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 administer to patients. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer Inc.

Vaccine Studied: PF-08044562 (combined COVID-19 and influenza vaccine)

Protocol Number: C5681001

Dates of Study: 31 January 2024 to 13 September 2024

Title of this Study: A Study to Learn About a Combined Injection for COVID-19 and Flu in Healthy Adults

[A Phase 1/2 Randomized Study to Evaluate the Safety, Tolerability, and Immunogenicity of a Modified RNA COVID-19 Vaccine and a Recombinant Influenza Vaccine Administered as a Single Injection in Healthy Adults 50 Years of Age or Older]

Date of this Report: 16 May 2025

– Thank You –

Pfizer

If you participated in this study, Pfizer, the Sponsor, 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.

Pfizer

Why was this study done?

What is COVID-19?

Coronavirus disease 2019 (or COVID-19) is caused by the virus called **S**evere **A**cute **R**espiratory **S**yndrome **C**oronavirus **2** (SARS-CoV-2) that infects the respiratory system. The respiratory system includes the nose, throat, and lungs. People with COVID-19 can have a runny or stuffy nose, sore throat, headache, muscle pain, body aches, 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 in the original virus give rise to new strains or **variants**. Compared to the original COVID-19 virus, the **Omicron** variant spreads more easily between people.

What is influenza?

Influenza, also known as flu, is caused by the influenza virus and also infects the respiratory system. Symptoms include a runny or stuffy nose, sore throat, cough, trouble breathing, headache, fever, chills, and muscle pain or body aches. Most of the symptoms are similar to the COVID-19 infection. The flu virus is also expected to change over time and give rise to new strains. Researchers studied 4 different strains (Strain 1, 2, 3, and 4) of the flu virus in this study.

One way to potentially prevent illness caused by viruses like COVID-19 and flu is to receive a vaccine. Vaccines help the body fight off infection and disease. Currently, it is possible to receive vaccines against COVID-19 and flu at the same time but as 2 separate injections. Researchers think that combining both the vaccines in a single injection could make it easier for people to choose to protect themselves against both COVID-19 and flu.

What is PF-08044562?

PF-08044562 is a combination of the COVID-19 vaccine, BNT162b2 (OmiXBB.1.5) and the influenza (flu) vaccine, Flublok®. BNT162b2 (OmiXBB.1.5) vaccine is a modified version of the original licensed **BNT162b2** vaccine (also known as Comirnaty®). The flu vaccine, Flublok®, includes protection against 4 flu strains (1, 2, 3, 4) and has been approved for use in many countries.

In this study, the COVID-19 and flu vaccines were given:

- As a combined single injection: **COVID-19/Flu vaccine**
- As 2 separate injections, one in each arm: **COVID-19** and **Flu vaccines**
- Alone: Either **COVID-19** or **Flu vaccine**

What was the purpose of this study?

The main purpose of this study was to learn about:

- the safety of the COVID-19 and flu vaccines
- the "immune response" after the participants received the COVID-19 and flu vaccines as a combined single injection or as 2 separate injections

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 your body uses to fight off an infection.
- An **immune response** refers to how your body recognizes and defends itself against bacteria, viruses and substances that may be harmful.
- Both, the COVID-19 and flu vaccines help the body's immune response by triggering it to produce antibodies.

Pfizer

To learn about safety, researchers looked for any local reactions, systemic events and medical problems, after the participants received the vaccines.

A **local reaction** includes symptoms such as redness, swelling, or pain at the injection site. The injection site is the skin area where the needle was inserted to administer the vaccine. A **systemic event** includes symptoms like fever, vomiting, diarrhea, headache, tiredness, chills, muscle pain, or joint pain. These are common and expected events when a vaccine is given. A **medical problem** includes all other symptoms except for local reactions and systemic events.

To learn about the immune response, researchers measured how many participants developed antibodies against the COVID-19 and flu viruses and measured the levels in the blood.

In this report, the COVID-19 and flu vaccines are referred to as **study vaccines**. Participants also received "placebo" injections during the study. A placebo vaccine does not have any components of a vaccine in it, but it looks just like the study vaccine.

Researchers wanted to know:

- **How many participants had local reactions within 7 days after vaccination?**
- **How many participants had systemic events within 7 days after vaccination?**
- **How many participants had medical problems through 1 month or serious medical problems through 6 months after vaccination?**
- **What was the difference in the immune responses before and 1 month after participants were given the study vaccines?**

Pfizer

What happened during the study?

How was the study done?

This study was conducted in 2 phases**: Phase 1 and Phase 2**. Both, phases had 4 vaccine groups, **Group 1, Group 2, Group 3, and Group 4**.

Phase 1: Phase 1 was done in 2 parts: Phase 1a and Phase 1b.

In **Phase 1a**, participants between 50 to 64 years of age received the study vaccines. Approximately 10 participants were placed in each vaccine group. Once the vaccines were found to be safely tolerated, **Phase 1b** was conducted. In **Phase 1b**, about 10 more participants aged 65 years or older were placed in each vaccine group and received the study vaccines.

Phase 2: Once the vaccines were found to be safely tolerated in **Phase 1** (participants aged 50 to 64 years in **Phase 1a** and 65 years or older in **Phase 1b**), researchers enrolled a larger number of participants aged 50 years and above in each of the 4 vaccine groups. Participants aged 50 through 64 years and 65 years of age and above were enrolled simultaneously.

Study participants were assigned equally to 1 of the 4 vaccine groups by chance alone. This process is called “randomization”. The vaccines were given as an injection into the muscle in the upper arm. Each participant received 2 injections (1 in each arm), one after the other.

Table 1 below shows the 4 vaccine groups and the vaccines given to the participants in each group.

Table 1: Vaccine groups in Phase 1 and Phase 2

Vaccine groups in Phase 1 and Phase 2	Vaccine given in left arm	Vaccine given in right arm
Group 1	 COVID-19/flu vaccine	 Placebo
Group 2	 COVID-19 vaccine	 Flu vaccine
Group 3	 COVID-19 vaccine	 Placebo
Group 4	 Flu vaccine	 Placebo

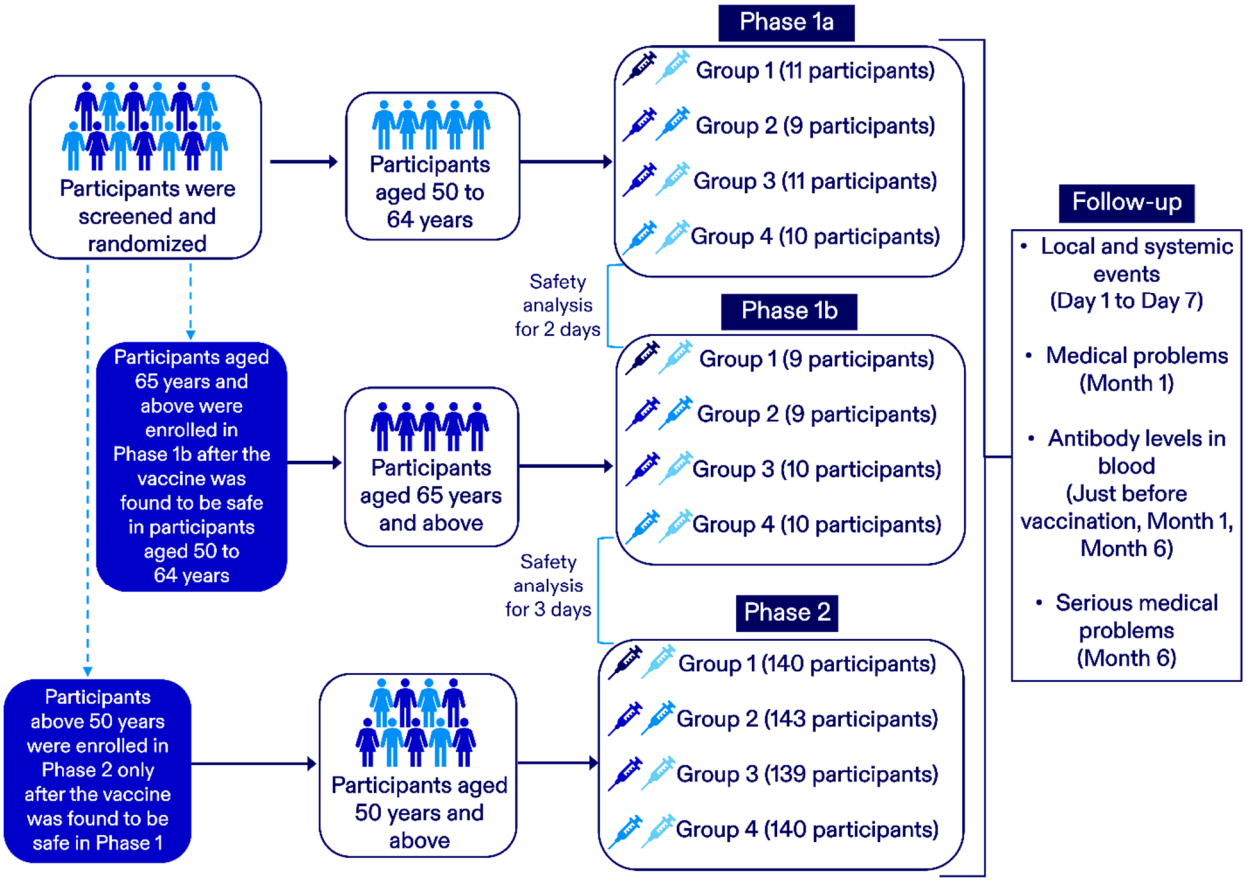
Participants were vaccinated on Day 1. The participants did not know who received which vaccine, but the researchers and the staff at the study site knew. This is known as a "single-blinded" study.

Each participant was given an electronic diary to record details of any local reactions or systemic events. This information was collected for about 7 days after vaccination. Participants also recorded details of any medication taken during this period to treat any pain symptoms or fever.

Researchers took samples of blood from the participants right before vaccination, and 1 month and 6 months after vaccination to measure the levels of antibodies in the blood. Researchers checked the participants' health during the study.

Researchers then compared the results of participants across each vaccine group in Phase 1 and Phase 2. **Figure 1** below shows the study design in detail.

Figure 1: Study design



Where did this study take place?

The Sponsor ran this study in the United States.

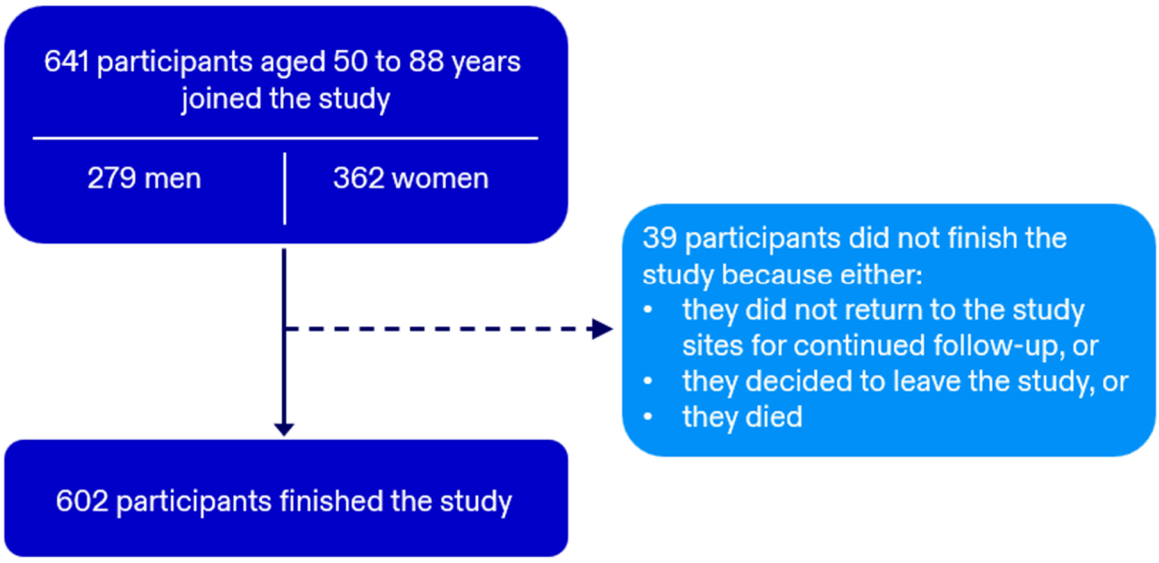
When did this study take place?

It began on 31 January 2024 and ended on 13 September 2024.

Who participated in this study?

The study included healthy participants who were 50 years or older. The health of participants was determined by their medical history, physical examination (if required), and clinical decision of the study doctor. **Figure 2** gives the details of the participants enrolled in the study.

Figure 2: Participants' details



How long did the study last?

Study participants were in the study for about 6 months. The entire study took 7 and a half months to complete. The study was completed as planned.

When the study ended in September 2024, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

What were the results of the study?

How many participants had local reactions within 7 days after vaccination?

The most frequently reported local reaction was pain at the injection site. The percentage of participants who reported local reactions after receiving the COVID-19/flu vaccine as a single injection was generally similar compared to the other vaccine groups. Local reactions were mostly mild or moderate in severity for all 4 vaccine groups. **Figure 3** shows the percentage of participants with local reactions in each vaccine group.

Figure 3: Number (percentage) of participants with local reactions in each vaccine group

		Pain at the injection site	Redness	Swelling
Group 1	COVID-19/ flu vaccine	56% 90 out of 160 participants	9% 14 out of 160 participants	9% 15 out of 160 participants
	Placebo	12% 19 out of 160 participants	1% 2 out of 160 participants	1% 2 out of 160 participants
Group 2	COVID-19 vaccine	59% 95 out of 161 participants	5% 8 out of 161 participants	6% 10 out of 161 participants
	Flu vaccine	39% 62 out of 161 participants	3% 5 out of 161 participants	3% 5 out of 161 participants
Group 3	COVID-19 vaccine	63% 100 out of 160 participants	5% 8 out of 160 participants	6% 9 out of 160 participants
	Placebo	9% 15 out of 160 participants	1% 1 out of 160 participants	1% 1 out of 160 participants
Group 4	Flu vaccine	37% 59 out of 160 participants	6% 10 out of 160 participants	5% 8 out of 160 participants
	Placebo	8% 13 out of 160 participants	1% 1 out of 160 participants	1% 1 out of 160 participants

How many participants had systemic events within 7 days after vaccination?

The most frequently reported systemic events were tiredness and headache. The percentage of participants who reported systemic events after receiving the COVID-19/flu vaccine as a single injection was generally similar compared to the other vaccine groups. Systemic events were mostly mild or moderate in severity for all 4 vaccine groups. **Table 2** below shows the percentage of participants with systemic events in each vaccine group.

Below are instructions on how to read Table 2.

Instructions for Understanding Table 2.

- The first row of the table shows the groups in the study and the number of participants in each group.
- The grey and white rows in Table 2 show systemic events that were reported by the participants.
- The **1st** column of Table 2 tells how many of the 160 participants in Group 1 who received the COVID-19/flu vaccine as a single injection + placebo reported each systemic event. Below the number is the percentage of 160 participants in Group 1 who received the COVID-19/flu vaccine as a single injection + placebo and reported the systemic event.
- The **2nd** column of Table 2 tells how many of the 161 participants in Group 2 who received the COVID-19 vaccine + flu vaccine simultaneously reported each systemic event. Below the number is the percentage of 161 participants in Group 2 who received the COVID-19 vaccine + flu vaccine simultaneously and reported the systemic event.

- The **3rd** column of Table 2 tells how many of the 160 participants in Group 3 who received the COVID-19 vaccine + placebo reported each systemic event. Below the number is the percentage of 160 participants in Group 3 who received the COVID-19 vaccine + placebo and reported the systemic event.
- The **4th** column of Table 2 tells how many of the 160 participants in Group 4 who received the flu vaccine + placebo reported each systemic event. Below the number is the percentage of 160 participants in Group 4 who received the flu vaccine + placebo and reported the systemic event.

Using these instructions, you can see that 3 out of the 160 participants [2%] in Group 1, 10 out of the 161 participants [6%] in Group 2, 10 out of the 160 participants [6%] in Group 3, and 0 out of the 160 participants [0%] in Group 4 reported fever.

Table 2. Systemic events reported by study participants

Group 1 COVID-19/Flu vaccine + Placebo (160 Participants)	Group 2 COVID-19 vaccine + Flu vaccine (161 Participants)	Group 3 COVID-19 vaccine + Placebo (160 Participants)	Group 4 Flu vaccine + Placebo (160 Participants)
Fever			
3 out of 160 participants (2%)	10 out of 161 participants (6%)	10 out of 160 participants (6%)	0 out of 160 participants (0%)
Tiredness			
58 out of 160 participants (36%)	63 out of 161 participants (39%)	65 out of 160 participants (41%)	53 out of 160 participants (33%)

Table 2. Systemic events reported by study participants			
Group 1 COVID-19/Flu vaccine + Placebo (160 Participants)	**Group 2 COVID-19 vaccine + Flu vaccine (161 Participants)**	**Group 3 COVID-19 vaccine + Placebo (160 Participants)**	**Group 4 Flu vaccine + Placebo (160 Participants)**
Headache			
39 out of 160 participants (24%)	50 out of 161 participants (31%)	43 out of 160 participants (27%)	27 out of 160 participants (17%)
Vomiting			
0 out of 160 participants (0%)	5 out of 161 participants (3%)	3 out of 160 participants (2%)	0 out of 160 participants (0%)
Diarrhea			
13 out of 160 participants (8%)	18 out of 161 participants (11%)	18 out of 160 participants (11%)	12 out of 160 participants (8%)
Chills			
14 out of 160 participants (9%)	24 out of 161 participants (15%)	24 out of 160 participants (15%)	11 out of 160 participants (7%)
Muscle pain			
21 out of 160 participants (13%)	36 out of 161 participants (22%)	24 out of 160 participants (15%)	13 out of 160 participants (8%)
Joint pain			
12 out of 160 participants (8%)	22 out of 161 participants (14%)	16 out of 160 participants (10%)	7 out of 160 participants (4%)

What was the difference in the immune responses before and 1 month after participants were given the study vaccines?

The results from 641 participants who received the study vaccines were assessed. Of these, 620 had blood samples collected properly and within appropriate study timeframes for analyses to be carried out to assess the immune response.

Researchers found that the single injection of the COVID-19/flu vaccine produced a strong immune response for most tests done for the COVID-19 virus and the flu virus.

Based on these results, the researchers have decided that the results are not likely the result of chance. 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 or vaccine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what effects a study vaccine might have on a participant.

Seven (7) out of 160 participants [4%] in **Group 1**, 6 out of 161 participants [4%] in **Group 2**, and 9 out of 160 participants [6%] each in **Group 3 and Group 4** had at least 1 medical problem within 1 month after vaccination. One (1) participant in Group 4 died and therefore, did not complete the study.

None of the medical problems were reported by more than 1 participant, in any vaccine group, except infection of the parts of the body that collect and pass out urine which was reported by 2 out of 160 participants [1%] in **Group 4**.

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.

Three (3) out of 160 participants (2%) in **Group 1**, 1 out of 161 participants (less than 1%) in **Group 2**, and 3 out of 160 participants (2%) in **Group 4** had serious medical problems. No participant in Group 3 reported serious medical problems.

None of the serious medical problems were reported by more than 1 participant. A study doctor at one of the study sites believed that a clot in a blood vessel in the right lung may have been caused by the flu vaccine in **Group 4**, but the researchers do not believe that any of the serious medical problems, including the clot in the blood vessel in the right lung were related to the study vaccines.

One (1) participant died during the study. Researchers do not believe the death was related to the study vaccines.

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 **C5681001**

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

www.clinicaltrials.gov

Use the study identifier **NCT06237049**

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!

Pfizer