3rd and 4th shots) than **Group 2b** at 1 month after getting **1 booster dose** of **BNT** (their 3rd shot).

In **Cohorts 2 and 3**, researchers did additional tests to find out the following:

- If **BNT Omi** works better than **BNT** based on the **antibody levels** against the Omicron BA.1 strain at 1 month after vaccination.
- If **BNT Omi** works as well as **BNT** based on **how many participants had strong immune responses** to the Omicron BA.1 strain at 1 month after vaccination.

Cohort 2

Figure 3. Cohort 2 at 1 month after vaccination in this study – Immune responses against the COVID-19 virus Omicron BA.1 strain

Figure 3-A

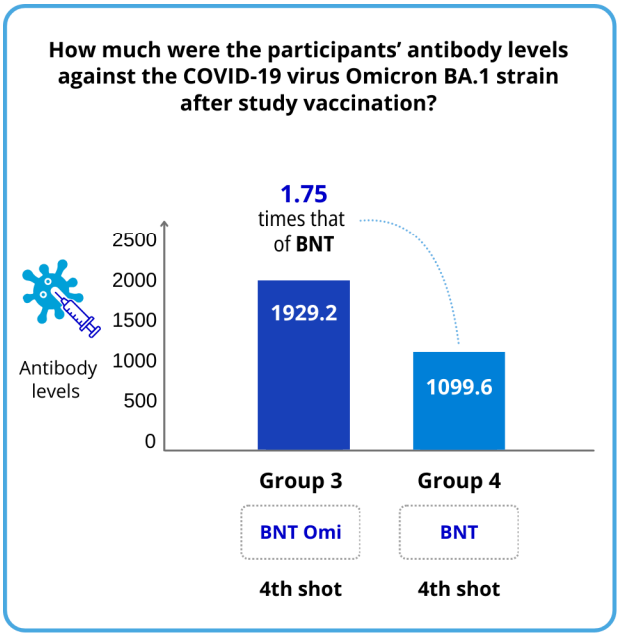
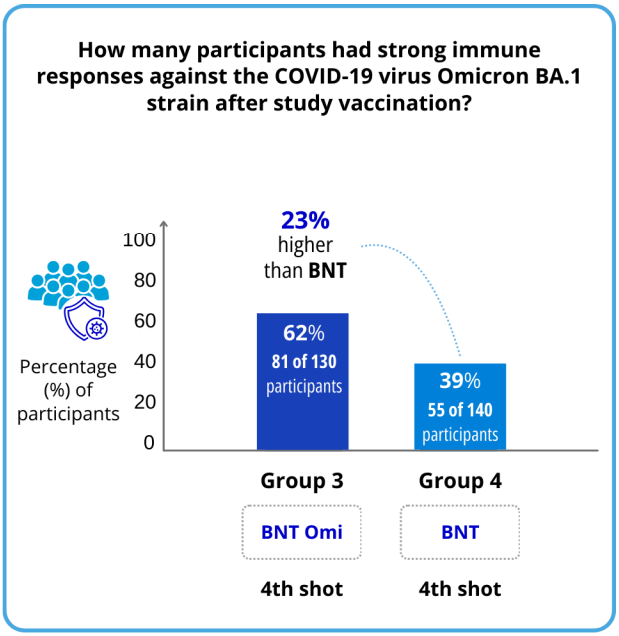


Figure 3-B



Cohort 2: Participants in **Groups 3 and 4** had gotten **3 shots of BNT** before joining the study

Cohort 2: Healthy adults who had gotten **2 primary doses and 1 booster dose of BNT** before joining this study

Figure 3-A above shows the antibody levels against the Omicron BA.1 strain at 1 month after participants in each group got their vaccinations in this study.

- The antibodies of **Group 3** at 1 month after getting **1 booster dose** of **BNT Omi** (their 4th shot) were **1.75 times** that of the antibodies of **Group 4** at 1 month after getting **1 booster dose** of **BNT** (their 4th shot).
- Researchers found that these results are likely not due to chance. This means that **1 booster dose** of **BNT Omi** (given as the 4th shot) may protect healthy adults against COVID-19 infection caused by Omicron BA.1 **better** than **1 booster dose** of **BNT** (given as the 4th shot).

Figure 3-B above shows the percentage of participants with strong immune responses to the Omicron BA.1 strain at 1 month after participants in each group got their vaccinations in this study.

- **23% more** participants in **Group 3** had strong immune responses at 1 month after getting **1 booster dose** of **BNT Omi** (their 4th shot) than **Group 4** at 1 month after getting **1 booster dose** of **BNT** (their 4th shot).
- Researchers found that these results are likely not due to chance. This means that **1 booster dose** of **BNT Omi** (given as the 4th shot) may help healthy adults produce a strong immune response against COVID-19 infection caused by Omicron BA.1 **as well as 1 booster dose** of **BNT** (given as the 4th shot).

Cohort 3

Figure 4. Cohort 3 at 1 month after vaccination in this study – Immune responses against the COVID-19 virus Omicron BA.1 strain

Figure 4-A

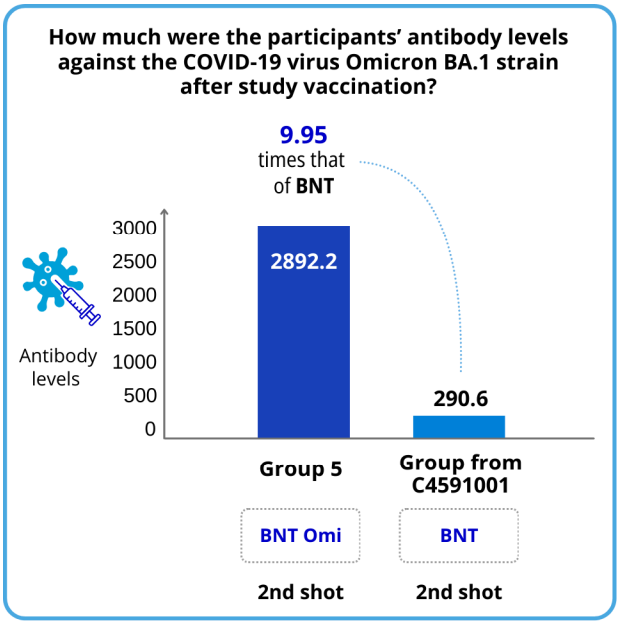
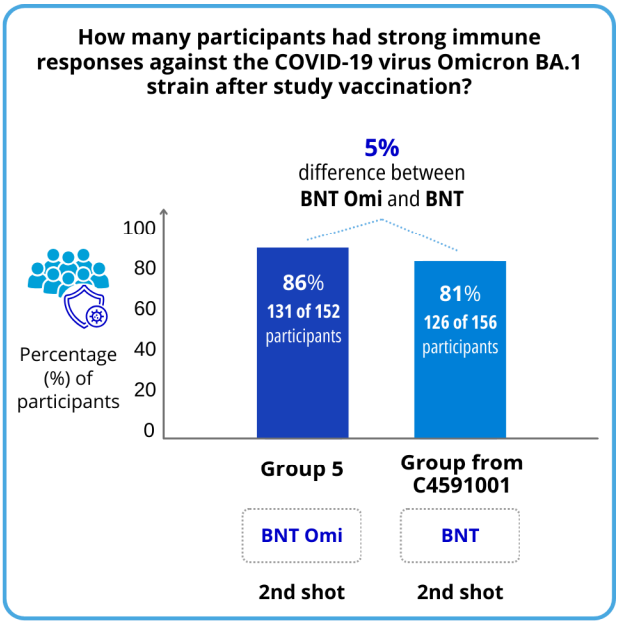


Figure 4-B



Cohort 3: Participants in **Group 5** and a **group of participants from another study** had **not** gotten any COVID-19 vaccine before joining the study.

Cohort 3: Healthy adults who had **not** gotten any COVID-19 vaccine before joining this study

The results of **Group 5** were compared to the results of a group of participants who got 2 primary doses of **BNT** 30 mcg in another study called **C4591001**. This group of participants from Study C4591001 were healthy adults of the same age group as the participants in this study.

Figure 4-A above shows the antibody levels against the Omicron BA.1 strain at 1 month after participants in Group 5 got their vaccination in this study. It also shows the results of the group of participants from Study **C4591001**.

- The antibodies of **Group 5** at 1 month after getting the **2nd primary dose** of **BNT Omi** (their 2nd shot) were **9.95 times** that of the antibodies of the **C4591001 group** at 1 month after getting the **2nd primary dose** of **BNT** (their 2nd shot).
- Researchers found that these results are likely not due to chance. This means that **2 primary doses** of **BNT Omi** (first 2 shots) may protect healthy adults against COVID-19 infection caused by Omicron BA.1 **better** than **2 primary doses** of **BNT** (first 2 shots).

Figure 4-B above shows the percentage of participants with strong immune responses to the Omicron BA.1 strain at 1 month after participants in Group 5 got their vaccinations in this study. It also shows the results of the group of participants from Study **C4591001**.

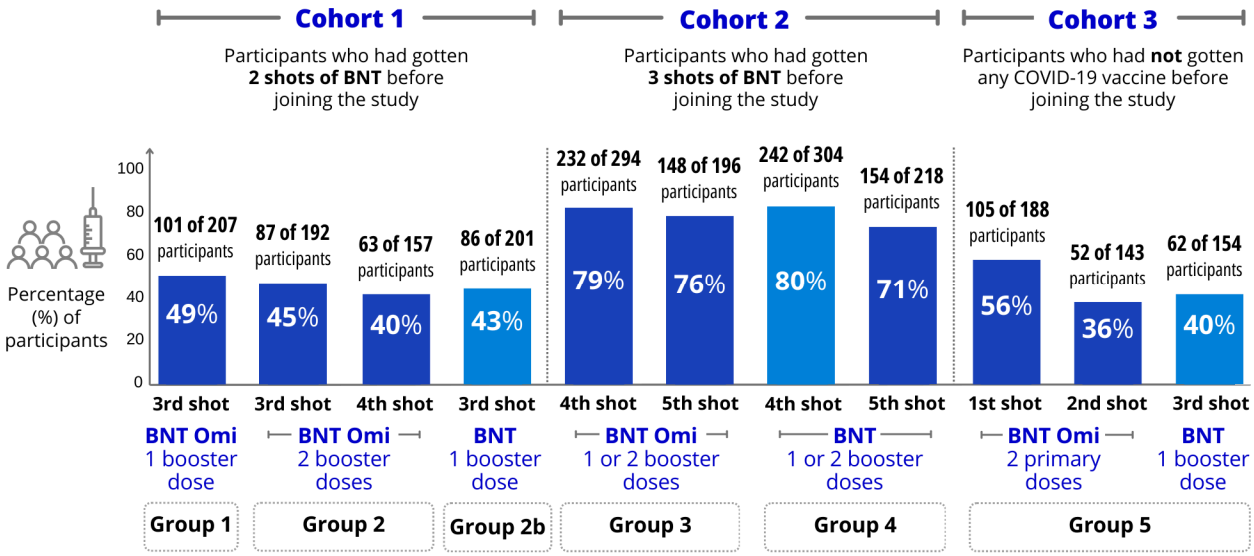
- The percentage of participants with strong immune responses to the Omicron BA.1 strain was **similar** (small 5% difference) between **Group 5** at 1 month after getting the **2nd primary dose** of **BNT Omi** (their 2nd shot) and the **C4591001 group** at 1 month after getting the **2nd primary dose** of **BNT** (their 2nd shot).
- Researchers found that these results are likely not due to chance. This means that **2 primary doses** of **BNT Omi** (the first 2 shots) may help healthy adults produce a strong immune response against COVID-19 infection caused by Omicron BA.1 **as well as** the **2 primary doses** of **BNT** (the first 2 shots).

How many participants had redness, swelling, or pain at the injection site within 7 days after vaccination?

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

Across the 3 cohorts, **36%** to **80%** of participants had at least 1 injection site reaction of redness, swelling, or pain within 7 days after each vaccination. These results are shown in Figure 5 below.

Figure 5. How many participants had redness, swelling, or pain at the injection site within 7 days after vaccination?



Across the 3 cohorts:

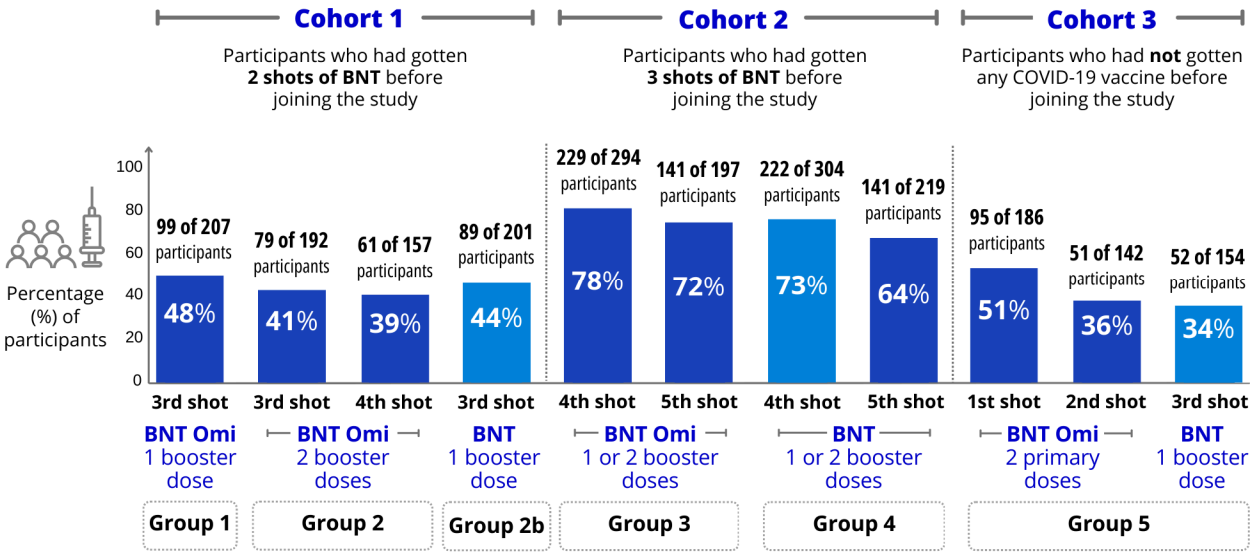
- Injection site reactions were mostly mild or moderate in severity and lasted about 1 to 2 days.
- The most common injection site reaction was pain.

How many participants had fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain within 7 days after vaccination?

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

Across the 3 cohorts, **34%** to **78%** of participants had at least 1 symptom of fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain within 7 days after each vaccination. These results are shown in Figure 6 below.

Figure 6. How many participants had fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain within 7 days after vaccination?



Across the 3 cohorts:

- These symptoms were mostly mild or moderate in severity and lasted about 1 to 2 days.
- The most common symptoms were tiredness and headache.

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 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.

This section describes the results of 1465 participants across the 3 cohorts who received their assigned doses of BNT Omi or BNT.

How many participants had a medical problem during the study?

Tables 2 to 4 below show that few participants across the 3 cohorts reported medical problems during the following timeframes:

- **Cohort 1:** from Vaccination 1 through 1 month after the last vaccination in this study.
- **Cohort 2:** within 1 month after each vaccination in this study.
- **Cohort 3:** from Vaccination 1 through 1 month after Vaccination 2 and from Vaccination 3 through 1 month after Vaccination 3 in this study.

Cohort 1

The 3 groups of participants in **Cohort 1** had gotten 2 primary doses of BNT before joining this study.

In this study, all groups got a booster as **Vaccination 1** (3rd shot). Group 2 also got **Vaccination 2** (4th shot).

Table 2. How many participants in Cohort 1 reported medical problems at any time from Vaccination 1 through 1 month after the last vaccination in this study?	
Group 1:	• 7 out of 216 participants (**3.2%**) from **Vaccination 1** of **BNT Omi** to 1 month after **Vaccination 1** of **BNT Omi**
Group 2:	• 12 out of 197 participants (**6.1%**) from **Vaccination 1** of **BNT Omi** to 1 month after **Vaccination 2** of **BNT Omi**
Group 2b:	• 4 out of 204 participants (**2.0%**) from **Vaccination 1** of **BNT** to 1 month after **Vaccination 1** of **BNT**

Cohort 2

The 2 groups of participants in **Cohort 2** had gotten 2 primary doses and 1 booster dose of BNT before joining this study.

In this study, participants in both groups got a booster as **Vaccination 1** (4th shot). Some participants also got **Vaccination 2** (**optional** 5th shot).

Table 3. How many participants in Cohort 2 reported medical problems within 1 month after each vaccination in this study?	
Group 3:	• 13 out of 315 participants (**4.1%**) from **Vaccination 1** of **BNT Omi** to 1 month after **Vaccination 1** of **BNT Omi** • 5 out of 213 participants (**2.3%**) from **Vaccination 2** of **BNT Omi** to 1 month after **Vaccination 2** of **BNT Omi**
Group 4:	• 12 out of 323 participants (**3.7%**) from **Vaccination 1** of **BNT** to 1 month after **Vaccination 1** of **BNT** • 9 out of 238 participants (**3.8%**) from **Vaccination 2** of **BNT Omi** to 1 month after from **Vaccination 2** of **BNT Omi**

Cohort 3

The group of participants in **Cohort 3** had not gotten any COVID-19 vaccine before joining this study.

In this study, participants in Group 5 got their 2 primary doses as **Vaccinations 1 and 2** (1st and 2nd shots). Some participants also got **Vaccination 3** (**optional** 3rd shot).

Table 4. How many participants in Cohort 3 reported medical problems at any time from Vaccination 1 through 1 month after Vaccination 2 and from Vaccination 3 through 1 month after Vaccination 3 in this study?

Group 5:	• 14 out of 210 participants (**6.7%**) from **Vaccination 1** of **BNT Omi** to 1 month after **Vaccination 2** of **BNT Omi** • 1 out of 172 participants (**0.6%**) from **Vaccination 3** of **BNT** to 1 month after **Vaccination 3** of **BNT**

Cohorts 1, 2, and 3:

Across the 1465 participants in the 3 cohorts, **swelling of the lymph nodes** was the most common medical problem reported within 1 month after each vaccination.

- This was reported by 6 participants in **Cohort 2** as shown below.

Group 3	Group 4
○ 1 out of 315 participants (**0.3%**) after their booster dose of **BNT Omi** (Vaccination 1)	○ 4 out of 323 participants (**1.2%**) after their booster dose of **BNT** (Vaccination 1) ○ 1 out of 238 participants (**0.4%**) after their booster dose of **BNT Omi** (Vaccination 2)

- For these 6 participants, swelling of the lymph nodes lasted 2 to 8 days, after which their lymph nodes returned to normal. Researchers thought these medical problems may have been related to BNT Omi or BNT.

No other medical problems were reported by more than 2 participants in any of the vaccine groups in the 3 cohorts from the first vaccination to 1 month after the last vaccination in this study.

During the study, from the first vaccination to 6 months after the last vaccination in this study:

- Across the 3 cohorts, 6 out of 1465 participants (**0.4%**) left the study early because of a medical problem they had during the study.
    - These 6 participants got BNT Omi during the study: 1 participant from Group 2, 3 participants from Group 3, and 2 participants from Group 5.
    - Researchers did not think these medical problems were related to BNT Omi.
- No participant reported Bell's palsy, myocarditis, or pericarditis from the first vaccination to 6 months after the last vaccination.

Bell's palsy is a temporary weakness or paralysis of the muscles on one side of the face.

Myocarditis is an inflammation (or swelling) of the heart muscle. This heart condition can make it harder for the heart to pump blood.

Pericarditis is an inflammation of the lining around the heart (called the pericardium).

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.

How many participants had a serious medical problem during the study?

Tables 5 to 7 below show that few participants across the 3 cohorts reported serious medical problems from Vaccination 1 through 6 months after the last vaccination in this study.

Cohort 1

The 3 groups of participants in **Cohort 1** had gotten 2 primary doses of BNT before joining this study.

In this study, all groups got a booster as **Vaccination 1** (3rd shot). Group 2 also got **Vaccination 2** (4th shot).

Table 5. How many participants in Cohort 1 reported serious medical problems at any time from Vaccination 1 through 6 months after the last vaccination in this study?	
Group 1:	• 2 out of 216 participants (**0.9%**) from **Vaccination 1** of **BNT Omi** to 6 months after **Vaccination 1** of **BNT Omi**
Group 2:	• 3 out of 197 participants (**1.5%**) from **Vaccination 1** of **BNT Omi** to 6 months after **Vaccination 2** of **BNT Omi**
Group 2b:	• 2 out of 204 participants (**1.0%**) from **Vaccination 1** of **BNT** to 6 months after **Vaccination 1** of **BNT**

Cohort 2

The 2 groups of participants in **Cohort 2** had gotten 2 primary doses and 1 booster dose of BNT before joining this study.

In this study, participants in both groups got a booster as **Vaccination 1** (4th shot). Some participants also got **Vaccination 2** (**optional** 5th shot).

Table 6. How many participants in Cohort 2 reported serious medical problems from Vaccination 1 through 6 months after the last vaccination in this study?	
Group 3:	• 5 out of 315 participants (**1.6%**) from **Vaccination 1** of **BNT Omi** up to **Vaccination 2** of **BNT Omi** for those receiving 2 shots, or after **Vaccination 1** of **BNT Omi** for those receiving only 1 shot • 1 out of 213 participants (**0.5%**) from **Vaccination 2** of **BNT Omi** to 6 months after **Vaccination 2** of **BNT Omi**
Group 4:	• 2 out of 323 participants (**0.6%**) from **Vaccination 1** of **BNT** up to **Vaccination 2** of **BNT Omi** for those receiving 2 shots, or after **Vaccination 1** of **BNT** for those receiving only 1 shot • 3 out of 238 participants (**1.3%**) from **Vaccination 2** of **BNT Omi** to 6 months after **Vaccination 2** of **BNT Omi**

Cohort 3

The group of participants in **Cohort 3** had not gotten any COVID-19 vaccine before joining this study.

In this study, participants in Group 5 got their 2 primary doses as **Vaccinations 1 and 2** (1st and 2nd shots). Some participants also got **Vaccination 3** (**optional** 3rd shot).

Table 7. How many participants in Cohort 3 reported serious medical problems at any time from Vaccination 1 through 6 months after the last vaccination in this study?	
Group 5:	• 8 out of 210 participants (**3.8%**) from **Vaccination 1** of **BNT Omi** to 6 months after **Vaccination 3** of **BNT**

Cohorts 1, 2, and 3:

Across 1465 participants in the 3 cohorts, the most common serious medical problem reported during the study was **dilated cardiomyopathy**. This is when the heart becomes enlarged and cannot pump blood properly.

- This was reported by 2 out of 197 participants (**1.0%**) in **Group 2** of **Cohort 1** who got 2 doses of **BNT Omi**.
- Researchers did not think these serious medical problems were related to BNT Omi.

During the study, no other serious medical problems were reported by more than 1 participant in any of the vaccine groups in **Cohorts 1, 2, or 3**.

Overall, 6 out of 1465 participants (**0.4%**) across the 3 cohorts died during the study.

- Of these 6 participants:
    - 2 were from **Group 2** (BNT Omi 2-dose group) and 1 was from **Group 2b** (BNT 1-dose group) of **Cohort 1**.
    - 1 was from **Group 3** (BNT Omi group) of **Cohort 2**.
    - 2 were from **Group 5** (BNT Omi group) of **Cohort 3**.
- They died from different medical conditions that were not related to BNT Omi or BNT.

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 **C4591031 Substudy D**

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

www.clinicaltrials.gov	Use the study identifier **NCT04955626**
www.clinicaltrialsregister.eu	Use the study identifier **2021-005197-25**

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 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!