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 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:	Combination Influenza and COVID-19 mRNA Vaccine
Protocol Number:	C5261002
Dates of Study:	20 December 2023 to 26 November 2024
Title of this Study:	A Study to Learn About the Responses to the Combined COVID-19 and Flu Vaccine in Healthy People [A Phase 3, Randomized, Observer-Blinded Study to Evaluate the Safety, Tolerability, and Immunogenicity of a Combined Modified RNA Vaccine Candidate Against COVID-19 and Influenza in Healthy Individuals]
Date of this Report:	31 October 2025

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

Why was this study done?

What are influenza (flu) and coronavirus disease 2019 (COVID-19)?

The flu (caused by influenza virus) and COVID-19 (caused by SARS-CoV-2 virus) are diseases that can spread easily from one person to another.

Flu and COVID-19 can cause mild illness with symptoms such as body aches, fever, and cough. These 2 diseases can also cause serious illness or death. Older adults, young children, and those with health conditions (such as heart or lung diseases) are more likely to develop serious illness.

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What are the flu and COVID-19 combination vaccines?

The injectable combination vaccines are investigational, which means they are still being studied and not approved by health authorities. This study tested 2 combination vaccines:

- **flu and COVID-19 combination A vaccine**
- **flu and COVID-19 combination B vaccine**

Each of these **combination vaccines** contains 2 different vaccines:

- an investigational **flu vaccine**, and
- a **COVID-19 vaccine**

> The COVID-19 and flu vaccines were designed to target the strains of the COVID-19 and flu viruses that were circulating (going around) at the time of this study.
>
> The COVID-19 vaccine used in the study was **BNT162b2** (also known as Comirnaty® [koe-mir'-na-tee] or the Pfizer-BioNTech COVID-19 vaccine). It was approved by health authorities in the United States and in many countries around the world.

Researchers think that the combination vaccines may help protect against the flu and COVID-19. The flu and COVID-19 combination vaccine is a single shot instead of 2 shots given separately in different arms.

What was the purpose of this study?

The purpose of this study was to understand the safety and immune responses to the flu and COVID-19 combination vaccines. The combination vaccines were compared to separate vaccines for protection against flu and COVID-19.

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

The main questions that researchers had are listed below.

Researchers wanted to know:

- **Did the flu and COVID-19 combination B vaccine produce immune responses?**
- **What medical problems did participants have during the study?**

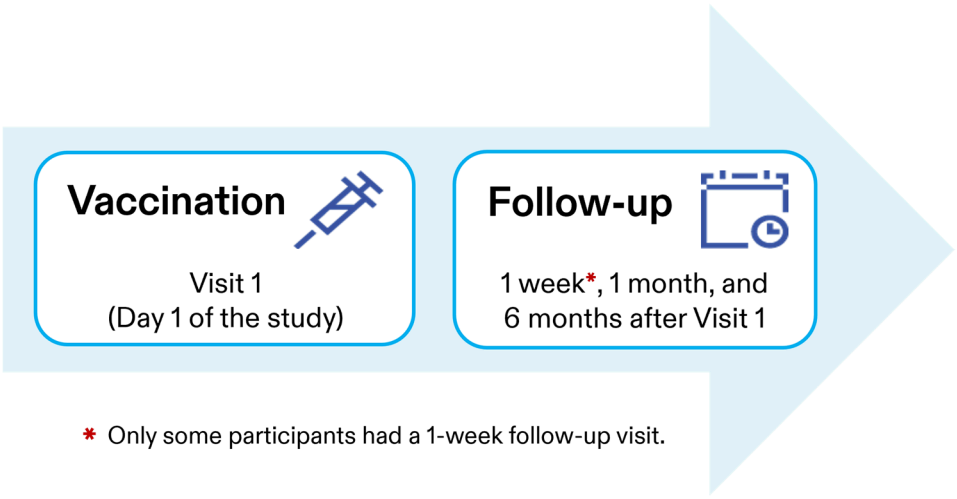
What happened during the study?

How was the study done?

As seen in Figure 1 below, participants were vaccinated on Day 1 of the study (Visit 1). Then, they had their follow-up checks:

- Some participants who agreed to have an additional blood test had a follow-up visit at 1 week after vaccination.
- All participants had follow-up visits at 1 month and 6 months after vaccination.

Figure 1. Schedule of study visits



During the study, researchers monitored the participants' safety and looked at the body's immune responses to the vaccination.

This study had 3 large groups of participants called "**cohorts**." Participants in each cohort were randomly assigned to a vaccine group. The participants and researchers did not know which vaccine group the participants were in and which vaccine(s) they got, but the person who gave the shots knew. This is known as an **"observer-blinded"** study.

Cohort 1 and Cohort 2

As seen in Figure 2 below, participants in Cohort 1 and Cohort 2 got 2 shots (1 shot in each arm). The **flu and COVID-19 combination A vaccine** (Group A) and the **flu and COVID-19 combination B vaccine** (Group C) given in 1 arm plus placebo in the other arm were compared with the 2 vaccines (**COVID-19 vaccine** and **licensed flu vaccine**) given separately at the same time in different arms (Groups B and D).

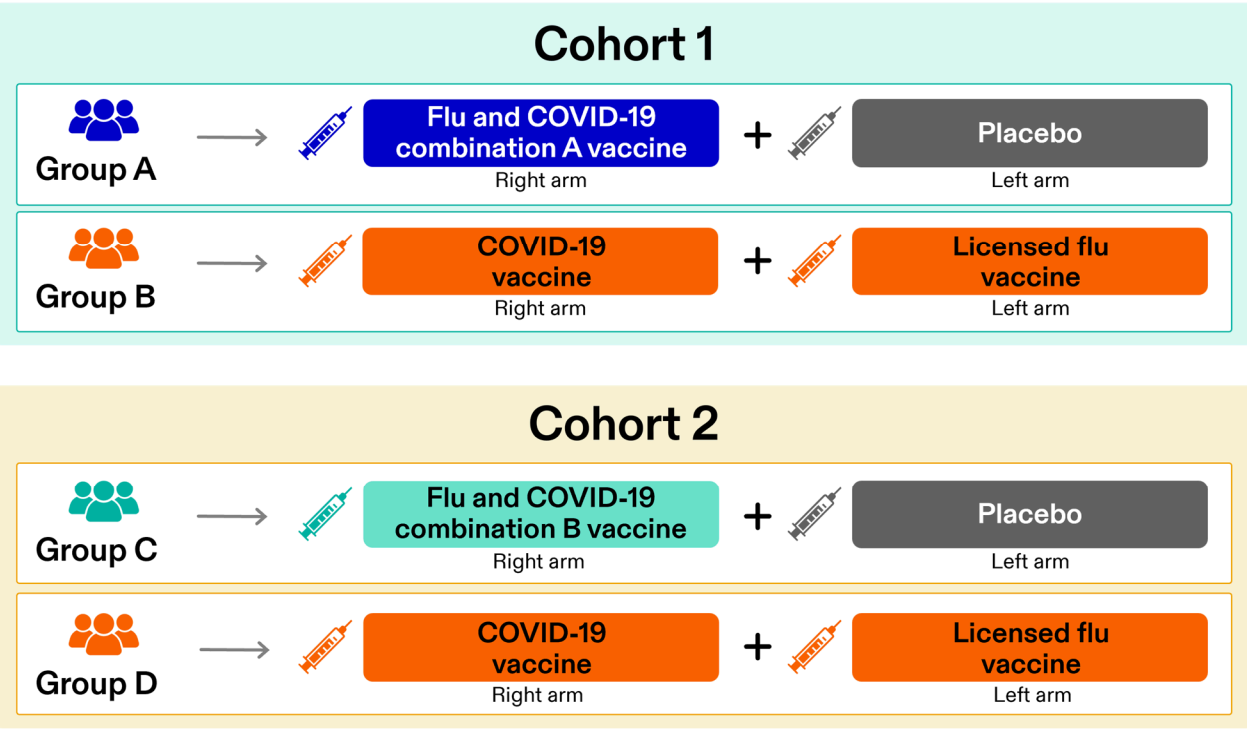
A "**placebo**" does not have any active ingredients but looks like a study vaccine.

Placebo was given to participants who got the combination vaccine (Groups A and C) to make sure that everyone in Cohorts 1 and 2 got the same number of shots. This way, participants and researchers could not know whether they got the combination or the separate vaccines.

The **COVID-19 vaccine** given as part of the combination vaccine or as a single vaccine was BNT162b2.

The "**licensed flu vaccine**" is a flu vaccine approved by health authorities.

Figure 2. Vaccines given to Cohort 1 and Cohort 2

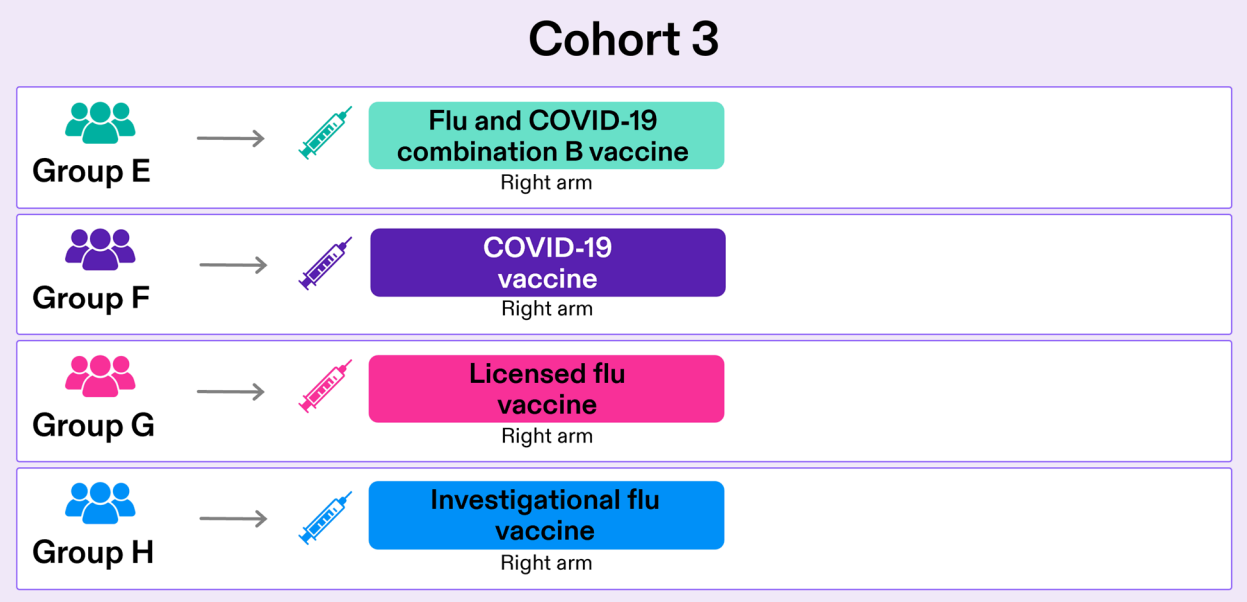


Cohort 3

As seen in Figure 3 below, participants in Cohort 3 got 1 shot in their right arm. The **flu and COVID-19 combination B vaccine** (Group E) was compared with the 3 vaccines given separately to 3 different groups:

- **COVID-19 vaccine** (Group F)
- **Licensed flu vaccine** (Group G)
- **Investigational flu vaccine** (Group H)

Figure 3. Vaccines given to Cohort 3



Where did this study take place?

This study was run in the United States.

When did this study take place?

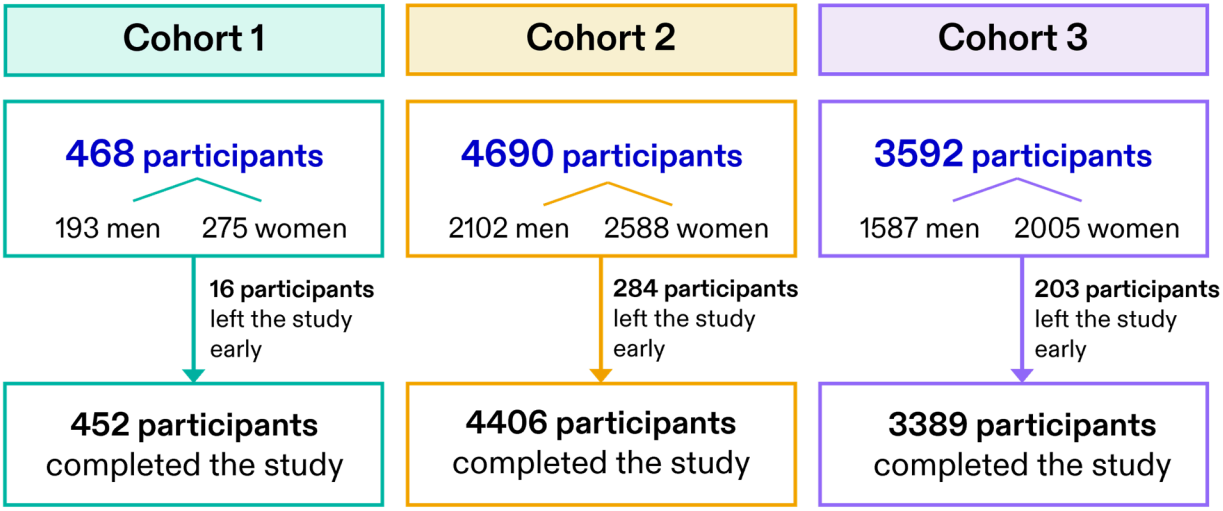
It began on 20 December 2023 and ended on 26 November 2024.

Who participated in this study?

The study included adult participants who were healthy or who had stable (controlled) health conditions before the study started. All participants were between the ages of 18 years and 64 years.

Figure 4 below shows how many participants were vaccinated in the study.

Figure 4. Number of participants in the study



As seen in Figure 4 above, some participants left the study after vaccination and stopped taking part in the study. The most common reasons were:

- Participants could not be contacted for their check-up.
- Participants chose to stop taking part in the study.

How long did the study last?

Each study participant was in the study for about 6 months. The entire study took about 11 months to complete. The study was completed as planned.

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

What were the results of the study?

Did the flu and COVID-19 combination B vaccine produce immune responses?

In **Cohort 2**, researchers wanted to learn whether the body's immune responses to the **flu and COVID-19 combination B vaccine,** given as 1 shot in 1 arm (**Group C**), were the same with the immune responses to the **COVID-19 vaccine** and **licensed flu vaccine**, each given as 1 shot separately at the same time in different arms (**Group D**).

To answer this question, researchers took blood samples from participants to see their antibody levels against flu strains and the COVID-19 strain. Researchers checked the antibody levels before and after vaccination.

> "**Antibodies**" are proteins that can fight off infections and help prevent diseases. Antibodies can tell us about the body's immune response. An "**immune response**" is the body's ability to find and fight germs that cause diseases.

Researchers also checked how many participants had **strong immune responses** against flu strains and the COVID-19 strain.

> In this study, a strong immune response means the antibody levels were at least **4 times higher** at 1 month **after** vaccination compared to **before** vaccination.

Study results:

The **flu and COVID-19 combination B vaccine**, given in 1 arm, produced immune responses against most (but not all) flu strains and the COVID-19 strain similar to the immune responses to the **COVID-19 vaccine** and **licensed flu vaccine**, given separately at the same time in different arms. The researchers decided the results were not likely due to 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 the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many vaccine groups in many studies, doctors try to understand what effects a study vaccine might have on a participant.

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

- **Local reactions** are the body's response at the injection site (spot in the arm where the study vaccine was injected). These can include injection site redness, swelling, or pain.
- **Systemic events** are symptoms that affect the whole body or specific parts of the body like the head or joints. These can include fever, tiredness, headache, chills, vomiting, diarrhea, new or worsened muscle pain, or new or worsened joint pain.

Cohorts 1, 2, and 3:

Overall, most local reactions and systemic events were mild or moderate in severity and lasted 1 to 2 days.

- The most common local reaction was pain at the injection site.
- The most common systemic events were tiredness, headache, new or worsened muscle pain, and chills.

Figure 5 below shows how many participants had **local reactions** (**Chart A**) on their right arm and **systemic events** (**Chart B**) within 7 days after vaccination.

Figure 5. Number of participants with local reactions and systemic events within 7 days after vaccination

Chart A: Local Reactions

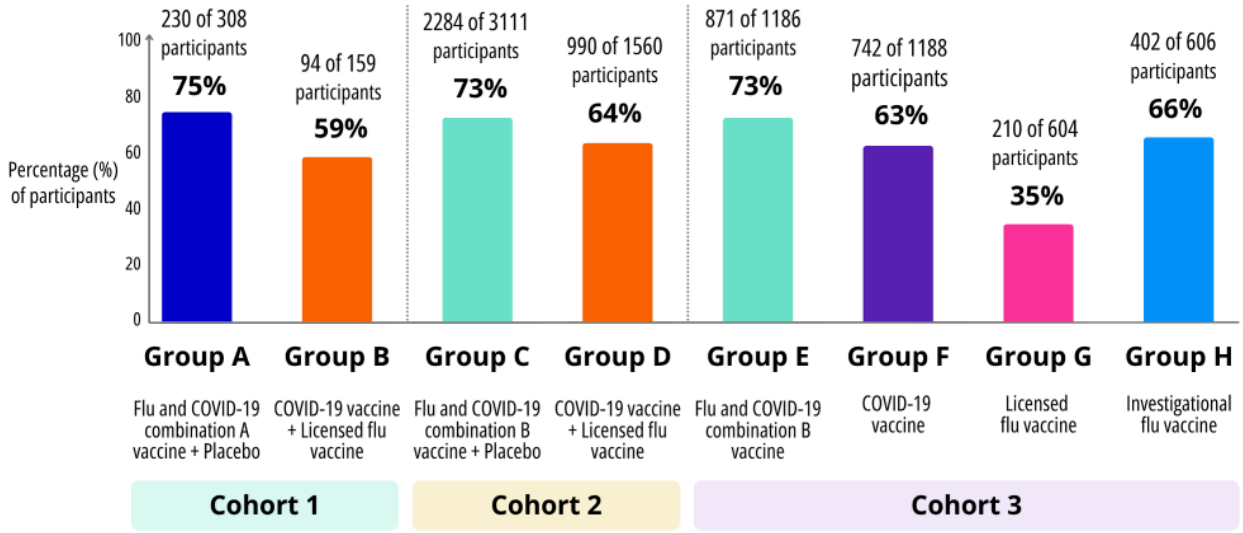
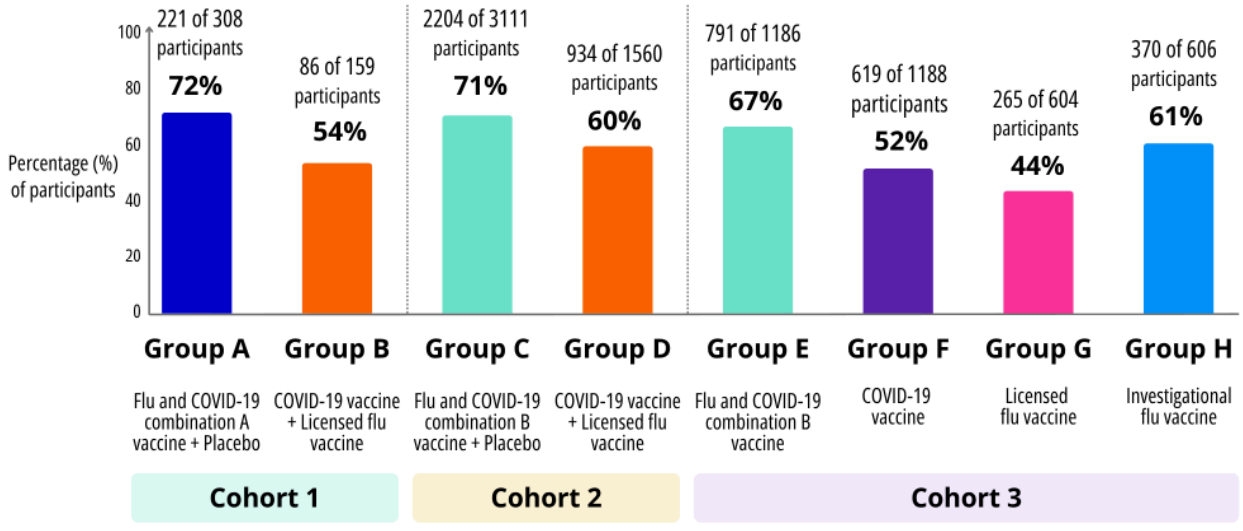


Chart B: Systemic Events



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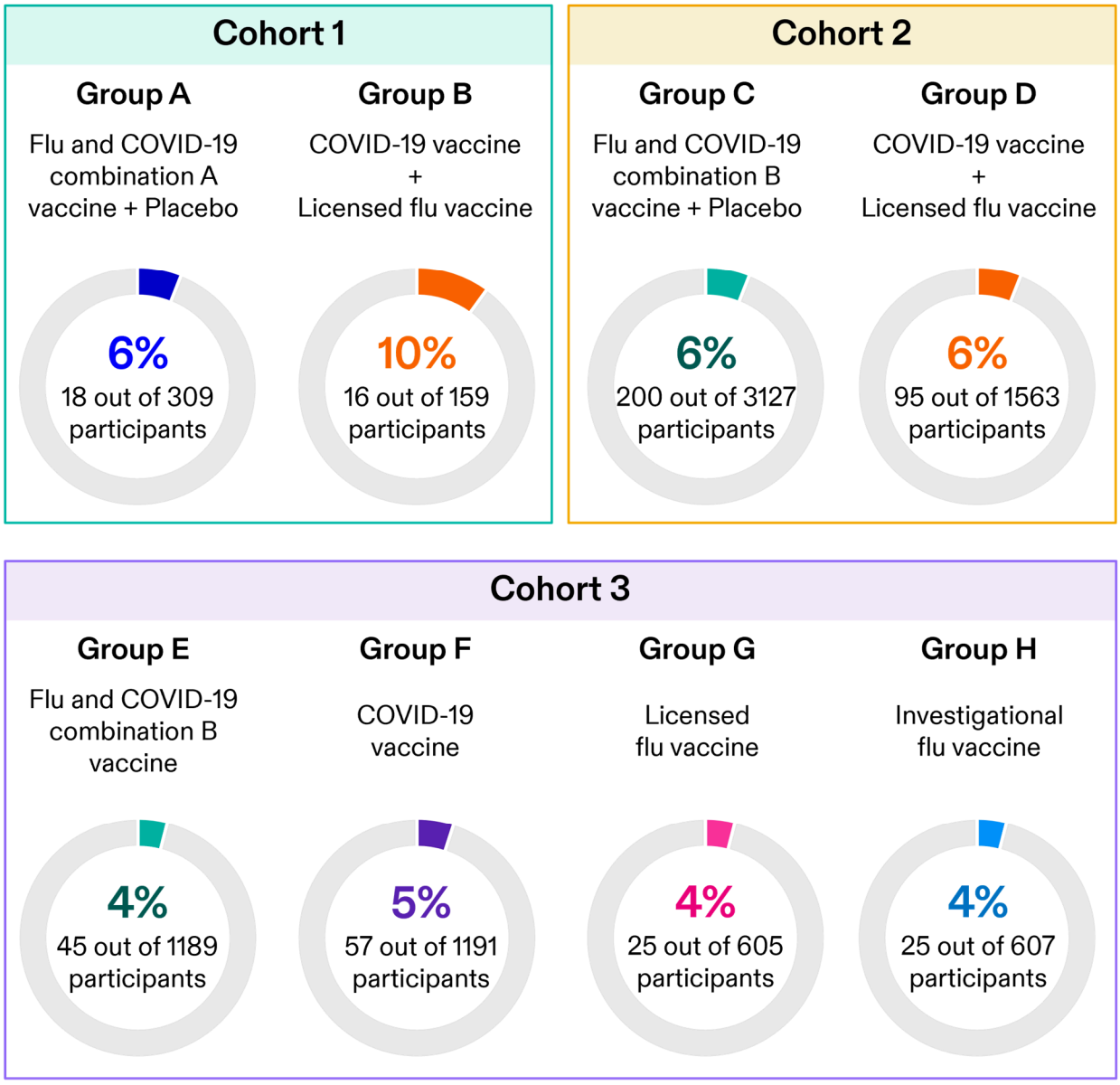
How many participants had medical problems within 1 month after vaccination?

Figure 6 below shows the answer to this question.

Figure 6. Number of participants with at least 1 medical problem within 1 month after vaccination



The most common medical problems – those reported by at least 1 in every 100 participants (1%) in any group within 1 month after vaccination – were infection of the upper respiratory tract (nose, throat, and sinuses) and COVID-19 as listed below.

Infection of the upper respiratory tract	
Cohort 1	**Cohort 2**
• 4 out of 309 participants (**1%**) in **Group A** • 3 out of 159 participants (**2%**) in **Group B**	• 15 out of 3127 participants (**below 1%**) in **Group C** • 17 out of 1563 participants (**1%**) in **Group D**
Cohort 3	
• 3 out of 1189 participants (**below 1%**) in **Group E** • 6 out of 1191 participants (**below 1%**) in **Group F**	• 1 out of 605 participants (**below 1%**) in **Group G** • 3 out of 607 participants (**below 1%**) in **Group H**

COVID-19	
Cohort 1	**Cohort 2**
• 1 out of 309 participants (**below 1%**) in **Group A** • 2 out of 159 participants (**1%**) in **Group B**	• 15 out of 3127 participants (**below 1%**) in **Group C** • 10 out of 1563 participants (**below 1%**) in **Group D**
Cohort 3	
• 2 out of 1189 participants (**below 1%**) in **Group E** • 2 out of 1191 participants (**below 1%**) in **Group F**	• 3 out of 605 participants (**below 1%**) in **Group G** • 0 out of 607 participants (**0%**) in **Group H**

Did study participants have any serious medical problems?

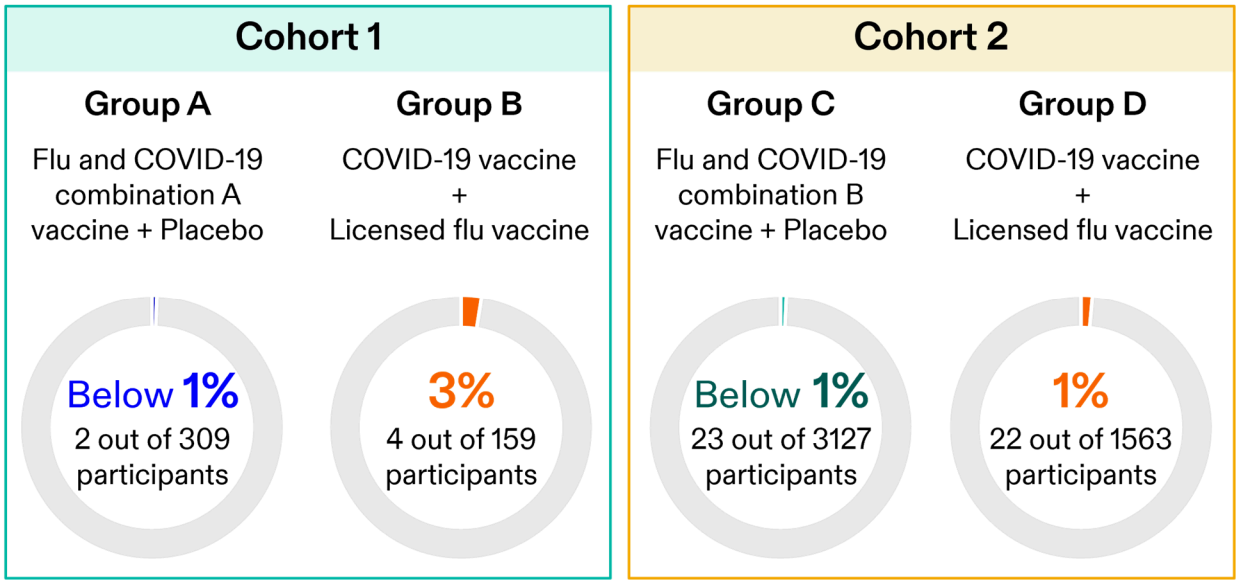
A medical problem is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems.

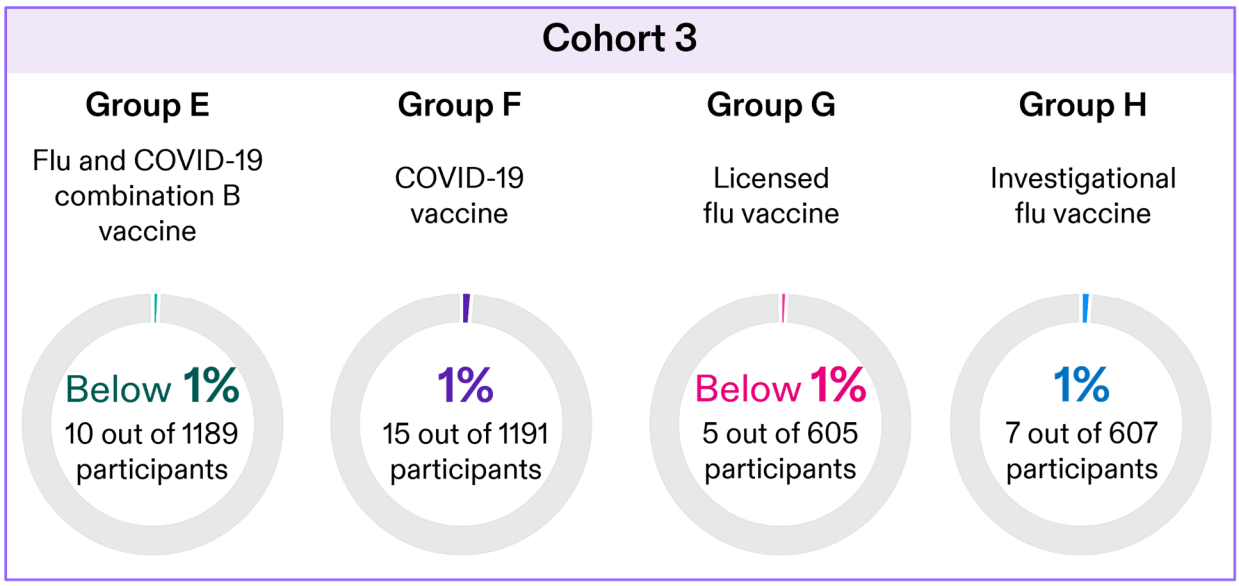
How many participants had serious medical problems within 6 months after vaccination?

Figure 7 below shows the answer to this question.

There were no commonly reported serious medical problems. Each single serious medical problem happened in 2 or fewer participants in any cohort. Researchers believe that none of the serious medical problems were caused by the study vaccines.

Figure 7. Number of participants with at least 1 serious medical problem within 6 months after vaccination





Overall, 7 participants died because of serious medical problems they had during the study:

- 1 participant in **Cohort 1** (Group A)
- 3 participants in **Cohort 2** (2 in Group C and 1 in Group D)
- 3 participants in **Cohort 3** (1 each in Group E, Group G, and Group H)

Researchers believe that none of the deaths were caused by the study vaccines.

A total of 8 participants did not finish the study because of medical problems they had during the study. Researchers believe that none of these medical problems were caused by the study vaccines. Of these 8 participants:

- 7 participants were those who died during the study
- 1 participant chose to stop taking part in 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 **C5261002**

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

www.clinicaltrials.gov

Use the study identifier **NCT06178991**

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!

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