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 E
Dates of Study:	22 February 2022 to 17 January 2023
Title of this Study:	A Study of a Booster Shot of Different BNT162b2 COVID-19 Vaccines in Healthy Adults Who Had Already Received 3 Doses of BNT162b2 COVID-19 Vaccine Before [Substudy E 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:	14 March 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 different strains or **variants**. Compared to the original COVID-19 virus, the **Delta** and **Omicron** strains spread more easily between people.

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

BNT162b2 (BNT) and BNT162b2 Omi (BNT Omi) are injectable vaccines that may help the body's immune system to defend against COVID-19.

BNT162b2 (also known as Comirnaty®) is called **BNT** in this summary. BNT is the original monovalent COVID-19 vaccine that can target the original 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.

A **monovalent** COVID-19 vaccine can target 1 strain of the COVID-19 virus.

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

BNT162b2 Omi is called **BNT Omi** in this summary. BNT Omi is an Omicron-modified form of the original BNT162b2 COVID-19 vaccine. BNT Omi is 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.

BNT162b2 plus BNT162b2 Omi is a combination of the BNT162b2 and the BNT162b2 Omi vaccines. This combination is called the bivalent **BNT plus BNT Omi** in this summary. The bivalent **BNT plus BNT Omi** was designed to target both the original and Omicron BA.1 strains of the COVID-19 virus.

A **bivalent** COVID-19 vaccine can target 2 strains of the COVID-19 virus.

This is the first time that **BNT Omi** was studied in humans. **BNT Omi** and the bivalent **BNT plus BNT Omi** are investigational vaccines, which means they were tested in this study to see if they are safe and how they work.

What was the purpose of this study?

The main purpose of this study was to learn if a booster shot of different BNT vaccines works well against COVID-19 caused by Omicron BA.1 and is safe in healthy adult participants. Participants had already received 3 doses of BNT before the start 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.

A person's immune protection from a disease can fade over time.

- A **booster shot** is the extra dose of a vaccine after receiving 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:

- **At 1 month after the booster shot, how much of an immune response did participants have against the Omicron BA.1 strain of the COVID-19 virus?**
- **How many participants had redness, swelling, or pain at the injection site within 7 days after the booster shot?**
- **How many participants had fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain within 7 days after the booster shot?**
- **How many participants had high troponin I levels after the booster shot?**
- **What medical problems did participants have during the study?**

Troponin I is a protein in the blood that can rise when there is a heart injury.

What happened during the study?

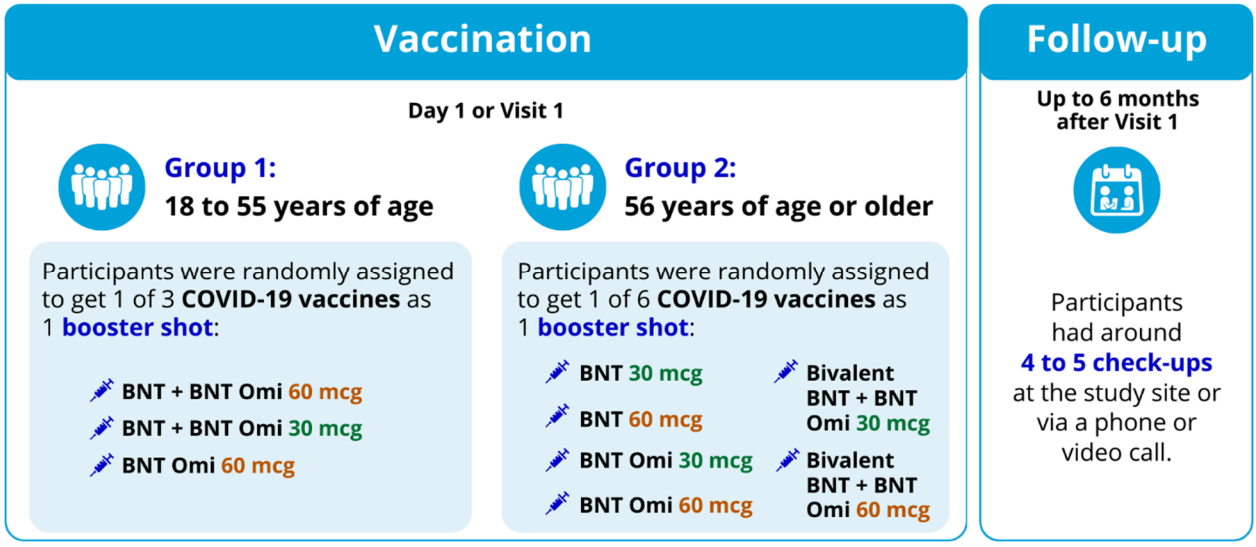
How was the study done?

This study had 2 main groups of participants:

- **Group 1:** 18 to 55 years of age
- **Group 2:** 56 years of age or older

Figure 1 below shows what happened during the study.

Figure 1. What happened in this study?



Throughout the study, each participant had blood samples taken and had health checks done.

At the start of the study, small groups of participants in each age group signed up to receive a vaccine. These small groups of participants were called the **Sentinel** (**S**) subgroups: **Group 1S** (18 to 55 years of age) **and Group 2S** (56 years of age or older).

Each participant was randomly assigned with equal chance to get 1 of the vaccines listed for their age group in Figure 1.

The healthcare staff who gave the injections and some of the researchers knew which booster shot the participants got. The participants did not know which booster shot they got.

An independent group of experts and some of the researchers checked on the safety of these participants first before letting more participants sign up.

Later in the study, more participants for each age group were allowed to sign up. These were participants in the **Expanded** (**E**) subgroups: **Group 1E** (18 to 55 years of age) and **Group 2E** (56 years of age or older).

Each participant was randomly assigned to get 1 of the vaccines listed for their age group in Figure 1.

- **Group 1E:** Each participant had 3 in 6 chances (50%) to get bivalent BNT plus BNT Omi 60 mcg, 1 in 6 chances (17%) to get bivalent BNT plus BNT Omi 30 mcg, and 2 in 6 chances (33%) to get BNT Omi 60 mcg.
- **Group 2E:** Each participant had an equal chance to get 1 of the vaccines listed for Group 2 in Figure 1.

Only the healthcare staff who gave the injections knew which booster shot the participants got. The study participants and researchers did not know which booster shot was given.

Where did this study take place?

This study ran at 46 locations in the United States.

When did this study take place?

It began on 22 February 2022 and ended on 17 January 2023.

Who participated in this study?

The study included healthy adults who had already received 3 doses of BNT before the start of this study.

- **Group 1:** Participants must have been from 18 to 55 years of age to join this group.
- **Group 2:** Participants must have been 56 years of age or older to join this group.

In total, 3020 participants started the study.

Group 1: Participants who joined this group were from 18 to 55 years of age.

Group 1S:

- 90 participants started the study and received a vaccine.
- 85 (94.4%) finished the study, and 5 (5.6%) did not.
- There were 44 men (48.9%) and 46 women (51.1%).

Group 1E:

- 964 participants started the study, and 962 (99.8%) received a vaccine.
- 903 (93.7%) finished the study, and 59 (6.1%) did not.
- There were 424 men (44.1%) and 538 women (55.9%).

Group 2: Participants who joined this group were from 56 to 87 years of age.

Group 2S:

- 120 participants started the study and received a vaccine.
- 115 (95.8%) finished the study, and 5 (4.2%) did not.
- There were 59 men (49.2%) and 61 women (50.8%).

Group 2E:

- 1846 participants started the study, and 1842 (99.8%) received a vaccine.
- 1781 (96.5%) finished the study, and 61 (3.3%) did not.
- 1838 participants received the planned dose of the vaccine, and 4 participants did not receive the planned dose due to medication errors.
- Out of the 1838 participants who received the planned dose of the vaccine, there were 909 men (49.5%) and 929 women (50.5%).

In Groups 1 and 2, the most common reasons as to why some participants did not finish the study were:

- There were protocol deviations in their participation. This means that the study requirements were not followed as planned.
- They left the study before it was over by their choice.
- They could not be contacted for follow-up.

How long did the study last?

Study participants were in the study for around 6 months. The entire study took around 11 months to complete.

When the study ended in January 2023, the Sponsor agent reviewed 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?

At 1 month after the booster shot, how much of an immune response did participants have against the Omicron BA.1 strain of the COVID-19 virus?

This was tested on **Group 2E** participants **56 years of age or older** who did not have COVID-19 infection up to 1 month after getting their booster shot in this study.

Researchers checked the results of participants who got a booster shot of 1 of the vaccines listed below:

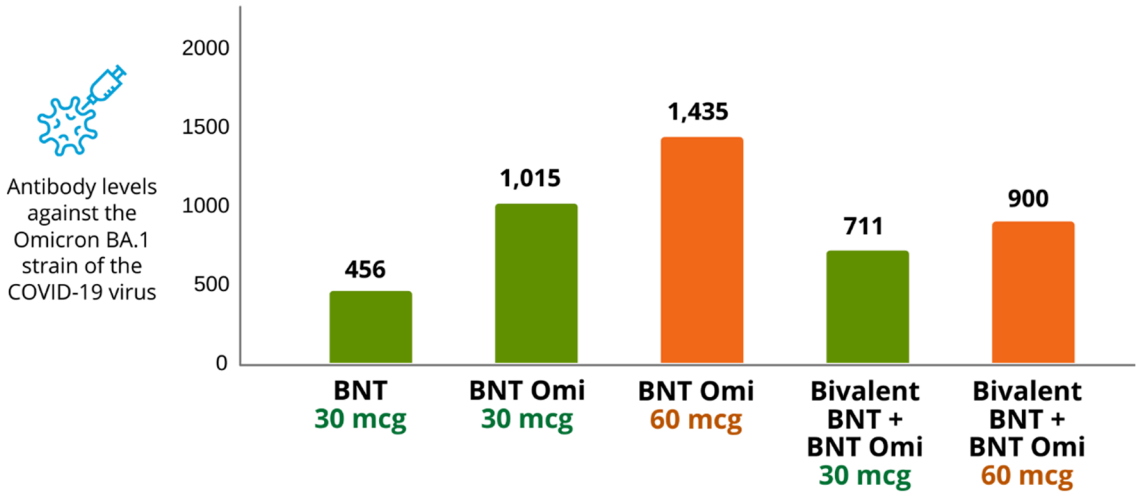
- BNT 30 mcg
- BNT Omi 60 mcg
- BNT Omi 30 mcg
- Bivalent BNT plus BNT Omi 60 mcg
- Bivalent BNT plus BNT Omi 30 mcg

Researchers wanted to know if the **Omicron-modified vaccines** worked better than **BNT 30 mcg** based on the amount of antibodies against the **Omicron BA.1** strain of the COVID-19 virus.

- Researchers measured the antibody levels (against the **Omicron BA.1** strain of the COVID-19 virus) before and 1 month after the booster shot.
- Then, researchers compared the results of participants who got an Omicron-modified vaccine to the results of participants who got BNT 30 mcg.

Figure 2 below shows the antibody levels 1 month after the booster shot.

Figure 2. At 1 month after the booster shot, how much antibodies were produced against the Omicron BA.1 strain of the COVID-19 virus?



Compared to those who got a booster shot of **BNT 30 mcg**, participants who got a booster shot of 1 of the vaccines listed below produced higher antibody levels against the Omicron BA.1 strain of the COVID-19 virus.

- **BNT Omi 60 mcg**
- Bivalent **BNT plus BNT Omi 30 mcg**
- Bivalent **BNT plus BNT Omi 60 mcg**

The study results mean that a booster shot of any of the vaccines listed above may protect against the Omicron BA.1 strain of the COVID-19 virus better than a booster shot of BNT 30 mcg.

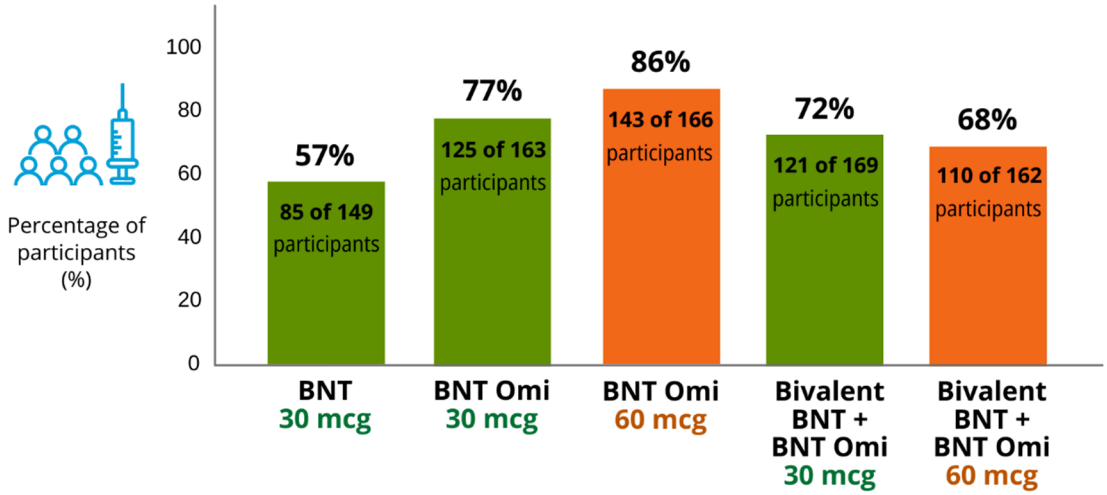
Compared to those who got a booster shot of **BNT 30 mcg**, participants who got booster shot of **BNT Omi 30 mcg** produced higher antibody levels against the COVID-19 virus. But, a formal statistical comparison test could not be done to find out the significance of these results because of rules in the study.

Researchers also wanted to know if the **Omicron-modified vaccines** worked as well as **BNT 30 mcg** based on how many participants had antibodies that were at least 4 times higher at 1 month after the booster shot from before the booster shot.

- Researchers checked how many participants had antibodies against the **Omicron BA.1** strain of the COVID-19 virus that were at least 4 times higher at 1 month after the booster shot from before the booster shot.
- Then, researchers compared the results of participants who got an Omicron-modified vaccine to the results of participants who got BNT 30 mcg.

Figure 3 below shows how many participants had antibodies that were at least 4 times higher at 1 month after the booster shot from before the booster shot.

Figure 3. How many participants had antibodies (against the Omicron BA.1 strain of the COVID-19 virus) that were at least 4 times higher at 1 month after the booster shot from before the booster shot?



Compared to those who got a booster shot of **BNT 30 mcg**, more participants who got a booster shot of 1 of the vaccines listed below had antibodies (against the Omicron BA.1 strain of the COVID-19 virus) that were at least 4 times higher at 1 month after the booster shot from before the booster shot.

- **BNT Omi 60 mcg**
- Bivalent **BNT plus BNT Omi 30 mcg**
- Bivalent **BNT plus BNT Omi 60 mcg**

The study results mean that a booster shot of any of the vaccines listed above may protect against the Omicron BA.1 strain of the COVID-19 virus as well as a booster shot of BNT 30 mcg.

Compared to those who got a booster shot of **BNT 30 mcg**, more participants who got a booster shot of **BNT Omi 30 mcg** had antibodies (against the Omicron BA.1 strain of the COVID-19 virus) that were at least 4 times higher at 1 month after the booster shot from before the booster shot. But, a formal statistical comparison test could not be done to find out the significance of these results because of rules in the study.

Overall, the study results suggest that, for healthy adults 56 years of age or older who had already received 3 doses of BNT COVID-19 vaccine before:

A booster shot of an Omicron-modified BNT vaccine may offer better protection against COVID-19 infection caused by Omicron BA.1 compared to a booster shot of the original BNT 30 mcg.

This study also checked the immune response against the original and Omicron BA.1 strains of the COVID-19 virus after different booster shots. This was studied in the following participants:

- Participants **56 years of age or older** after their booster shot of BNT 30 mcg or 60 mcg, BNT Omi 30 mcg or 60 mcg, or bivalent BNT plus BNT Omi 30 mcg or 60 mcg.
- Participants **18 to 55 years of age** after their booster shot of BNT Omi 60 mcg or bivalent BNT plus BNT Omi 30 mcg or 60 mcg.

These results are not included in this summary because these were not the main focus of the study.

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

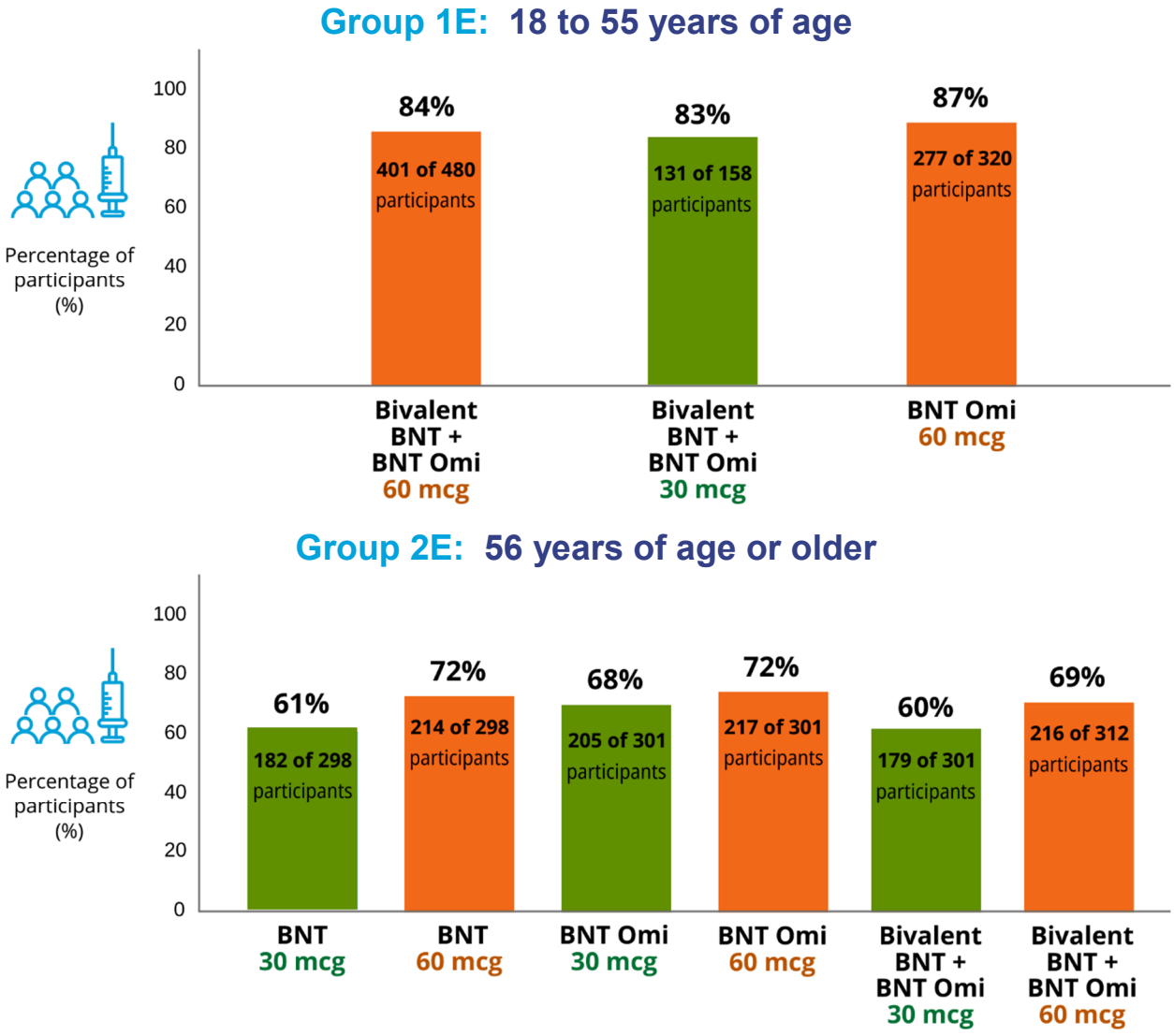
To answer this question, researchers checked the electronic diary records of participants.

Figure 4 on the next page shows that most participants in **Groups 1E and 2E** had at least 1 injection site reaction of any redness, swelling, or pain within 7 days after the booster shot.

- **Group 1E: 83%** to **87%** of participants
- **Group 2E: 60%** to **72%** of participants

Most of the injection site reactions were mild or moderate in severity and lasted about 1 to 3 days. The most common reaction was pain at the injection site.

Figure 4. How many participants in Groups 1E and 2E had at least 1 injection site reaction of any redness, swelling, or pain at the injection site within 7 days after the booster shot?



The results of participants in the Sentinel groups (**Groups 1S and 2S**) were similar to those shown above for the respective Expanded groups (**Groups 1E and 2E**).

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

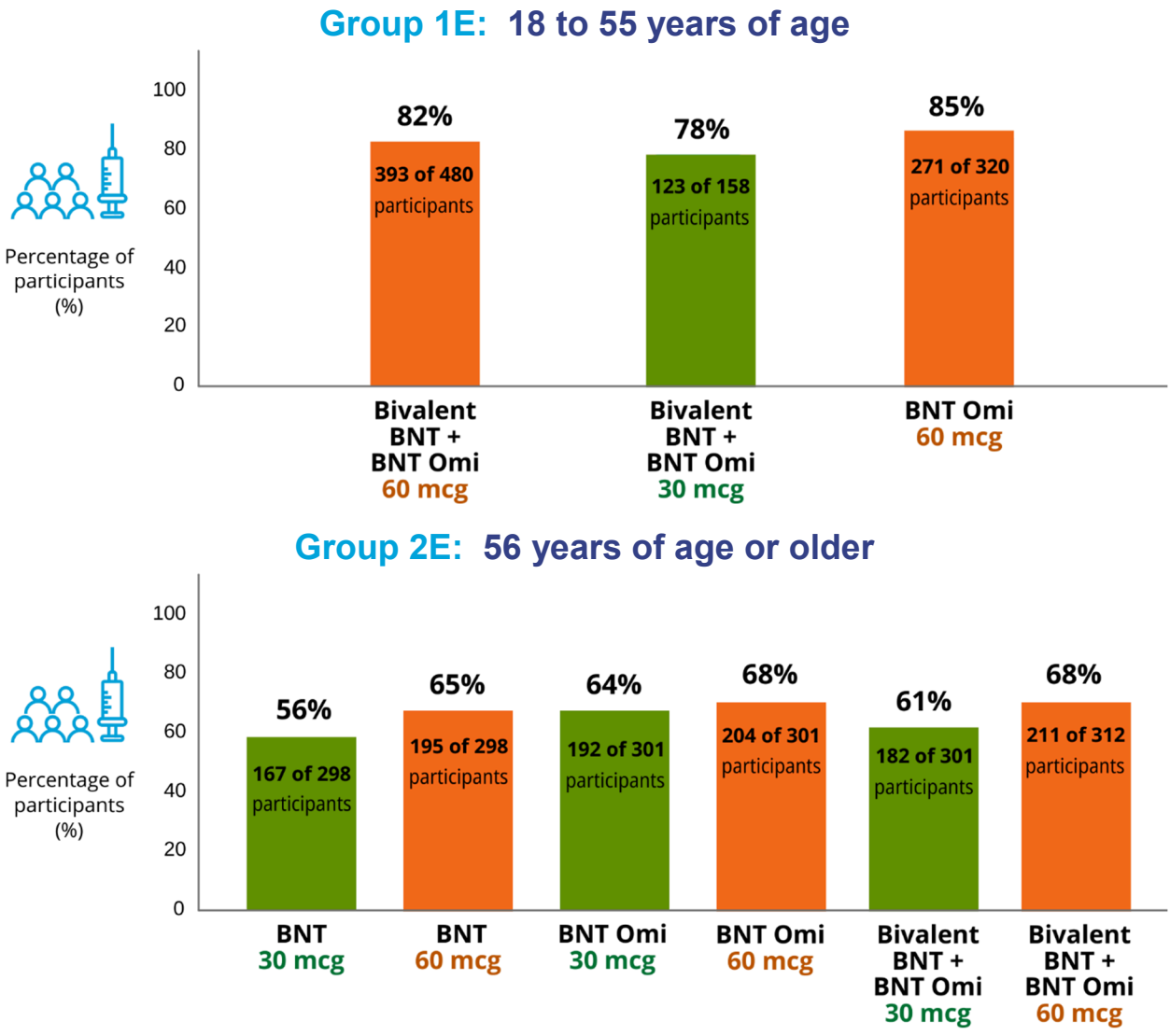
To answer this question, researchers checked the electronic diary records of participants.

Figure 5 on the next page shows that most participants in **Groups 1E and 2E** had at least 1 symptom of any fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain within 7 days after the booster shot.

- **Group 1E: 78%** to **85%** of participants
- **Group 2E: 56%** to **68%** of participants

Most of these symptoms were mild or moderate in severity and lasted about 1 to 2 days. The most common symptom was tiredness.

Figure 5. How many participants in Groups 1E and 2E had at least 1 symptom of any fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain within 7 days after the booster shot?



The results of participants in the Sentinel groups (**Groups 1S and 2S**) were generally similar to those shown above for the respective Expanded groups (**Groups 1E and 2E**).

How many participants had high troponin I levels after the booster shot?

Troponin I is a protein in the blood that can rise when there is a heart injury.

This was tested on **Group 1S** participants **18 to 55 years of age**.

Researchers wanted to find out if participants had high troponin I levels 3 days after the booster shot. Troponin I levels were measured before and after the booster shot.

No participant in **Group 1S** had high troponin I levels before or 3 days after they got a booster shot of 1 of the vaccines listed below:

- Bivalent BNT plus BNT Omi 60 mcg.
- Bivalent BNT plus BNT Omi 30 mcg.
- BNT Omi 60 mcg.

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.

Overall, 3 participants left the study early because of medical problems, which researchers believe were not related to the study vaccine. These participants were from:

- **Group 2S:** 1 participant who got BNT 30 mcg.
- **Group 2E:** 1 participant who got BNT Omi 30 mcg, and 1 participant who got BNT Omi 60 mcg.

How many participants had a medical problem within 1 month after the booster shot?

Figure 6 on the next page shows that few participants in **Groups 1E and 2E** had at least 1 medical problem within 1 month after the booster shot.

- **Group 1E: 6%** to **9%** of participants
- **Group 2E: 4%** to **10%** of participants

Figure 6. How many participants in Groups 1E and 2E had at least 1 medical problem within 1 month after the booster shot?

Group 1E: 18 to 55 years of age

Bivalent BNT plus BNT Omi 60 mcg	Bivalent BNT plus BNT Omi 30 mcg	BNT Omi 60 mcg
37 of 482 participants (**8%**)	10 of 159 participants (**6%**)	30 of 321 participants (**9%**)

Group 2E: 56 years of age or older

BNT 30 mcg	BNT 60 mcg	BNT Omi 30 mcg
18 of 305 participants (**6%**)	20 of 302 participants (**7%**)	26 of 307 participants (**9%**)

BNT Omi 60 mcg	Bivalent BNT plus BNT Omi 30 mcg	Bivalent BNT plus BNT Omi 60 mcg
11 of 306 participants (**4%**)	19 of 305 participants (**6%**)	33 of 316 participants (**10%**)

The results of participants in the Sentinel groups (**Groups 1S and 2S**) were similar to those shown above for the respective Expanded groups (**Groups 1E and 2E**).

Group 1E:

Table 1 on the next page lists the most common medical problems reported within 1 month after the booster shot. These medical problems were reported by 3 or more participants in at least 1 vaccine group.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists the medical problems that were commonly reported within 1 month after the booster shot. All medical problems reported by 3 or more participants in any vaccine group are listed.
- The **2nd** column tells how many of the 482 participants who got the bivalent BNT plus BNT Omi 60 mcg reported each medical problem. Next to this number is the percentage of the 482 participants in this group who reported the medical problem.
- The **3rd** column tells how many of the 159 participants who got the bivalent BNT plus BNT Omi 30 mcg reported each medical problem. Next to this number is the percentage of the 159 participants in this group who reported the medical problem.
- The **4th** column tells how many of the 321 participants who got BNT Omi 60 mcg reported each medical problem. Next to this number is the percentage of the 321 participants in this group who reported the medical problem.
- For example, using these instructions, you can see how many participants reported swollen lymph nodes.
    - 5 of 482 participants (1.0%) in the bivalent BNT plus BNT Omi 60 mcg group.
    - 3 of 159 participants (1.9%) in the bivalent BNT plus BNT Omi 30 mcg group.
    - 2 of 321 participants (0.6%) in the BNT Omi 60 mcg group.

Table 1. Most common medical problems reported within 1 month after the booster shot in Group 1E			
Medical Problem	**Bivalent BNT plus BNT Omi 60 mcg (482 participants)**	**Bivalent BNT plus BNT Omi 30 mcg (159 Participants)**	**BNT Omi 60 mcg (321 Participants)**
Swollen lymph nodes	5 of 482 participants (1.0%)	3 of 159 participants (1.9%)	2 of 321 participants (0.6%)
Nausea	0 of 482 participants (0%)	0 of 159 participants (0%)	3 of 321 participants (0.9%)
Pain at injection site	2 of 482 participants (0.4%)	0 of 159 participants (0%)	4 of 321 participants (1.2%)
Tiredness	2 of 482 participants (0.4%)	0 of 159 participants (0%)	3 of 321 participants (0.9%)

Group 2E:

Table 2 on the next page lists the most common medical problems reported within 1 month after the booster shot. These medical problems were reported by 3 or more participants in at least 1 vaccine group.

Instructions on how to read Table 2 are similar to those for Table 1.

Table 2. Most common medical problems reported within 1 month after the booster shot in Group 2E

Medical Problem	BNT 30 mcg 305 Participants	BNT 60 mcg 302 Participants	BNT Omi 30 mcg 307 Participants	BNT Omi 60 mcg 306 Participants	Bivalent BNT plus BNT Omi 30 mcg 305 Participants	Bivalent BNT plus BNT Omi 60 mcg 316 participants
Swollen lymph nodes	1 of 305 participants (0.3%)	3 of 302 participants (1.0%)	1 of 307 participants (0.3%)	0 of 306 participants (0%)	1 of 305 participants (0.3%)	2 of 316 participants (0.6%)
Diarrhea	0 of 305 participants (0%)	0 of 302 participants (0%)	3 of 307 participants (1.0%)	0 of 306 participants (0%)	0 of 305 participants (0%)	0 of 316 participants (0%)
Pain at injection site	0 of 305 participants (0%)	4 of 302 participants (1.3%)	3 of 307 participants (1.0%)	1 of 306 participants (0.3%)	2 of 305 participants (0.7%)	2 of 316 participants (0.6%)
Tiredness	0 of 305 participants (0%)	4 of 302 participants (1.3%)	1 of 307 participants (0.3%)	1 of 306 participants (0.3%)	2 of 305 participants (0.7%)	2 of 316 participants (0.6%)
Muscle pain	0 of 305 participants (0%)	0 of 302 participants (0%)	1 of 307 participants (0.3%)	0 of 306 participants (0%)	3 of 305 participants (1.0%)	2 of 316 participants (0.6%)
Headache	0 of 305 participants (0%)	2 of 302 participants (0.7%)	2 of 307 participants (0.7%)	1 of 306 participants (0.3%)	4 of 305 participants (1.3%)	2 of 316 participants (0.6%)
Dizziness	1 of 305 participants (0.3%)	1 of 302 participants (0.3%)	0 of 307 participants (0%)	1 of 306 participants (0.3%)	3 of 305 participants (1.0%)	0 of 316 participants (0%)
Skin rash	0 of 305 participants (0%)	1 of 302 participants (0.3%)	0 of 307 participants (0%)	0 of 306 participants (0%)	0 of 305 participants (0%)	3 of 316 participants (0.9%)

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 within 6 months after the booster shot?

Figure 7 on the next page shows that few participants in **Groups 1E and 2E** had at least 1 serious medical problem within 6 months after the booster shot.

- **Group 1E: 0.6%** to **1.3%** of participants
- **Group 2E: 0.7%** to **3.9%** of participants

Groups 1E and 2E:

The most common serious medical problems reported within 6 months after the booster shot are listed below. These medical problems were reported by 2 or more participants in at least 1 vaccine group.

- **Group 1E:** No specific serious medical problem was reported by more than 1 participant in any of the vaccine groups.
- **Group 2E:**
    - 3 participants who got bivalent BNT plus BNT Omi 60 mcg reported an irregular and rapid heart rhythm.
    - 2 participants who got BNT 30 mcg reported a lung infection.

Researchers believe that 1 serious medical problem reported by a participant may be related to the study vaccine. This serious medical problem was dehydration. It was reported by 1 participant in Group 2E who got BNT Omi 30 mcg.

Researchers do not believe that any of the other serious medical problems reported by participants were related to the study vaccines.

Figure 7. How many participants in Groups 1E and 2E had at least 1 serious medical problem within 6 months after the booster shot?

Group 1E: 18 to 55 years of age

Bivalent BNT plus BNT Omi 60 mcg	Bivalent BNT plus BNT Omi 30 mcg	BNT Omi 60 mcg
3 of 482 participants (**0.6%**)	2 of 159 participants (**1.3%**)	3 of 321 participants (**0.9%**)

Group 2E: 56 years of age or older

BNT 30 mcg	BNT 60 mcg	BNT Omi 30 mcg
6 of 305 participants (**2%**)	2 of 302 participants (**0.7%**)	12 of 307 participants (**3.9%**)

BNT Omi 60 mcg	Bivalent BNT plus BNT Omi 30 mcg	Bivalent BNT plus BNT Omi 60 mcg
4 of 307 participants (**1.3%**)	4 of 304 participants (**1.3%**)	6 of 313 participants (**1.9%**)

Groups 1S and 2S:

No participant in **Group 1S** had a serious medical problem. The list below shows that 2 participants in **Group 2S** had a serious medical problem during the study:

- 1 of 20 participants (5.0%) in the BNT 30 mcg group had a brain tumor.
- 1 of 20 participants (5.0%) in the bivalent BNT plus BNT Omi 60 mcg had heart and lung failure.

Researchers do not believe that either of the serious medical problems listed above were related to the study vaccine.

Overall:

In total, 4 participants died during the study. These participants were from:

- **Group 2S:** 1 participant died from heart disease. This participant was from the bivalent BNT plus BNT Omi 60 mcg group.
- **Group 2E:**
  - 1 participant died from septic shock, or a serious reaction to an infection. This participant was from the BNT Omi 30 mcg group.
  - 1 participant died from a cardiac arrest, or the heart suddenly stopped beating. This participant was from the bivalent BNT plus BNT Omi 60 mcg group.
  - 1 participant died from an unknown cause. This participant was from the BNT Omi 60 mcg group.

Researchers do not believe that any of these serious medical problems that led to death were related to the study vaccine.

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 E**

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!