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:	C4591030
Dates of Study:	20 April 2022 to 05 October 2022
Title of this Study:	A Study of the BNT162b2 COVID-19 Vaccine Given at the Same Time as a Flu Vaccine in Adults [A Phase 3, Randomized, Observer-Blind Trial to Evaluate the Safety and Immunogenicity of BNT162b2 When Coadministered With Seasonal Inactivated Influenza Vaccine (SIIV) in Adults 18 Through 64 Years of Age]
Date of this Report:	03 October 2023

– 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.

What is BNT162b2 COVID-19 vaccine?

BNT162b2 (also called Comirnaty®) is an injectable vaccine that can help the body's immune system to defend against 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.

BNT162b2 is the original COVID-19 vaccine that targets the original strain of the COVID-19 virus. This COVID-19 vaccine had been approved for use in adults in Australia and New Zealand at the time of this study.

The **BNT162b2 vaccine** is called the "**COVID-19 vaccine**" in this summary.

What was the purpose of this study?

The main purposes of this study were:

- To learn about the safety of the **COVID-19 vaccine** (booster shot) and a **flu vaccine** when given at the same time and when given about 1 month apart.
- To learn if the immune responses produced by the **COVID-19 vaccine** (booster shot) and a **flu vaccine** when given at the same time were similar to when the vaccines were given about 1 month apart.

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

Researchers wanted to know more about these 2 vaccines being given at the same time because the recommended period for people to get the COVID-19 vaccine booster shot can happen during the recommended flu vaccination period.

Flu (also called "influenza") is caused by influenza viruses. People with flu can have runny nose, sore throat, cough, body aches, or tiredness.

A flu vaccine can protect against a few of the most common influenza viruses, which can change from year to year. Health experts from different countries recommend people to get a flu vaccine every year.

The participants got a **flu vaccine** called Afluria Quad in this study. This flu vaccine is an injectable shot that contains inactivated influenza virus.

The **Afluria Quad vaccine** is called the "**flu vaccine**" in this summary.

In this study, participants got the COVID-19 vaccine and flu vaccine at the same time or about 1 month apart.

Researchers wanted to know:

- **Did participants who got the COVID-19 vaccine and flu vaccine at the same time have immune responses against the COVID-19 virus that are similar to those who got the COVID-19 vaccine on its own about 1 month after the flu vaccine?**
- **Did participants who got the COVID-19 vaccine and flu vaccine at the same time have immune responses against the flu virus that are similar to those who got the flu vaccine on its own?**
- **How many participants had redness, swelling, or pain at the injection site within 7 days after each vaccination?**
- **How many participants had fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain 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 within 1 month after each vaccination?**

What happened during the study?

How was the study done?

The study doctor checked on the participants to make sure they met the requirements to join the study. This was known as the screening period.

Before this study:

Participants had already gotten 3 doses of 30 micrograms (also called mcg) of BNT162b2 COVID-19 vaccine as per the recommended dosing schedule. They must have gotten their third dose (booster shot) of BNT162b2 COVID-19 vaccine at least 90 days before Visit 1 of this study.

In this study:

Researchers tested a fourth dose (booster shot) of the BNT162b2 **COVID-19 vaccine** 30 mcg in 2 groups of study participants 18 to 64 years old. Participants in both groups also got a **flu vaccine**.

Participants got a total of 3 injections into the muscle across 2 visits during the study. The vaccine(s) that participants got at each visit depended on which of the 2 different groups they were assigned to by chance alone (or "randomized") at Visit 1:

Group A

COVID-19 vaccine and flu vaccine were given at the same time:

- **Visit 1:** **COVID-19 vaccine** in the left arm and **flu vaccine** in the right arm
- **Visit 2:** **Placebo** in the left arm

Group B

COVID-19 vaccine and flu vaccine were given about 1 month apart:

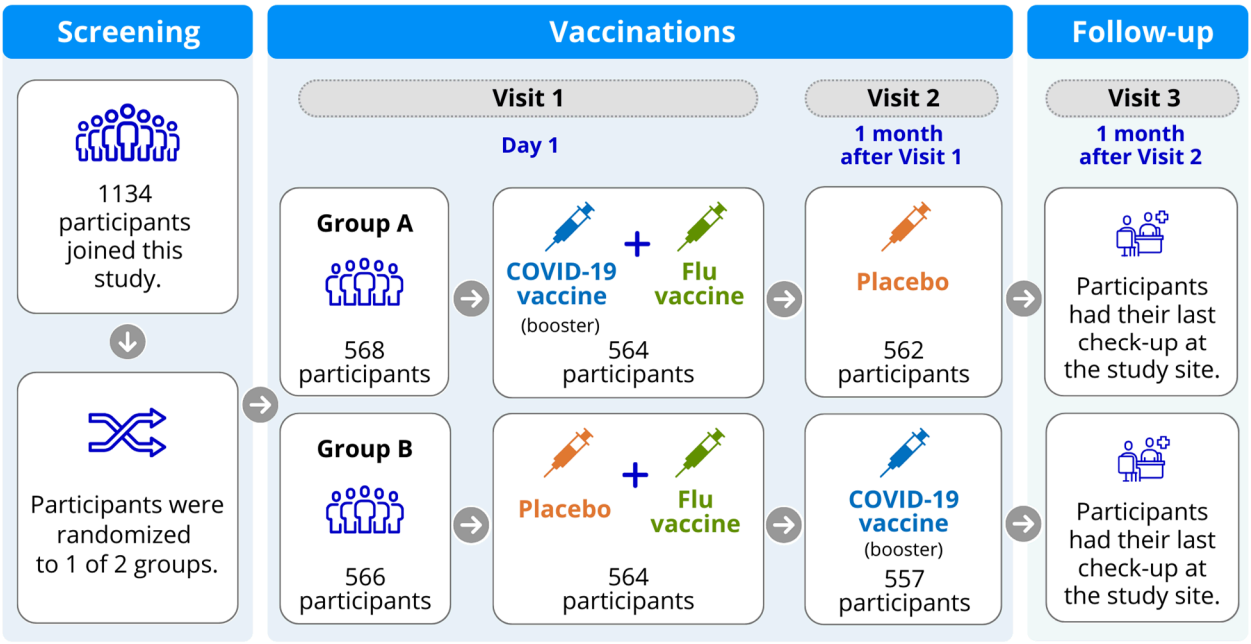
- **Visit 1:** **Placebo** in the left arm and **flu vaccine** in the right arm
- **Visit 2:** **COVID-19 vaccine** in the left arm

A **placebo** does not have any active ingredients in it.

Researchers compared the results of Group A participants to those of Group B participants.

Figure 1 below shows what happened during the study.

Figure 1. What happened in this study?



Out of the 1134 participants, 6 did not get vaccinated in the study.

At Visits 1, 2, and 3:

- Participants had blood samples taken and had health checks.
- The study doctor or team asked participants questions about their health.

This study was “observer-blinded”. This means that only the healthcare staff who gave the injections knew which participants got the COVID-19 vaccine and flu vaccine at the same time and who got the vaccines about 1 month apart. The study participants and other researchers did not know which order the participants got the vaccines.

Where did this study take place?

This study ran at 26 locations in 2 countries: Australia and New Zealand.

When did this study take place?

It began on 20 April 2022 and ended on 05 October 2022.

Who participated in this study?

The study included participants who:

- Were assessed as healthy by the study doctors.
- Were 18 to 64 years old at Visit 1 of the study.
- Had gotten 3 doses of the BNT162b2 COVID-19 vaccine before joining this study, with the third dose (booster shot) of the vaccine given at least 90 days before Visit 1 of this study.
- Had not gotten any flu vaccine in the 6 months before joining this study.
- Were not allergic to any of the ingredients in the study vaccines.
- Did not have COVID-19 in the 28 days before Visit 1.

In total, 1134 participants joined this study. Six (6) participants did not get a study vaccine. Overall, 1128 participants got at least 1 study vaccine:

- A total of 411 men (36%) and 717 women (64%) participated.
- 814 participants (72%) were between the ages of 18 and 49 years, and 314 participants (28%) were between the ages of 50 to 64 years.

Of the 1128 participants who got at least 1 study vaccine:

- 1115 (98%) finished the study.
- 13 (1%) did not finish the study. The most common reason was they left before the study was over by their choice after Visit 1 or 2.

How long did the study last?

Study participants were in the study for about 2 months. The entire study took about 5 months to complete.

When the study ended in October 2022, 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 who got the COVID-19 vaccine and flu vaccine at the same time have immune responses against the COVID-19 virus that are similar to those who got the COVID-19 vaccine on its own about 1 month after the flu vaccine?

Researchers measured the amount of antibodies against the **COVID-19 virus** 1 month after participants got the COVID-19 vaccine:

Group A	Group B
COVID-19 vaccine and **flu vaccine** given at the same time at Visit 1	**COVID-19 vaccine** given at Visit 2, which was about 1 month after the **flu vaccine** was given at Visit 1

One month after getting the COVID-19 vaccine, **Group A** participants' **COVID-19 antibody levels** were within a range considered similar to those seen in **Group B** participants.

These results mean that:

> Participants who got the COVID-19 vaccine and flu vaccine at the same time had **immune responses against the COVID-19 virus** that were similar to those who got the COVID-19 vaccine on its own about 1 month after the flu vaccine.

Did participants who got the COVID-19 vaccine and flu vaccine at the same time have immune responses against the flu virus that are similar to those who got the flu vaccine on its own?

Researchers measured the amount of antibodies against the **flu virus** 1 month after participants got the flu vaccine:

Group A	Group B
COVID-19 vaccine and **flu vaccine** given at the same time at Visit 1	**Placebo** and **flu vaccine** given at the same time at Visit 1

A **placebo** does not have any active ingredients in it.

One month after getting the flu vaccine, **Group A** participants' **flu antibody levels** were within a range considered similar to those seen in **Group B** participants.

These results mean that:

Participants who got the COVID-19 vaccine and flu vaccine at the same time had **immune responses against the flu virus** that were similar to those who got the flu vaccine on its own.

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

Researchers checked the records of participants who had electronic diary entries within 7 days after each vaccination. Participants recorded on an electronic diary or app on their phone if they had any **injection site reactions** on their left arm where the COVID-19 vaccine or placebo was injected.

The following participants had at least 1 injection site reaction (any redness, swelling, or pain) to the COVID-19 vaccine or placebo within 7 days after each vaccination:

Group A:

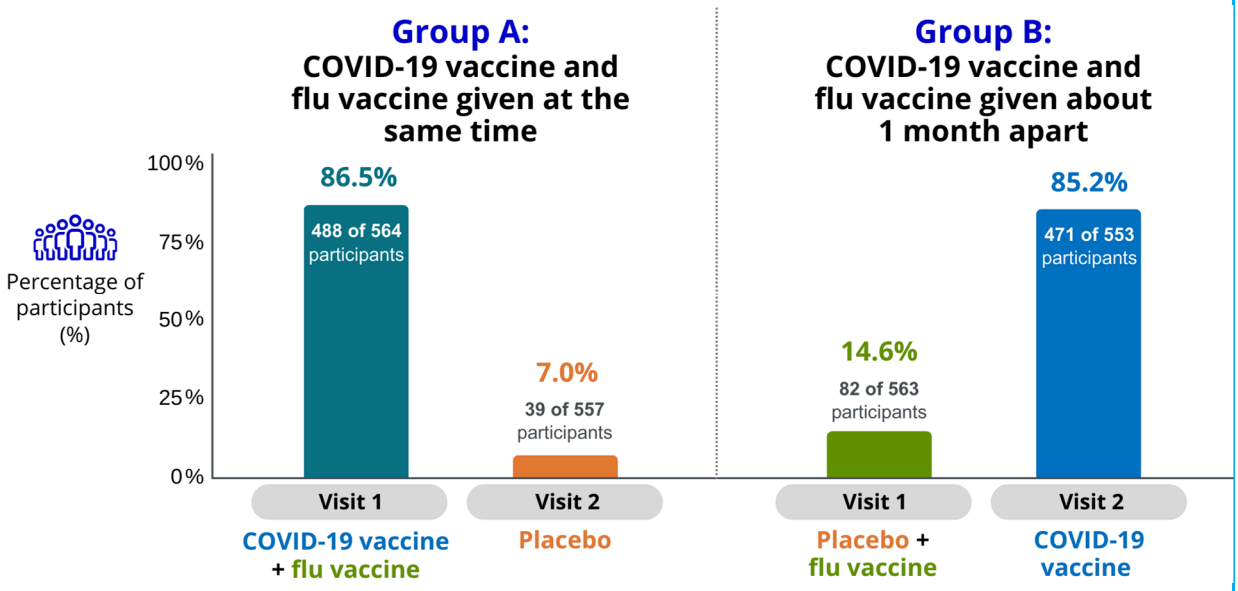
- 488 of 564 participants (86.5%) after they got the COVID-19 vaccine plus flu vaccine.
- 39 of 557 participants (7.0%) after they got a placebo.

Group B:

- 82 of 563 participants (14.6%) after they got a placebo plus flu vaccine.
- 471 of 553 participants (85.2%) after they got the COVID-19 vaccine.

Figure 2 below shows these results.

Figure 2. How many participants had any redness, swelling, or pain at the COVID-19 vaccine or placebo injection site within 7 days after each vaccination?



Most of these injection site reactions to the COVID-19 vaccine or placebo were mild or moderate in severity and went away after about 1 to 3 days. The most common injection site reaction to the COVID-19 vaccine or placebo was pain.

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

Researchers checked the records of participants who had electronic diary entries within 7 days after each vaccination.

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

Group A:

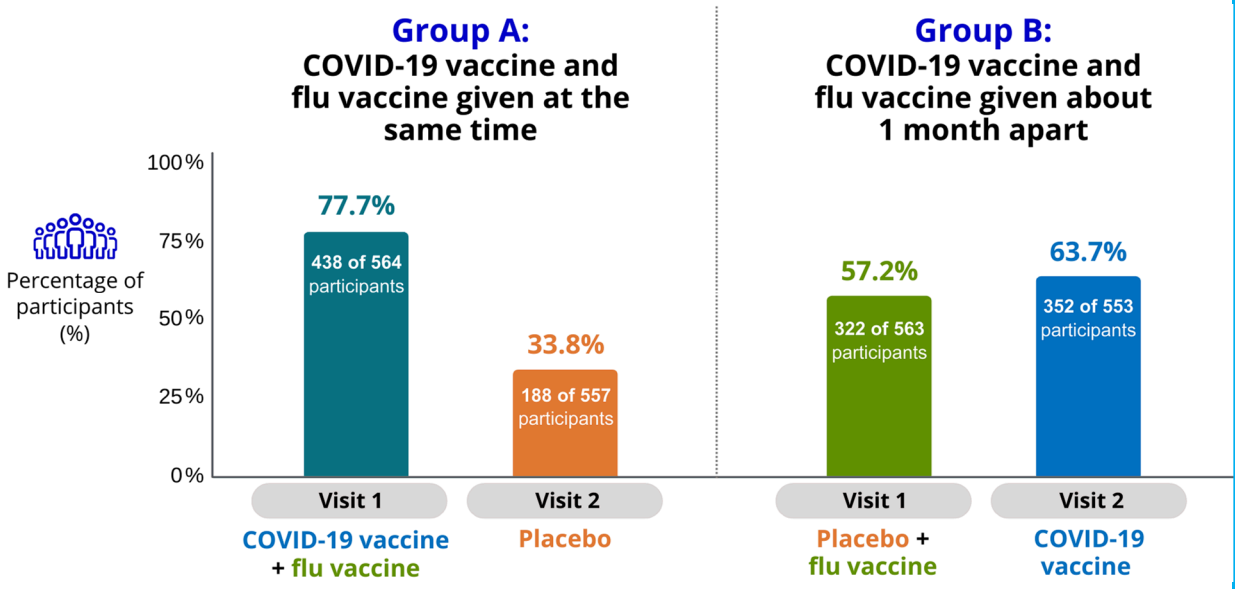
- 438 of 564 participants (77.7%) after they got the COVID-19 vaccine plus flu vaccine.
- 188 of 557 participants (33.8%) after they got a placebo.

Group B:

- 322 of 563 participants (57.2%) after they got a placebo plus flu vaccine.
- 352 of 553 participants (63.7%) after they got the COVID-19 vaccine.

Figure 3 below shows these results.

Figure 3. How many participants had any fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain within 7 days after each vaccination?



Most of these symptoms were mild or moderate in severity and went away after about 1 to 2 days. The most common symptom after each vaccination was tiredness.

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.

In total, 2 participants left the study early because of medical problem(s) they had during the study.

How many participants had a medical problem within 1 month after each vaccination?

The following participants had at least 1 medical problem within 1 month after each vaccination:

Group A:

- 178 of 564 participants (31.6%) after they got the COVID-19 vaccine plus flu vaccine.
- 163 of 562 participants (29.0%) after they got a placebo.

Group B:

- 172 of 564 participants (30.5%) after they got a placebo plus flu vaccine.
- 140 of 557 participants (25.1%) after they got the COVID-19 vaccine.

Figure 4 below shows these results.

Figure 4. How many participants had a medical problem within 1 month after each vaccination?

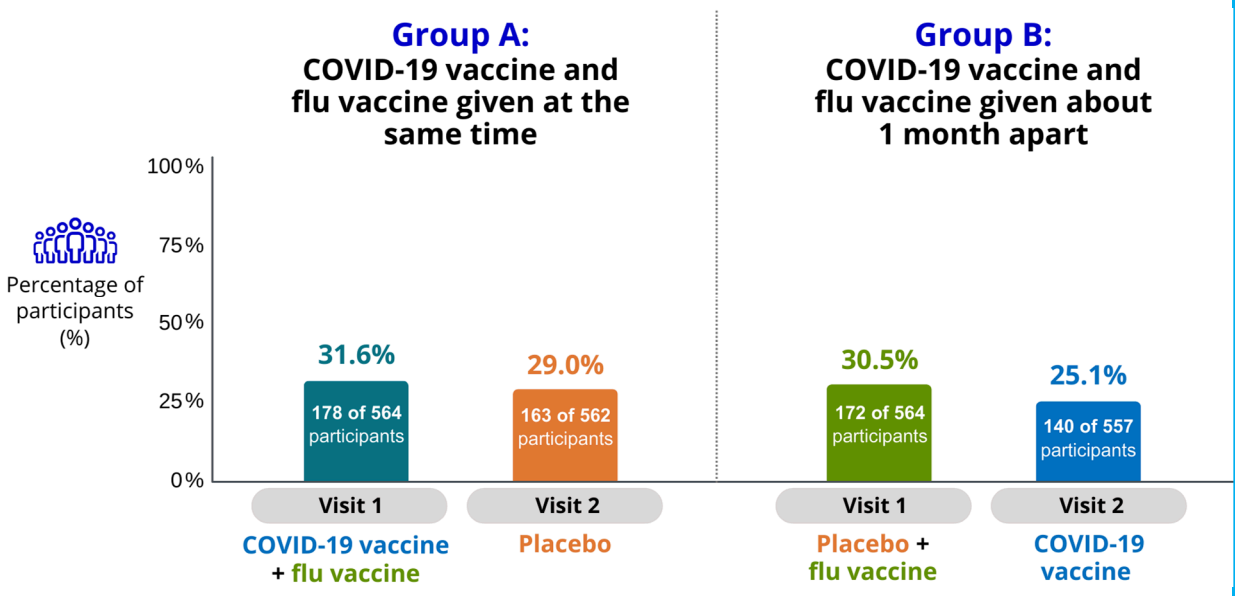


Table 1 lists the most common medical problems that happened within 1 month after each vaccination in Group A and Group B. These medical problems were reported by more than 5 participants (0.9%) after vaccination at either Visit 1 or 2.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of the table lists the most common medical problems reported within 1 month after each vaccination in Group A and Group B. The table lists all medical problems seen in more than 5 participants (0.9%) after vaccination at either Visit 1 or 2.

- The **2nd** column shows how many of the 564 participants in Group A reported each medical problem after getting the COVID-19 vaccine plus flu vaccine. Next to this number is the percentage of the 564 participants in this group who reported the medical problem.
- The **3rd** column shows how many of the 562 participants in Group A reported each medical problem after getting a placebo. Next to this number is the percentage of the 562 participants in this group who reported the medical problem.
- The **4th** and **5th** columns show how many participants in Group B reported each medical problem after each vaccination. The instructions for these columns in Group B are the same as those written for the 2nd and 3rd columns in Group A. But, the order that Group B participants got the vaccines are different from that of Group A participants.
- For example, you can see in Table 1 the following participants who had flu-like illness:
  - 9 out of the 564 participants (1.6%) in Group A after getting the COVID-19 vaccine plus flu vaccine at Visit 1.
  - 9 out of the 562 participants (1.6%) in Group A after getting a placebo at Visit 2.
  - 12 out of the 564 participants (2.1%) in Group B after getting a placebo plus flu vaccine at Visit 1.
  - 7 out of the 557 participants (1.3%) in Group B after getting the COVID-19 vaccine at Visit 2.

Table 1. Commonly reported medical problems within 1 month after each vaccination

Medical Problem	Group A: COVID-19 Vaccine and Flu Vaccine Given at the Same Time		Group B: COVID-19 Vaccine and Flu Vaccine Given About 1 Month Apart	
	Visit 1: COVID-19 Vaccine Plus Flu Vaccine (564 Participants)	Visit 2: Placebo (562 Participants)	Visit 1: Placebo Plus Flu Vaccine (564 Participants)	Visit 2: COVID-19 Vaccine (557 Participants)
Flu-like illness	9 out of 564 participants (1.6%)	9 out of 562 participants (1.6%)	12 out of 564 participants (2.1%)	7 out of 557 participants (1.3%)
Injection site pain	16 out of 564 participants (2.8%)	1 out of 562 participants (0.2%)	14 out of 564 participants (2.5%)	1 out of 557 participants (0.2%)
COVID-19 infection	46 out of 564 participants (8.2%)	63 out of 562 participants (11.2%)	56 out of 564 participants (9.9%)	48 out of 557 participants (8.6%)
Infection of the nose, sinuses, or throat	27 out of 564 participants (4.8%)	31 out of 562 participants (5.5%)	24 out of 564 participants (4.3%)	22 out of 557 participants (3.9%)
Stomach flu	8 out of 564 participants (1.4%)	6 out of 562 participants (1.1%)	7 out of 564 participants (1.2%)	5 out of 557 participants (0.9%)
Viral infection of the nose, sinuses, or throat	4 out of 564 participants (0.7%)	6 out of 562 participants (1.1%)	6 out of 564 participants (1.1%)	7 out of 557 participants (1.3%)

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 1 month after each vaccination?

The following participants had at least 1 serious medical problem within 1 month after each vaccination:

Group A:

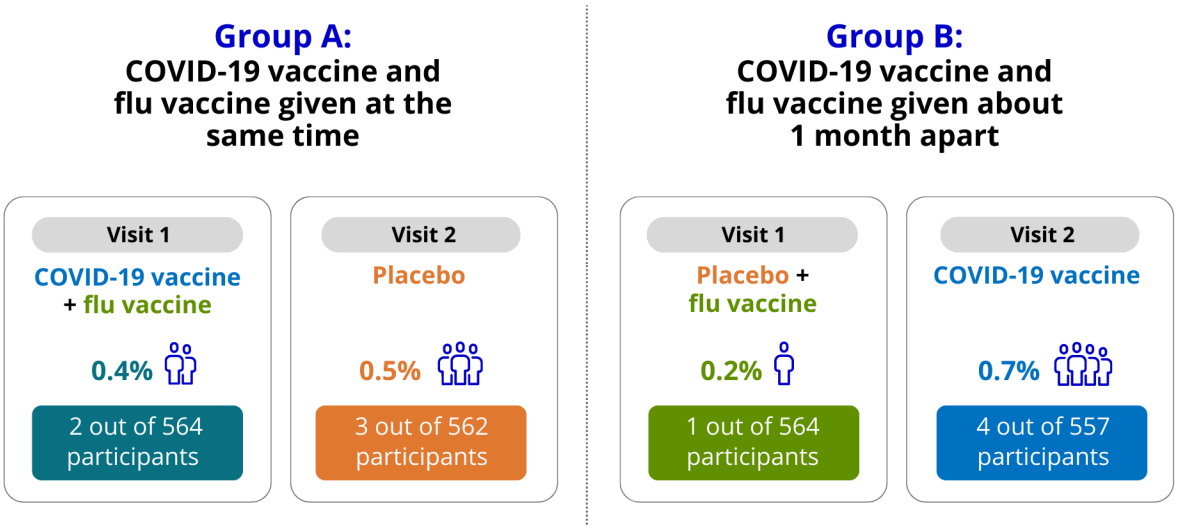
- 2 out of 564 participants (0.4%) after they got the COVID-19 vaccine plus flu vaccine.
- 3 out of 562 participants (0.5%) after they got a placebo.

Group B:

- 1 out of 564 participants (0.2%) after they got a placebo plus flu vaccine.
- 4 out of 557 participants (0.7%) after they got the COVID-19 vaccine.

Figure 5 below shows these results.

Figure 5. How many participants had a serious medical problem within 1 month after each vaccination?



Researchers do not believe that any of the serious medical problems seen in participants were related to the COVID-19 vaccine or flu vaccine.

No specific serious medical problem happened to more than 1 participant after each vaccination in Group A or B.

No participant 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 **C4591030**

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

www.clinicaltrials.gov

Use the study identifier **NCT05310084**

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!