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: Pfizer Inc.

Vaccine Studied: Abrysvo® (respiratory syncytial virus [RSV] stabilized prefusion F subunit vaccine), also called RSVpreF or PF-06928316

Protocol Number: C3671023 (Substudy B)

Dates of Study: 16 May 2023 to 18 March 2024

Title of this Study: A Study to Assess the Safety, Tolerability, and Immunogenicity of RSVpreF in Adults at High Risk of Severe RSV Disease (MONET) (Substudy B)

[Substudy B Final Analysis: A Phase 3 Protocol to Evaluate the Safety, Tolerability, and Immunogenicity of Respiratory Syncytial Virus (RSV) Prefusion F Subunit Vaccine in Adults at High Risk of Severe RSV Disease]

Date of this Report: 19 March 2025

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– Thank You –

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.

Why was this study done?

What is respiratory syncytial virus?

Respiratory syncytial [sin-SISH-ul] virus (RSV) is a common cause of respiratory infections. It may cause severe respiratory infections in older adults and those with weakened immune systems and long-term medical conditions that increase their risk of experiencing severe RSV disease or complications.

At the time of this report, there is no treatment for RSV disease. Current treatment plans mainly include treating RSV symptoms to make a person feel better.

What is RSV stabilized prefusion F subunit vaccine?

RSV stabilized prefusion F subunit vaccine (RSVpreF), also known as Abrysvo® or PF-06928316, is an injectable RSV vaccine that can help the body's immune system make antibodies (proteins) to protect against RSV. At the time this study began, RSVpreF was investigational, which means it was still being tested and had not been approved for use outside of research studies.

At the time of this report, health authorities in some countries have approved RSVpreF to prevent LRTD-RSV ("lower respiratory tract disease" caused by RSV) in adults. RSVpreF is also approved for use in pregnant people to protect their infants from LRTD-RSV.

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What was the purpose of this study?

The main purpose of this study was to learn if RSVpreF is safe and may produce immune responses against RSV in adults at high risk of severe RSV disease.

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.

The study was divided into 2 substudies: Substudy A and Substudy B, each with their own group of participants. This report only includes what happened in **Substudy B**. Results of **Substudy A** are discussed in a separate report.

Researchers wanted to know:

- **Can RSVpreF produce immune responses to protect against RSV disease in adults with weakened immune systems?**
- **What medical problems did participants have during the study?**

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What happened during the study?

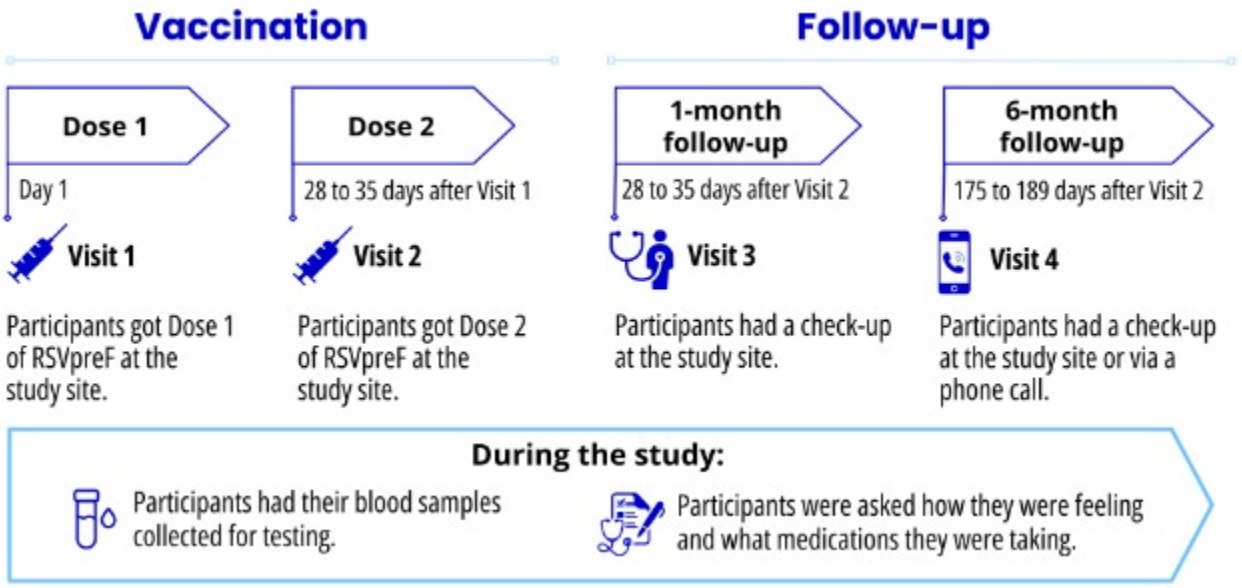
How was the study done?

Participants were divided into 2 age groups:

- 18 years through 59 years of age
- 60 years of age and older

Participants in each age group got 2 doses of RSVpreF in this study, with Dose 2 given 1 month after Dose 1. Figure 1 below shows how the study was done.

Figure 1. Study plan



This study was “open-label”, which means that the study participants and researchers knew that all participants got RSVpreF in this study.

Where did this study take place?

The Sponsor ran this study in the United States.

When did this study take place?

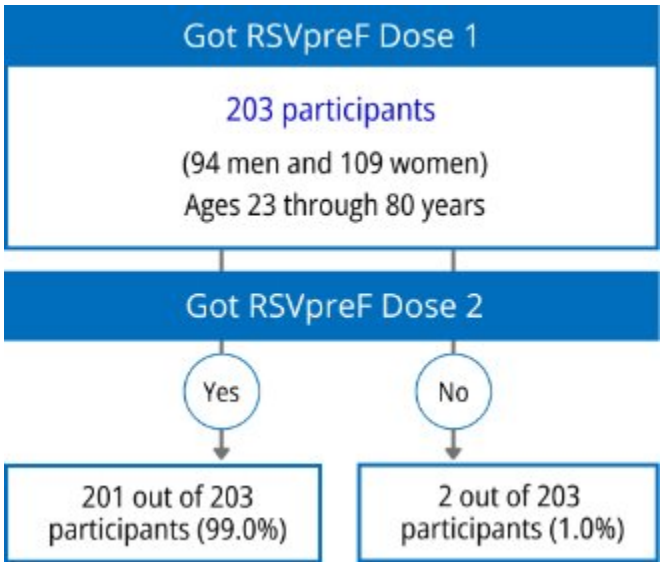
The study began on 16 May 2023 and ended on 18 March 2024.

Who participated in this study?

The study included adults 18 years of age and older who had certain medical conditions, or were being treated with medications, that would weaken their immune systems.

Figure 2 shows the number of participants who got vaccinated in the study.

Figure 2. Number of participants who got vaccinated



Of the 203 participants who got at least 1 dose of RSVpreF, 194 (95.6%) completed the study (completed the 6-month follow-up) and 9 (4.4%) did not complete the study. The most common reason as to why some participants did not finish the study was because they could not be contacted for follow-up checks.

How long did the study last?

Study participants were in the study for about 7 months. The entire study took about 10 months to complete. The study was completed as planned.

When the study ended in March 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?

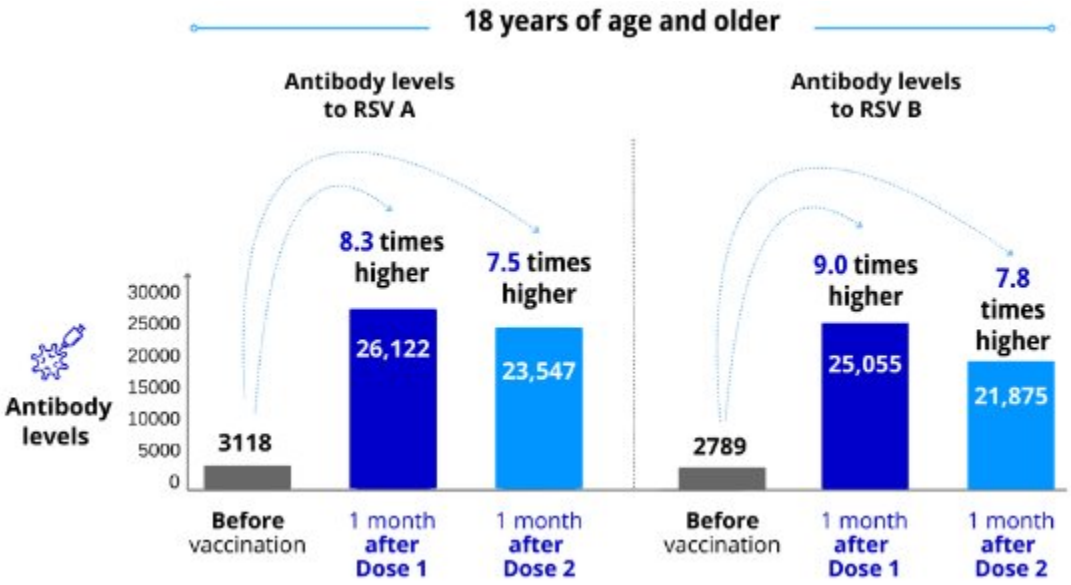
Can RSVpreF produce immune responses to protect against RSV disease in adults with weakened immune systems?

To answer the question:

Researchers measured the participants' **antibody levels** against the most common types of RSV – **RSV A** and **RSV B**. RSV A and RSV B often spread at the same time in the same place and can cause similar symptoms.

Figure 3 below shows the participants' antibody levels against RSV A and RSV B **before** and 1 month **after** each dose of RSVpreF. It also shows the average rise in antibodies from before to after each vaccination.

Figure 3. Antibody levels against RSV A and RSV B



As shown in Figure 3 above:

- The participants' **antibody levels** against RSV A and RSV B **increased** **after** each dose of RSVpreF compared to **before** vaccination.
- RSV A and RSV B antibodies, respectively, were:
  - **8.3 to 9.0** times higher at 1 month **after Dose 1** of RSVpreF
  - **7.5 to 7.8** times higher at 1 month **after Dose 2** of RSVpreF

The researchers have decided that these results are not likely due to chance.

Overall, study results showed that 1 dose of RSVpreF given to adult participants 18 years of age and older with weakened immune systems produced immune responses against RSV. A second dose of RSVpreF given 1 month after the first dose also produced immune responses against RSV, but it did not

further increase the immune responses produced by the first dose.

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 each dose of RSVpreF?

Injection site pain, redness, or swelling are called "**local reactions**".

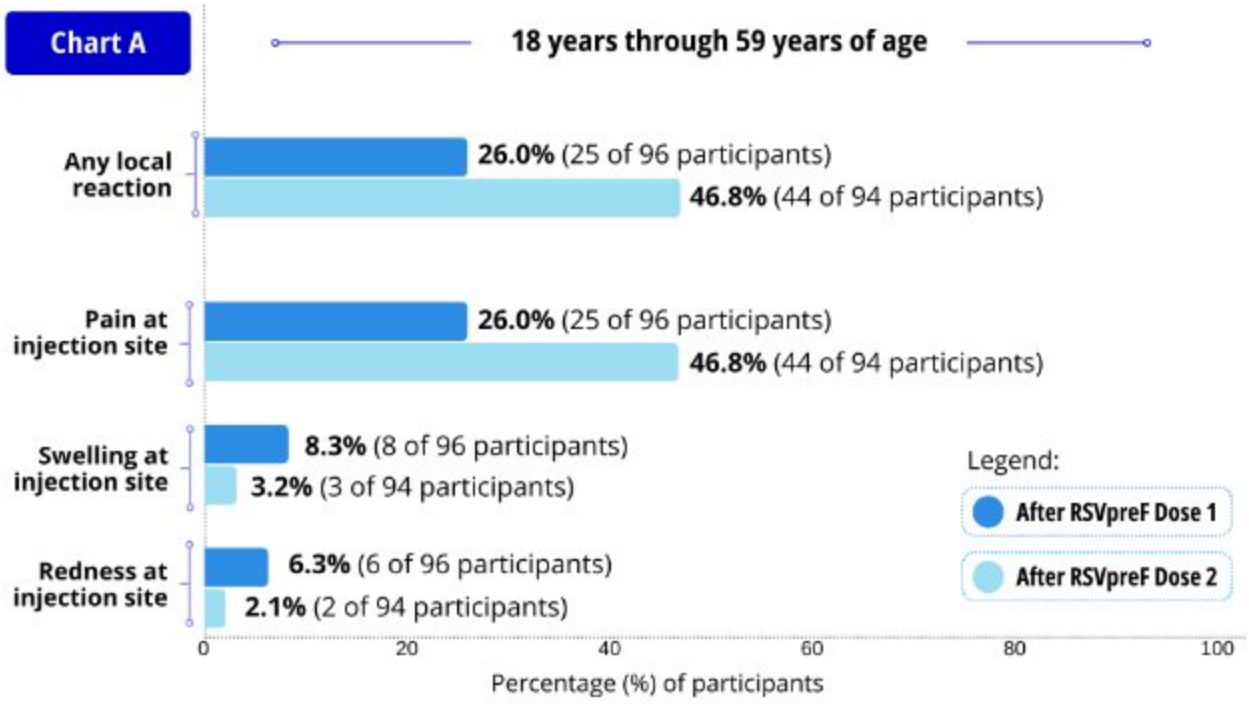
Reactions that affect the whole body like fever, nausea, diarrhea, vomiting, headache, tiredness, muscle pain, and joint pain are called "**systemic events**".

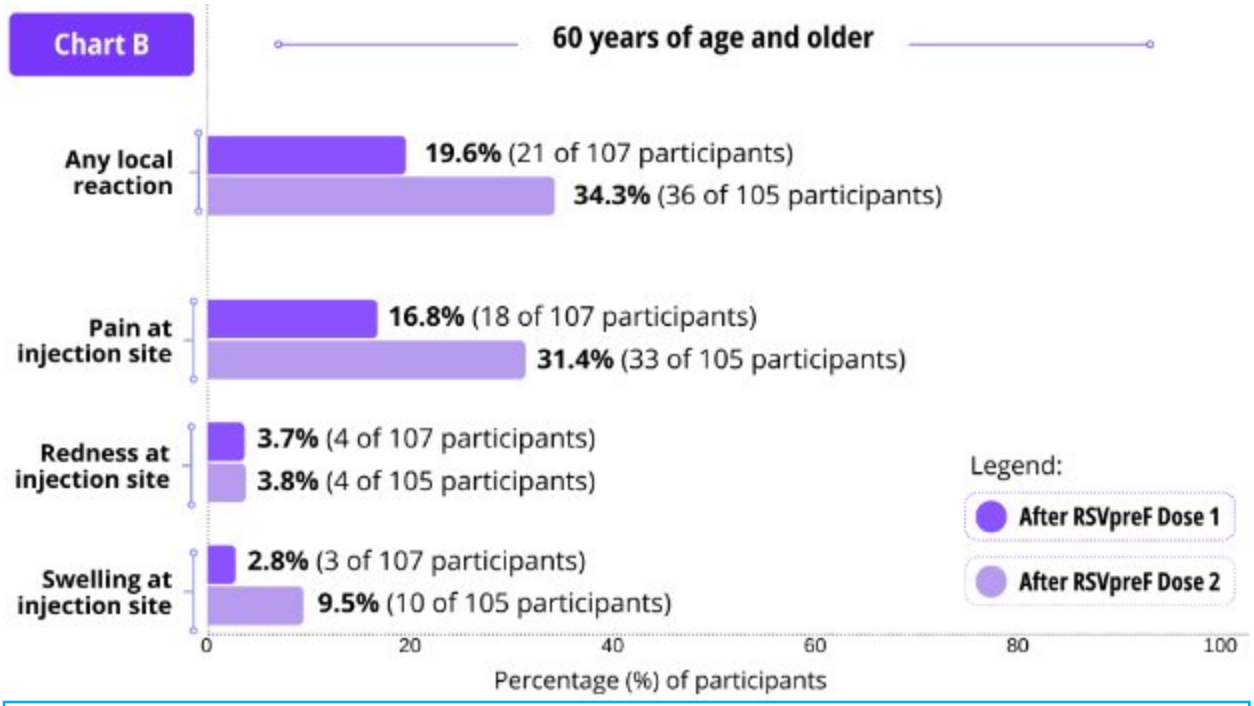
Figure 4 and Figure 5 show the answer to the question. In each figure:

- **Chart A** shows the results of participants 18 years through 59 years of age

- **Chart B** shows the results of participants 60 years of age and older

Figure 4. Number of participants with local reactions (injection site pain, swelling, and redness) within 7 days after each dose of RSVpreF

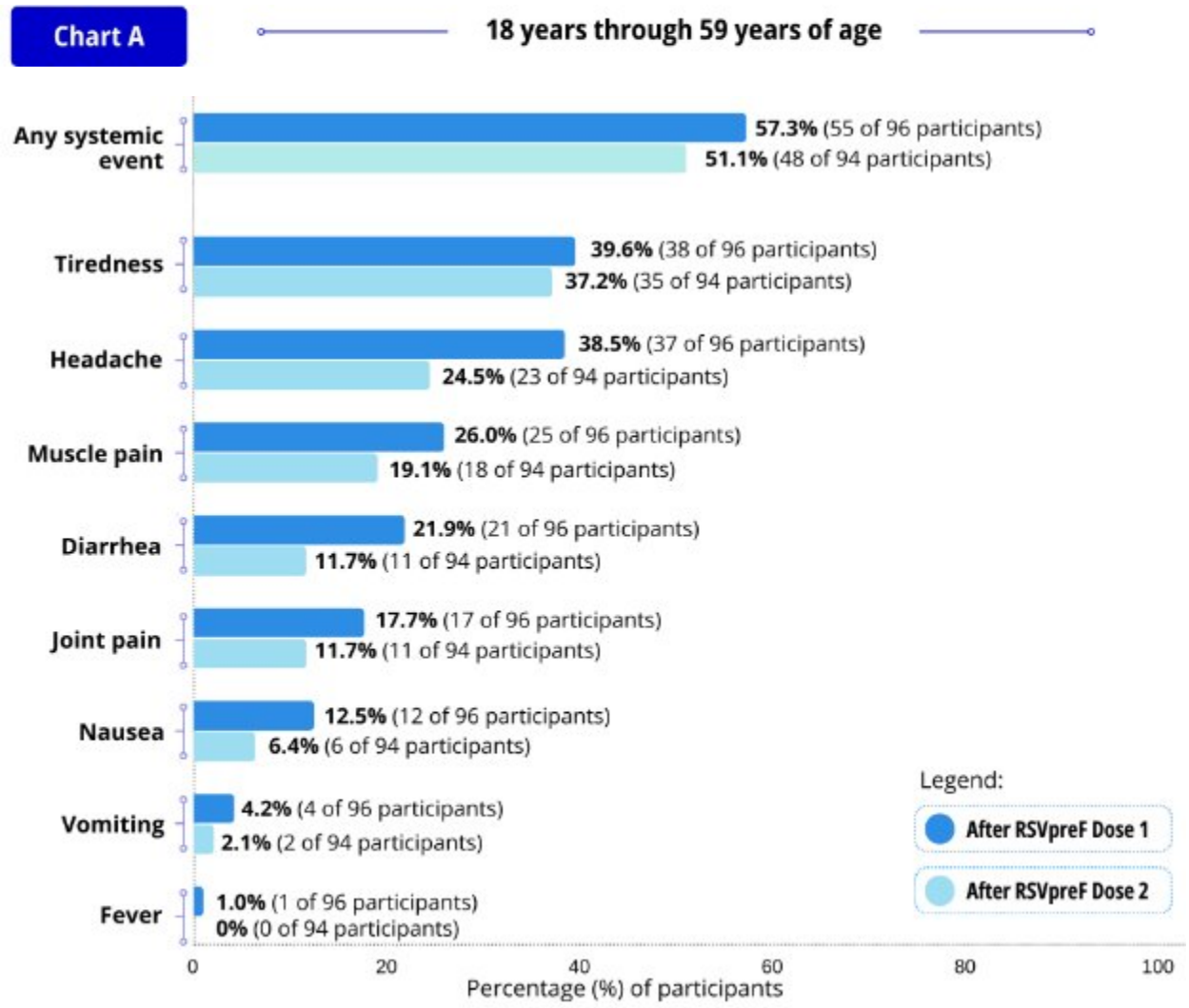


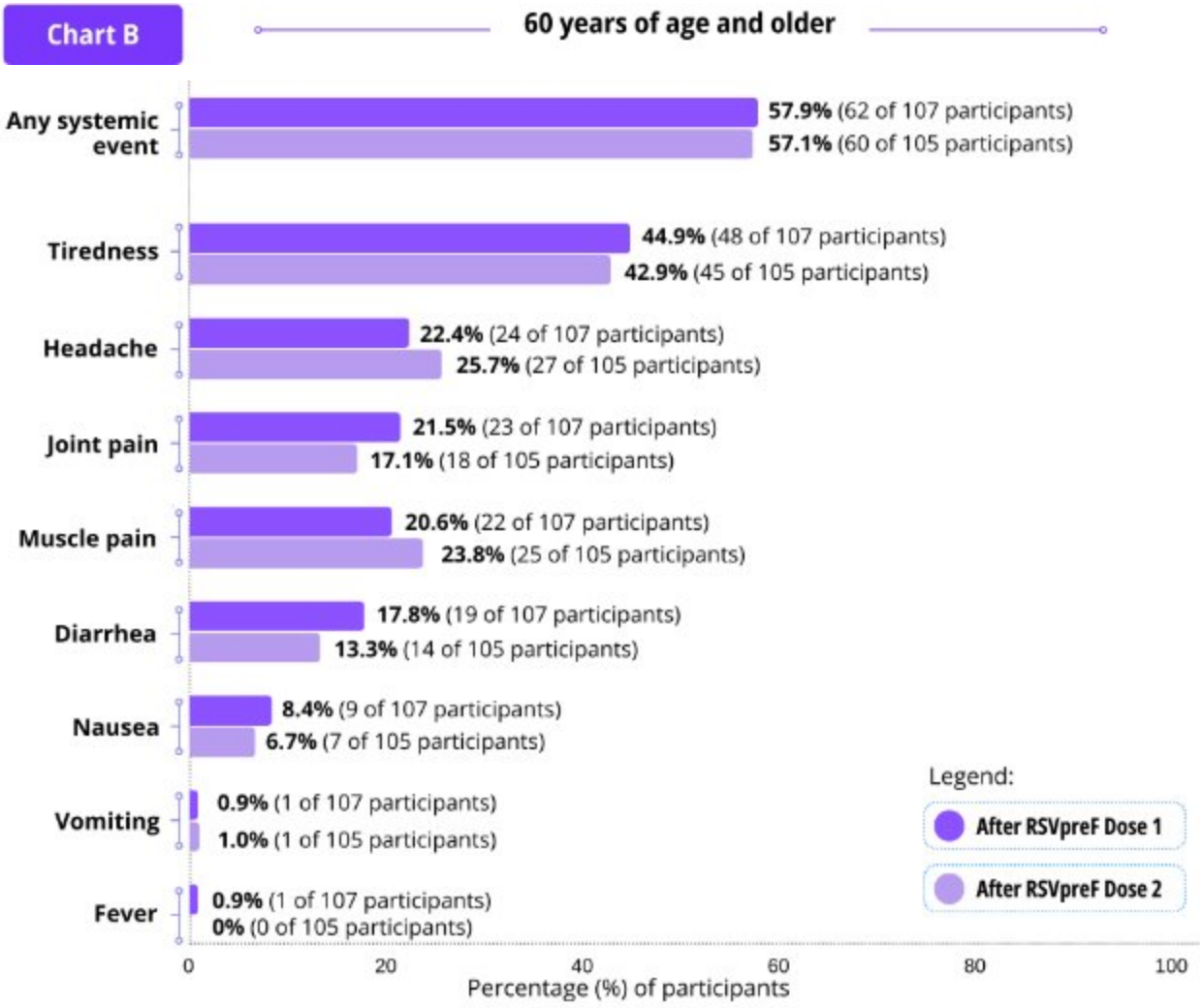


As shown in Figure 4 above, in both age groups, there were generally more participants who had local reactions after Dose 2 of RSVpreF than

after Dose 1. The most common local reaction in both age groups after each dose was **pain at the injection site**.

Figure 5. Number of participants with systemic events (tiredness, headache, muscle pain, diarrhea, joint pain, nausea, vomiting, and fever) within 7 days after each dose of RSVpreF





As shown in Figure 5 above, in both age groups, there were similar numbers of participants who had systemic events after each dose of RSVpreF. The most common systemic event in both age groups after each dose was **tiredness**.

How many participants had medical problems from Dose 1 through 1 month after Dose 2 of RSVpreF?

From Dose 1 through 1 month after Dose 2 of RSVpreF, medical problems were reported by:

- 13 out of 96 participants (13.5%) 18 years through 59 years of age
- 24 out of 107 participants (22.4%) 60 years of age and older

A total of 2 participants left the study because of medical problems, both in the 18 years through 59 years of age group.

The most common medical problems – those reported by 4 or more participants – are listed below.

- **Infection of the nose, sinuses, or throat** was reported by:
  - 2 out of 96 participants (2.1%) 18 years through 59 years of age
  - 3 out of 107 participants (2.8%) 60 years of age and older
- **Urinary tract infection**, or UTI
  - 2 out of 96 participants (2.1%) 18 years through 59 years of age
  - 2 out of 107 participants (1.9%) 60 years of age and older
- "**Cellulitis**" (skin infection caused by bacteria) was reported by:
  - 1 out of 96 participants (1.0%) 18 years through 59 years of age
  - 3 out of 107 participants (2.8%) 60 years of age and older
- **Fall** was reported by:
  - 1 out of 96 participants (1.0%) 18 years through 59 years of age
  - 3 out of 107 participants (2.8%) 60 years of age and older

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 during the study?

During the study, serious medical problems were reported by:

- 7 out of 96 participants (7.3%) 18 years through 59 years of age
- 15 out of 107 participants (14.0%) 60 years of age and older

All serious medical problems were reported by 1 participant each, except for “deep vein thrombosis” (a blood clot in the deep vein). This serious medical problem was reported by 2 participants in total, 1 in each age group.

Researchers believe that none of the serious medical problems during the study were caused by RSVpreF.

No participants died during the study.

How many participants were diagnosed with a new long-term medical condition during the study?

During the study, new long-term medical conditions were reported by:

- 2 out of 96 participants (2.1%) 18 years through 59 years of age
- 7 out of 107 participants (6.5%) 60 years of age and older

Each new long-term medical condition recorded during the study was reported only once (by 1 participant).

One (1) participant in the 60 years of age and older group had a new long-term medical condition that a researcher considered may have been caused by RSVpreF. This participant developed “atrial flutter”, a condition where the heart beats too quickly.

Researchers believe that the other new long-term medical conditions were not caused by RSVpreF.

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 **C3671023 (Substudy B)**

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

www.clinicaltrials.gov	Use the study identifier **NCT05842967**

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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