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 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 Vaccines (PF-07926307)

Protocol Number: C5261023

Dates of Study: 11 November 2024 to 15 July 2025

Title of this Study: A Study to Learn About Flu and COVID-19 Vaccine Responses in Healthy People

[A Phase 1/2, Randomized, Observer-Blinded Study to Evaluate the Safety, Tolerability, and Immunogenicity of Combined Vaccine Candidates Against Influenza and COVID-19 in Healthy Individuals]

Date of this Report: 02 July 2026

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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)?

Flu and COVID-19 are contagious diseases (can easily spread from person to person). **Flu** is caused by influenza viruses. **COVID-19** is caused by a virus called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Symptoms of 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.

What are flu and COVID-19 vaccines?

This study included injectable “investigational” and “licensed” vaccines. Licensed means the vaccines are approved by health authorities. Investigational means the vaccines are still being studied.

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There were 6 vaccines in this study:

Investigational flu vaccine	A vaccine that researchers think can help protect against flu
Investigational COVID-19 vaccine	A vaccine that researchers think can help protect people of different ages against COVID-19
Licensed Pfizer-BioNTech COVID-19 vaccine	Also called BNT162b2 or Comirnaty®, a licensed vaccine approved for use in people 12 years of age and older to protect against COVID-19
Licensed flu vaccine 1	A licensed vaccine designed to protect against flu in adults
Licensed flu vaccine 2	A licensed flu vaccine designed to give stronger protection and recommended for older adults
Investigational flu plus investigational or licensed COVID-19 vaccine	A combination (or combo) vaccine that researchers think can help protect against both flu and COVID-19 at once

The combination of investigational **flu** vaccine plus investigational or licensed **COVID-19** vaccine combined into **1 injection** is called **"flu plus COVID-19 combo vaccine"** in this summary.

What was the purpose of this study?

The main goal was to learn about the safety of flu and COVID-19 vaccines when given separately or when combined into 1 injection (in different dose levels) in healthy participants.

Researchers wanted to know:

Can healthy participants safely receive the flu and COVID-19 vaccines when given separately or when combined into 1 injection?

What happened during the study?

How was the study done?

Researchers studied the safety of flu and COVID-19 vaccines when given separately or when combined into 1 injection. The study enrolled 2 age groups (or cohorts) of participants:

- **Cohort 1**: Participants 18 years to 64 years old
- **Cohort 2**: Participants 65 years of age and older

In **Cohort 1**, participants were assigned at random (by chance) to 1 of the 14 vaccine groups:

- **Group 1:** COVID-19 vaccine – Dose Level 1
- **Group 2:** COVID-19 vaccine – Dose Level 2
- **Group 3:** COVID-19 vaccine – Dose Level 3
- **Group 4:** Investigational flu vaccine – Dose Level 1

- **Group 5:** Investigational flu vaccine – Dose Level 2
- **Group 6:** Investigational flu vaccine – Dose Level 3
- **Group 7:** Licensed flu vaccine 1 in one arm and licensed COVID-19 vaccine in the other arm
- **Group 8:** Flu plus COVID-19 Combo 1 vaccine
- **Group 9:** Flu plus COVID-19 Combo 2 vaccine
- **Group 10:** Flu plus COVID-19 Combo 3 vaccine
- **Group 11:** Flu plus COVID-19 Combo 4 vaccine
- **Group 12:** Flu plus COVID-19 Combo 5 vaccine
- **Group 13:** Flu plus COVID-19 Combo 6 vaccine
- **Group 14:** Flu plus COVID-19 Combo 7 vaccine

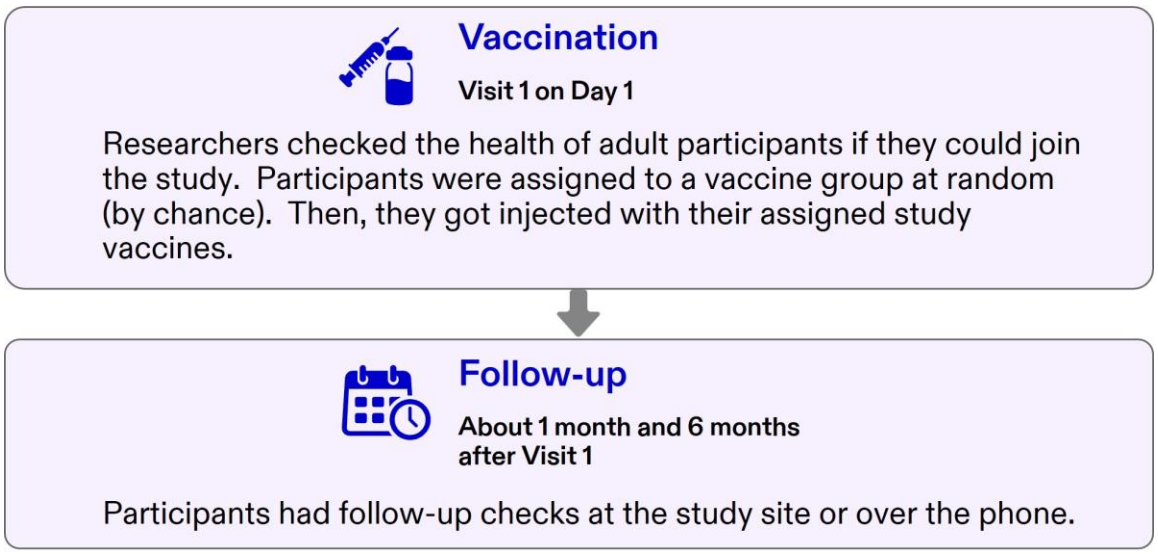
In **Cohort 2**, participants were assigned at random to 1 of the 13 vaccine groups:

- **Group 1:** COVID-19 vaccine – Dose Level 1
- **Group 2:** COVID-19 vaccine – Dose Level 2
- **Group 3:** COVID-19 vaccine – Dose Level 3
- **Group 4:** Investigational flu vaccine – Dose Level 1
- **Group 5:** Investigational flu vaccine – Dose Level 2
- **Group 6:** Investigational flu vaccine – Dose Level 3
- **Group 7:** Licensed flu vaccine 2 in one arm and licensed COVID-19 vaccine in the other arm
- **Group 8:** Flu plus COVID-19 Combo 1 vaccine
- **Group 9:** Flu plus COVID-19 Combo 2 vaccine

- **Group 10:** Flu plus COVID-19 Combo 3 vaccine
- **Group 11:** Flu plus COVID-19 Combo 4 vaccine
- **Group 12:** Flu plus COVID-19 Combo 5 vaccine
- **Group 13:** Flu plus COVID-19 Combo 6 vaccine

Figure 1 shows how the study was done.

Figure 1. Study plan



This study was "observer-blinded" and "Sponsor-open-label." Observer-blinded means that the researchers and participants did not know which study vaccines the participants got at Visit 1, but the person who gave the injections knew. Sponsor-open-label means that the Sponsor agent knew which study vaccines the participants got.

Where did this study take place?

The Sponsor agent ran this study in the United States.

When did this study take place?

It began on 11 November 2024 and ended on 15 July 2025.

Who participated in this study?

The study included healthy participants or those who had stable (controlled) health conditions before the study started. Cohort 1 included participants 18 years to 64 years old, and Cohort 2 included participants 65 years of age and older.

Table 1 shows the number of participants in each cohort.

Table 1. Number of participants in the study

	Cohort 1 307 men and 392 women (Between 18 years and 64 years of age)	Cohort 2 309 men and 339 women (Between 65 years and 89 years of age)
Got a study vaccine	699 participants	648 participants
Finished the study	669 out of 699 participants (96%)	629 out of 648 participants (97%)
Did not finish the study	30 out of 699 participants (4%)	19 out of 648 participants (3%)
Most common reason for not finishing the study	Participant could not be contacted for follow-up check	Participant could not be contacted for follow-up check

In Cohort 2, there were 2 more participants who got vaccinated during the study. However, they were not included in the results because they did not sign the informed consent at Visit 1.

How long did the study last?

Study participants were in the study for about 6 months. The entire study took about 8 months to complete. The study was completed as planned.

When the study ended in July 2025, 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?

Can healthy participants safely receive the flu and COVID-19 vaccines when given separately or when combined into 1 injection?

To answer this question, researchers looked at all the information collected on the participants' health throughout the study.

Researchers found that the tested doses of flu plus COVID-19 combo vaccine, flu vaccine alone, and COVID-19 vaccine alone were safe in healthy participants 18 years to 64 years old (Cohort 1) and 65 years of age and older (Cohort 2). No new safety concerns were found during the study.

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.

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What medical problems did participants have during the study?

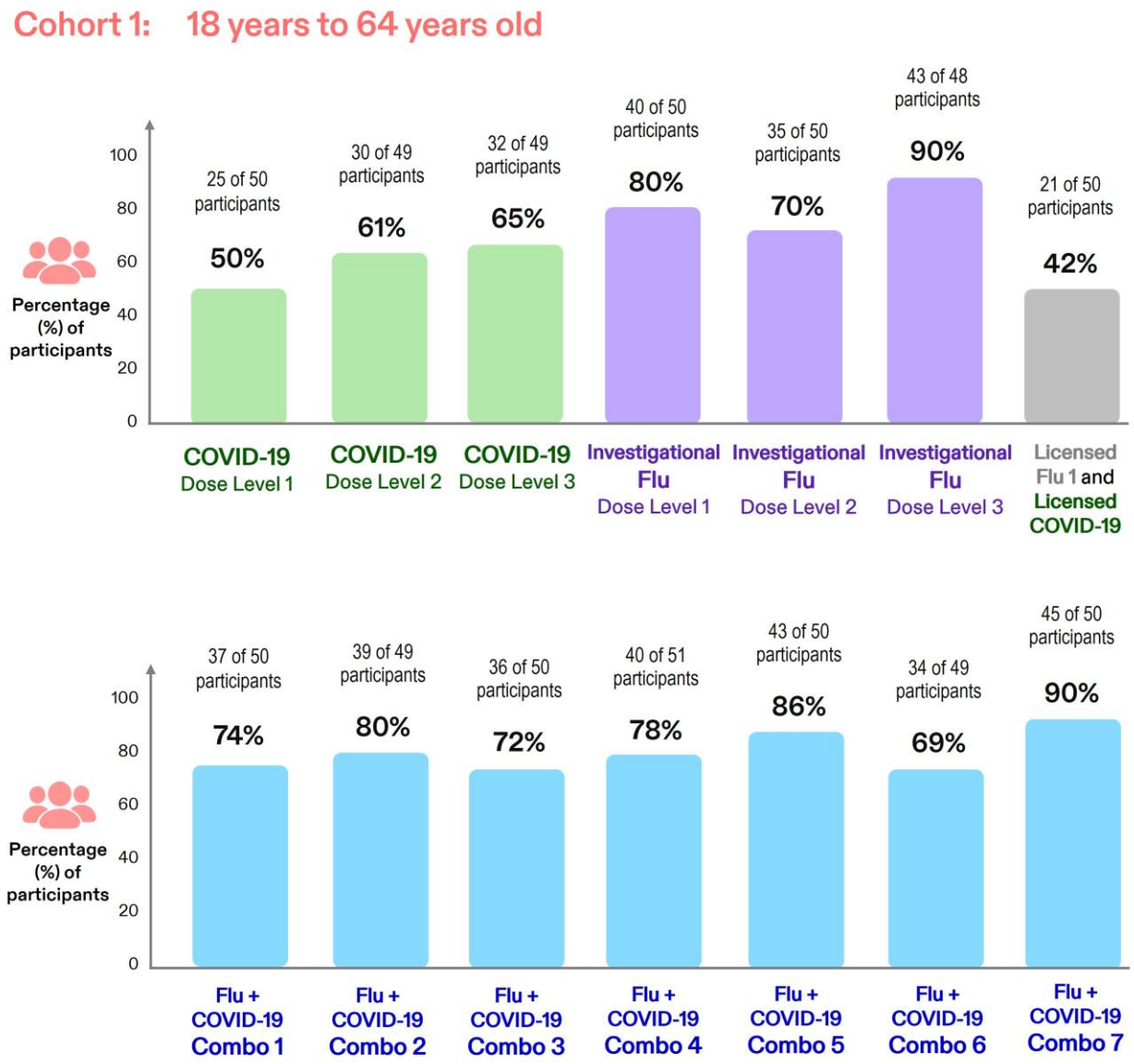
The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an unknown underlying disease or by chance). Or, medical problems could also have been caused by a study vaccine 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 any local reactions within 7 days after vaccination?

"**Local reactions**" include redness, swelling, and pain at the injection site (area on the right arm where the vaccine was injected).

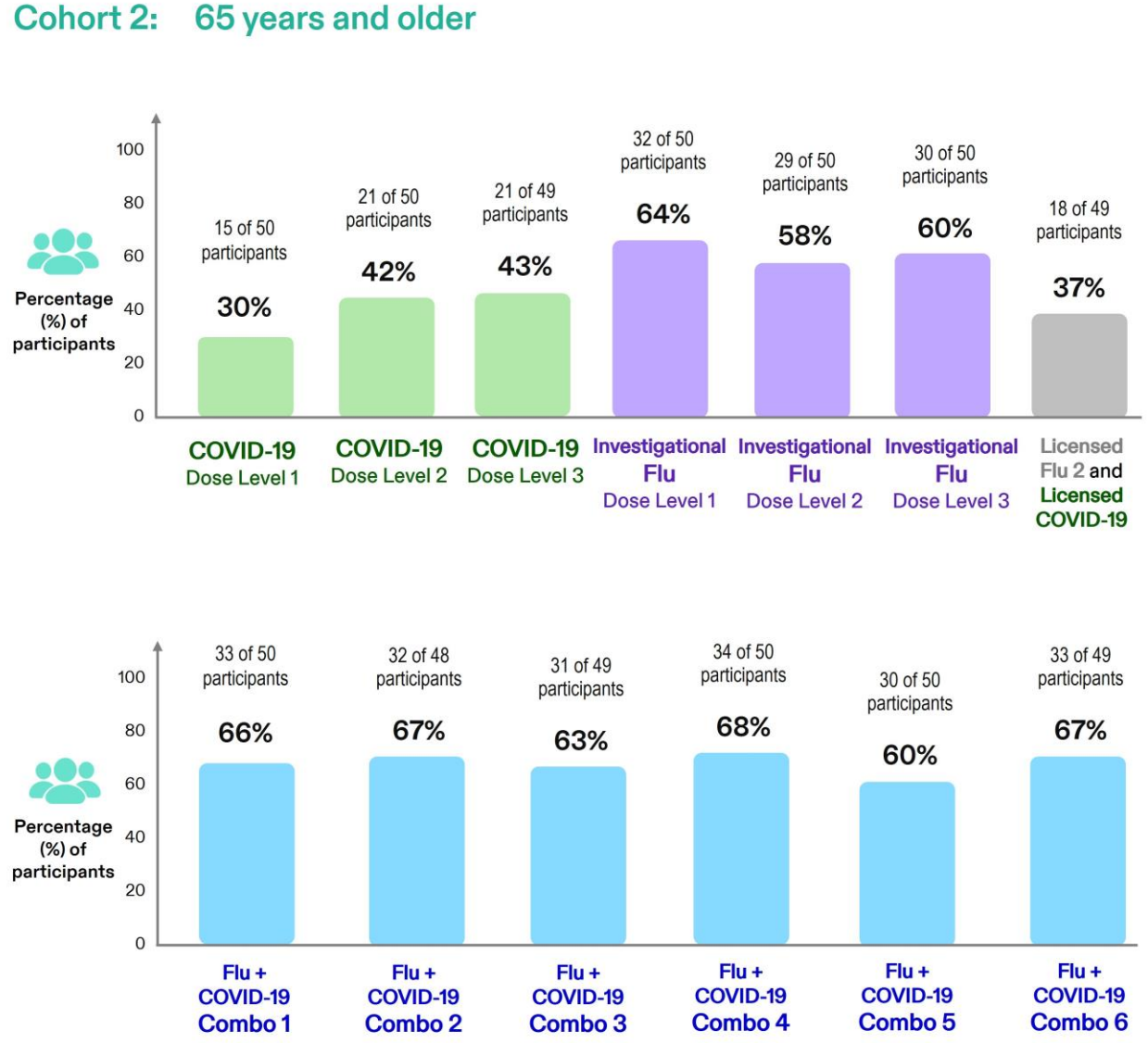
Figure 2 (Cohort 1) and Figure 3 (Cohort 2) show the number of participants who had local reactions within 7 days after vaccination.

Figure 2. How many participants in each vaccine group had any local reactions within 7 days after vaccination? - Cohort 1



The most common local reaction across all vaccine groups in Cohort 1 was pain at the injection site. Most local reactions were mild or moderate in severity.

Figure 3. How many participants in each vaccine group had any local reactions within 7 days after vaccination? – Cohort 2



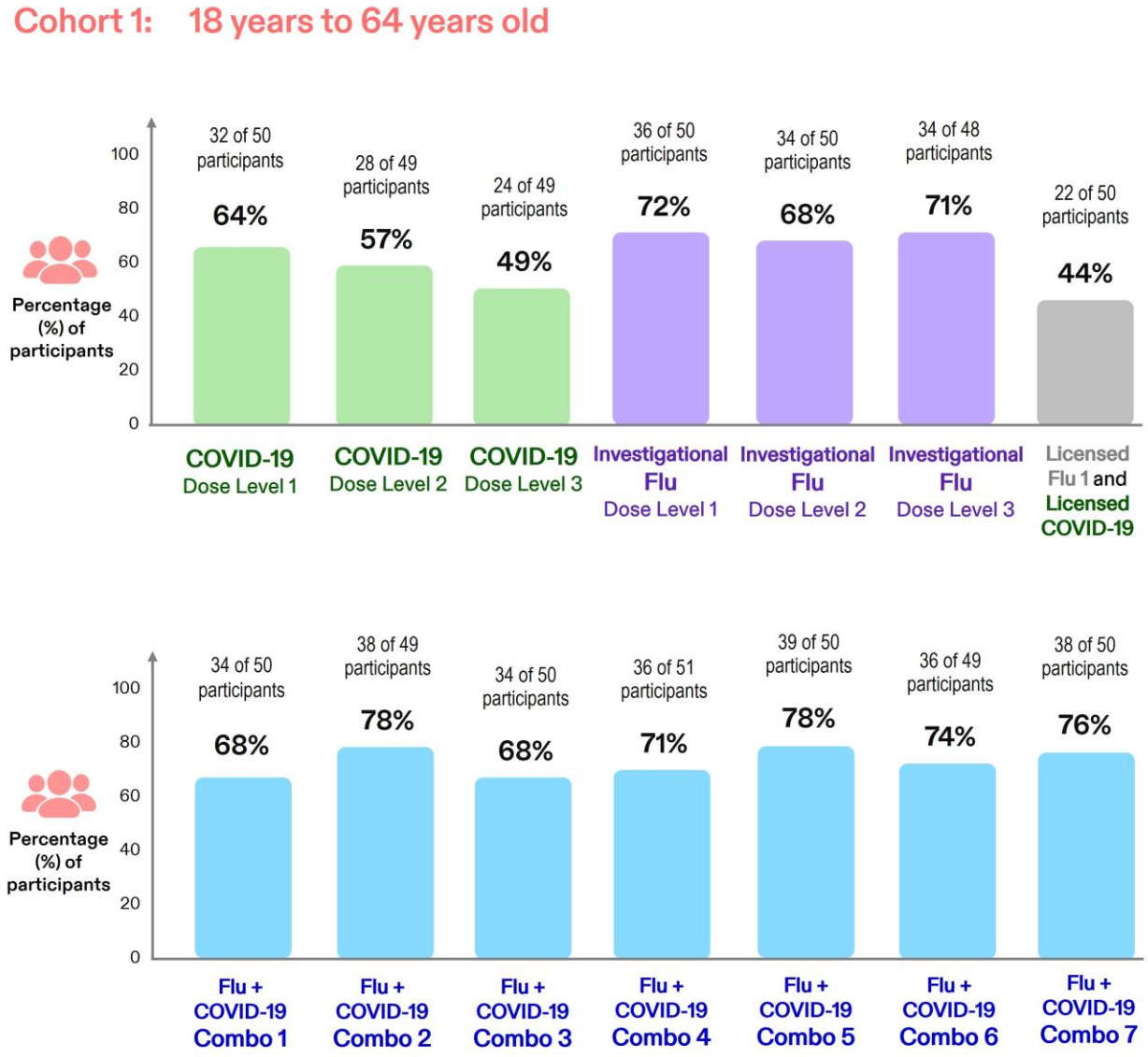
The most common local reaction across all vaccine groups in Cohort 2 was pain at the injection site. Most local reactions were mild or moderate in severity.

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

"**Systemic events**" are reactions that affect the whole body like fever, fatigue (tiredness), chills, vomiting, or diarrhea, or specific parts of the body like headache, new or worsened muscle pain, or new or worsened joint pain.

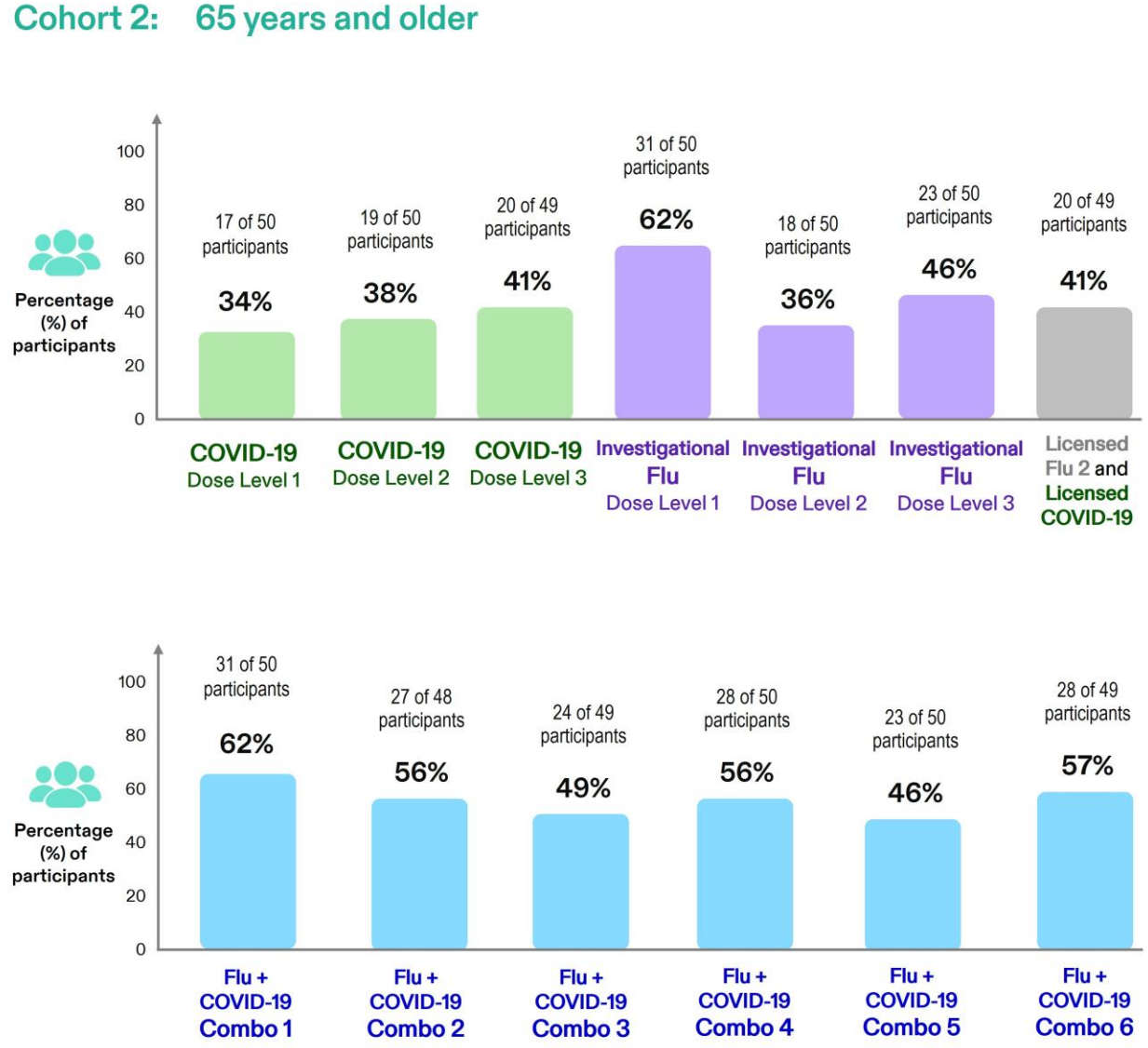
Figure 4 (Cohort 1) and Figure 5 (Cohort 2) show the number of participants who had systemic events within 7 days after vaccination.

Figure 4. How many participants in each vaccine group had any systemic events within 7 days after vaccination? – Cohort 1



The most common systemic event across all vaccine groups in Cohort 1 was fatigue (tiredness). Most systemic events were mild or moderate in severity.

Figure 5. How many participants in each vaccine group had any systemic events within 7 days after vaccination? – Cohort 2

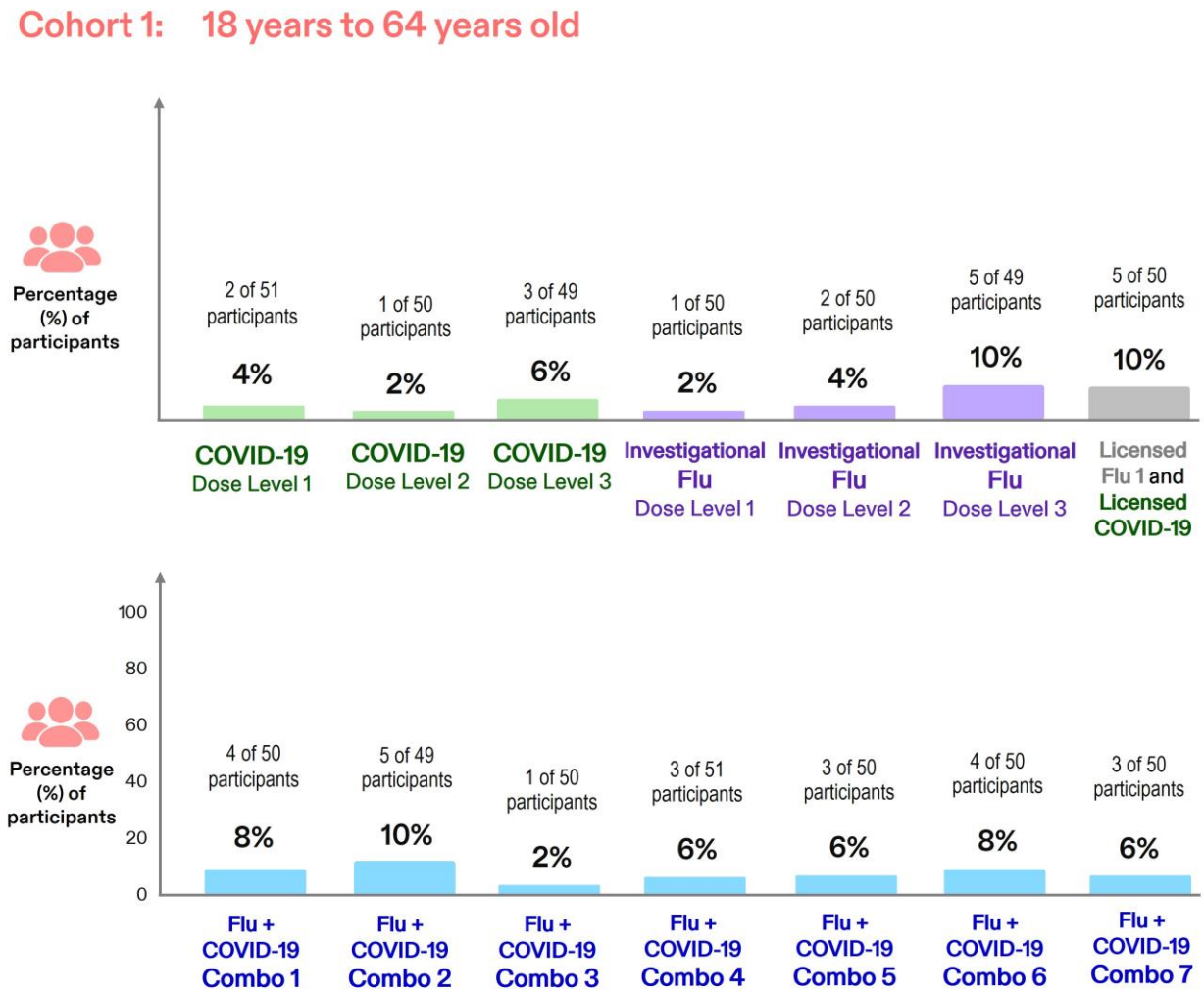


The most common systemic event across all vaccine groups in Cohort 2 was fatigue (tiredness). Most systemic events were mild or moderate in severity.

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

Figure 6 (Cohort 1) and Figure 7 (Cohort 2) show number of participants who had medical problems within 1 month after vaccination.

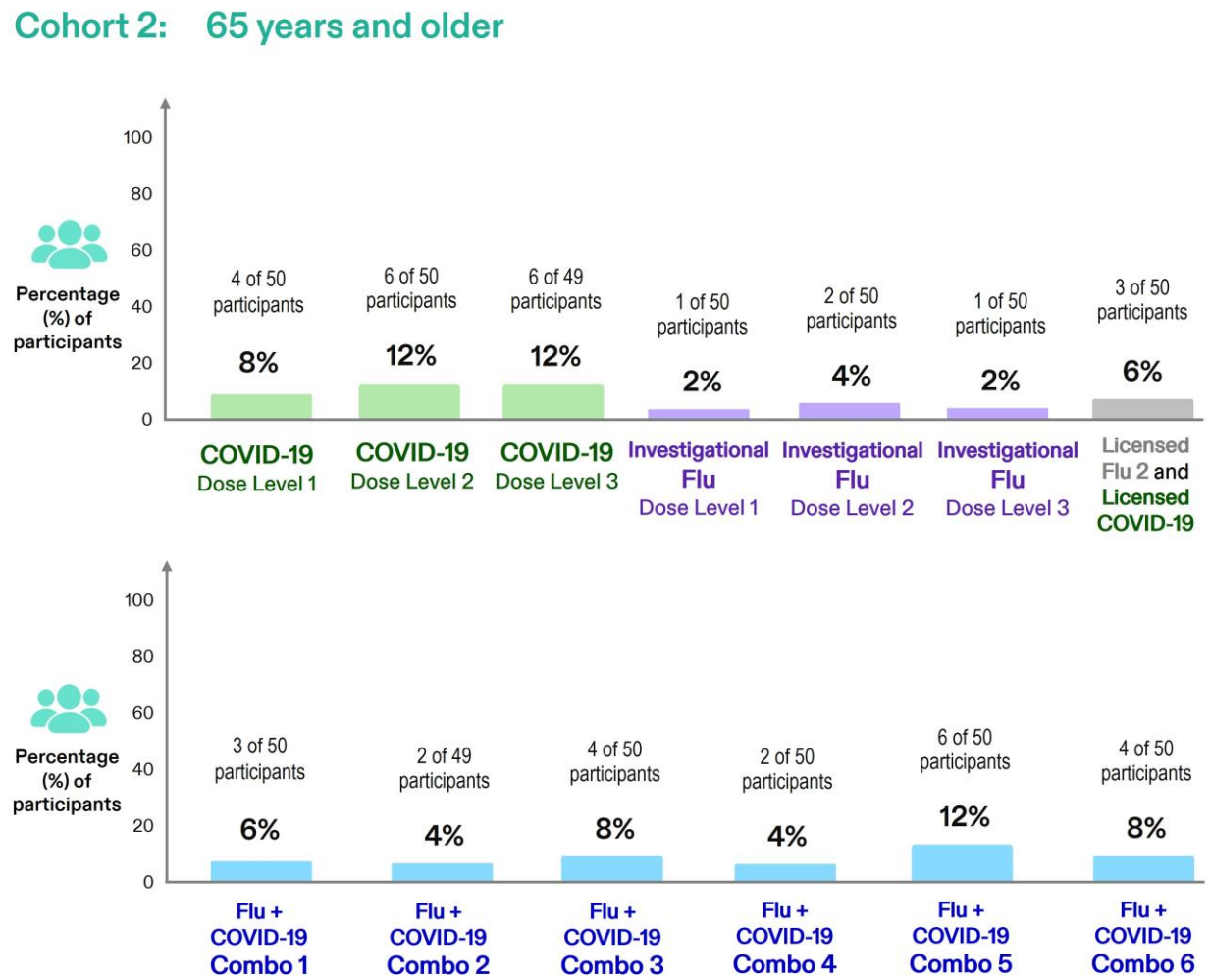
Figure 6. How many participants in each vaccine group had any medical problems within 1 month after vaccination? – Cohort 1



The most common medical problem within 1 month after vaccination in Cohort 1 – reported by at least 2 participants in any vaccine groups – was **nose and throat infection** seen in:

- 3 out of 49 participants (6%) who got flu plus COVID-19 Combo 2 vaccine
- 2 out of 51 participants (4%) who got flu plus COVID-19 Combo 4 vaccine
- 2 out of 50 participants (4%) who got licensed flu vaccine 1 and licensed COVID-19 vaccine

Figure 7. How many participants in each vaccine group had any medical problems within 1 month after vaccination? – Cohort 2



The most common medical problems within 1 month after vaccination in Cohort 2 – reported by at least 2 participants in any vaccine groups – were:

- **Runny nose** in 2 out of 50 participants (4%) who got COVID-19 Dose Level 2 vaccine
- **Inflammation of the nose and throat** in 2 out of 50 participants (4%) who got flu plus COVID-19 Combo 5 vaccine
- **Nose and throat infection** in 2 out of 50 participants (4%) who got flu plus COVID-19 Combo 5 vaccine

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?

In Cohort 1, a total of 4 out of 699 participants (less than 1%) had serious medical problems within 6 months after vaccination.

In Cohort 2, a total of 9 out of 648 participants (1%) had serious medical problems within 6 months after vaccination.

None of the individual serious medical problems in either cohort were reported by more than 1 participant. Researchers do not believe any of the serious medical problems reported by participants were related to the study vaccines.

A total of 2 participants died during the study. Both participants were in the 65 years of age and older group (Cohort 2). Researchers do not believe any of the deaths were 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 **C5261023**

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

www.clinicaltrials.gov	Use the study identifier **NCT06683352**

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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