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: PF-06928316 (Abrysvo®)

Protocol Number: C3671058

Dates of Study: 04 April 2025 to 30 September 2025

Title of this Study: A Study to Learn About an RSV Vaccine Given Together with a Shingles Vaccine in Adults (PISSARRO)

[A Phase 3, Multicenter, Parallel-Group, Open-Label Study to Evaluate the Safety, Tolerability, and Immunogenicity of Respiratory Syncytial Virus Prefusion F Subunit Vaccine When Coadministered With Herpes Zoster Subunit Vaccine in Adults ≥ 50 Years of Age]

Date of this Report: 22 September 2026

– Thank You –

090177e1a70c2fdf\Approved\Approved On: 22-Sep-2026 20:58 (GMT)

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.

090177e1a70c2fdf\Approved\Approved On: 22-Sep-2026 20:58 (GMT)

Pfizer

Why was this study done?

What is Respiratory Syncytial Virus infection?

Respiratory syncytial virus (RSV) is a virus that can cause an infection with symptoms that resemble a bad cold, such as cough, fever, sore throat, and runny nose. This infection can be serious in older adults and in those with certain health conditions. People with a serious RSV infection may have trouble breathing and may need to be hospitalized.

What is Shingles?

Shingles (also known as herpes zoster) is a painful skin rash caused by the varicella zoster virus, the virus that causes chickenpox. Shingles can develop in people years after they had chickenpox. The risk of developing shingles is highest in older adults and in people with weak immunity. Immunity is the body's ability to fight infections.

What are Abrysvo® and Shingrix®?

Abrysvo® (uh-BREEZ-voh), also known as RSV prefusion F vaccine or RSVpreF, helps protect against RSV infection. It is approved for people aged 60 years and older and for adults who are at increased risk of RSV infection.
Shingrix® (SHIN-griks) is a herpes zoster vaccine that helps protect against shingles. It is approved for people aged 50 years and older and for adults who are at increased risk of developing shingles.

In this study, Abrysvo was given as an injection into the upper arm muscle of the dominant arm (arm used most often), while Shingrix was given as an injection into the upper arm muscle of the non-dominant arm (arm used less often). In this report, both Abrysvo and Shingrix are referred to as study vaccines.

What was the purpose of this study?

090177e1a70c2fdf\Approved\Approved On: 22-Sep-2026 20:58 (GMT)

The main purpose of this study was to compare the safety and effects of Abrysvo and Shingrix when given together or separately at different times.

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 pain, redness, and swelling 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, tiredness, headache, vomiting, feeling sick, diarrhea, 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 effects researchers assessed the "immune response" after the participants received the vaccines.



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.
- **Immune response** refers to how your body recognizes and defends itself against bacteria, viruses, and substances that may be harmful.

090177e1a70c2fdf\Approved\Approved On: 22-Sep-2026 20:58 (GMT)

Researchers wanted to know:

- **One month after vaccination, were the immune responses to Abrysvo and Shingrix similar when the vaccines were given together compared with when they were given separately?**
- **How many participants had local reactions and systemic events within 7 days after each vaccination?**
- **How many participants had medical problems within 1 month after their last dose of the study vaccine, or serious medical problems at any time during the study?**

What happened during the study?

How was the study done?

The entire study had 5 scheduled visits — Visit 1 to 5.

At Visit 1, researchers identified the participants who could take part in the study. At the same visit, participants were assigned to one of two groups by chance (like flipping a coin). This process is called “randomization”.

- Group 1: Participants received Abrysvo and Shingrix (Dose 1) together at Visit 1, followed by Shingrix (Dose 2) at Visit 3.
- Group 2: Participants received Shingrix (Dose 1) at Visit 1, followed by Abrysvo at Visit 2 and Shingrix (Dose 2), at Visit 3.

Both the participants and the researchers knew which group each participant was in. This is known as an “open-label” study. Each participant was given an

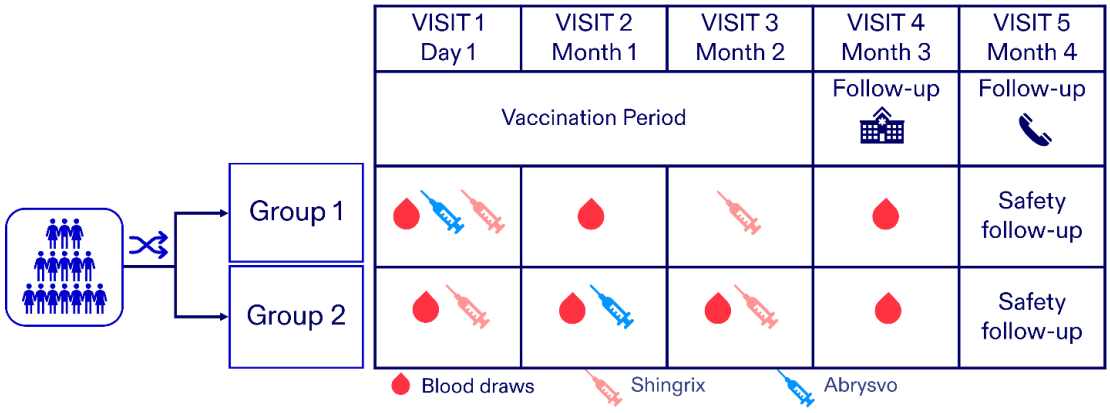
090177e1a70c2fdf\Approved\Approved On: 22-Sep-2026 20:58 (GMT)

electronic diary to record details of any local reactions or systemic events. This information was collected for about 7 days after each vaccination.

Researchers collected blood samples from participants at several times during the study to measure the antibody levels in the blood. They then compared the results of participants in each vaccine group. They also checked the participants' health during the study and asked them how they were feeling.

At Visit 4 (about 1 month after the last vaccination), researchers met with participants at the study site to measure antibody levels in their blood and to look for any medical problems. About 1 month later, at Visit 5 (end of study visit), researchers contacted participants by phone to ask about any serious medical problems. **Figure 1** below shows the study design.

Figure 1: Study design



Where did this study take place?

The Sponsor ran this study at 26 locations in the United States and Puerto Rico.

When did this study take place?

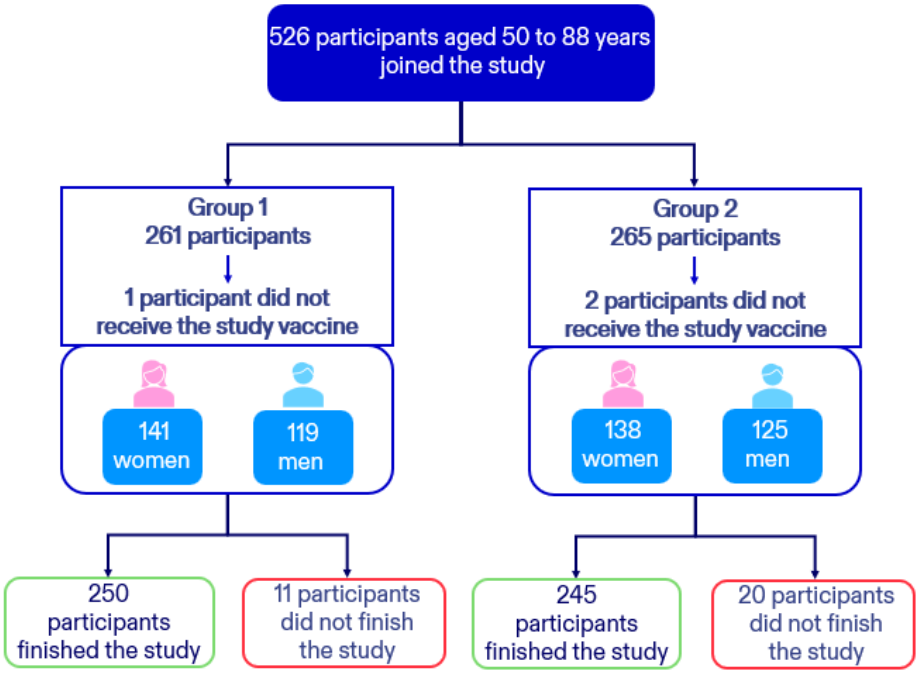
It began on 04 April 2025 and ended on 30 September 2025.

Who participated in this study?

090177e1a70c2fdf\Approved\Approved On: 22-Sep-2026 20:58 (GMT)

The study included participants aged 50 years or older. Participants were either healthy or had stable medical conditions. Health of the participants was determined by their medical history, physical examination, and clinical decision of the study doctor. **Figure 2** shows the participants' details.

Figure 2: Participants' details



The most common reasons participants did not finish the study were not returning to the study site for follow-up visits and choosing to leave the study. Other reasons included not following the study procedures, the study doctor deciding it was best for a participant to leave the study, experiencing medical problems, or death.

How long did the study last?

Study participants were in the study for about 4 months. The entire study took a little over 5 and a half months to complete.

090177e1a70c2fdf\Approved\Approved On: 22-Sep-2026 20:58 (GMT)

When the study ended in September 2025, 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?

One month after vaccination, were the immune responses to Abrysvo and Shingrix similar when the vaccines were given together compared with when they were given separately?

A total of 523 participants received at least 1 dose of the study vaccines. Of these, 491 participants were evaluable for RSV immune response analyses and 482 for shingles immune response analyses. The remaining participants were not evaluable for immune response analyses because they either did not receive the study vaccine or missed scheduled blood sample collection.

Researchers found that RSV and shingles vaccine antibody levels were similar in both groups. This means that participants who received the Abrysvo and Shingrix vaccines together had similar immune responses as those who received the two vaccines separately.

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

The percentage of participants who reported local reactions was generally similar in both groups. However, these reactions occurred more often with Shingrix than with Abrysvo. The most frequently reported local reaction was pain at the injection site, followed by swelling and redness. Local reactions were mostly mild or moderate in severity for both the vaccine groups. **Figure 3** shows the number of participants with local reactions in each vaccine group.

Figure 3: Percentage and number of participants with local reactions

090177e1a70c2fdf\Approved\Approved On: 22-Sep-2026 20:58 (GMT)

Systemic event	Group 1 Abrysvo	Group 1 Shingrix (dose 1)	Group1 Shingrix (dose 2)	Group 2 Abrysvo	Group 2 Shingrix (dose 1)	Group 2 Shingrix (dose 2)
Pain at the injection site	23% 59 out of 253 participants	69% 174 out of 253 participants	65% 157 out of 241 participants	17% 41 out of 243 participants	65% 168 out of 260 participants	61% 151 out of 247 participants
Swelling	9% 23 out of 253 participants	21% 53 out of 253 participants	18% 43 out of 241 participants	3% 8 out of 243 participants	14% 35 out of 260 participants	16% 39 out of 247 participants
Redness	9% 22 out of 253 participants	23% 58 out of 253 participants	17% 40 out of 241 participants	3% 6 out of 243 participants	13% 34 out of 260 participants	13% 33 out of 247 participants

The most frequently reported systemic event in both Group 1 and Group 2 was tiredness. Systemic events were mostly mild or moderate in severity for both the vaccine groups.

Figure 4 on the following page shows the number of participants with systemic events in each vaccine group.

090177e1a70c2fdf\Approved\Approved On: 22-Sep-2026 20:58 (GMT)

Figure 4: Percentage and number of participants with systemic events

Systemic event	Group 1 Abrysvo + Shingrix (dose 1)	Group 1 Shingrix (dose 2)	Group 2 Abrysvo alone	Group 2 Shingrix (dose 1)	Group 2 Shingrix (dose 2)
Tiredness	44% 113 out of 256 participants	38% 92 out of 244 participants	24% 57 out of 243 participants	47% 121 out of 260 participants	37% 92 out of 247 participants
Headache	30% 77 out of 256 participants	29% 70 out of 244 participants	14% 34 out of 243 participants	26% 67 out of 260 participants	26% 63 out of 247 participants
Muscle pain	27% 70 out of 256 participants	26% 64 out of 244 participants	10% 23 out of 243 participants	25% 64 out of 260 participants	26% 64 out of 247 participants
Joint pain	21% 55 out of 256 participants	20% 48 out of 244 participants	10% 24 out of 243 participants	19% 49 out of 260 participants	19% 47 out of 247 participants
Feeling sick	11% 28 out of 256 participants	11% 26 out of 244 participants	5% 10 out of 243 participants	10% 25 out of 260 participants	9% 23 out of 247 participants
Diarrhea	11% 29 out of 256 participants	8% 19 out of 244 participants	9% 21 out of 243 participants	11% 28 out of 260 participants	10% 24 out of 247 participants
Fever	3% 8 out of 256 participants	3% 8 out of 244 participants	1% 2 out of 243 participants	2% 5 out of 260 participants	5% 12 out of 247 participants
Vomiting	1% 3 out of 256 participants	3% 6 out of 244 participants	<1% 1 out of 243 participants	2% 5 out of 260 participants	0% 0 out of 247 participants

090177e1a70c2fdfApproved On: 22-Sep-2026 20:58 (GMT)

Pfizer

Based on these results, the researchers have decided that the results are not likely the result of chance.

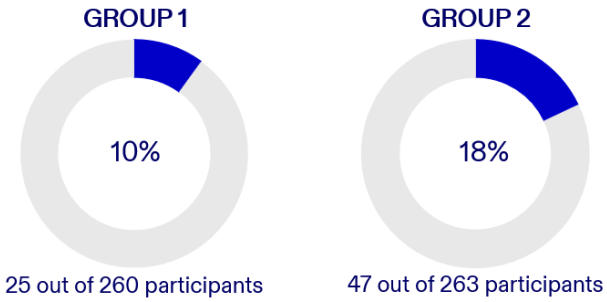
This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

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 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.

Figure 5 shows the number of participants who had at least 1 medical problem within 1 month after the last vaccination. No participants left the study because of medical problems.

Figure 5: Number (%) of participants with at least 1 medical problem



090177e1a70c2fdf\Approved\Approved On: 22-Sep-2026 20:58 (GMT)

Pfizer

The most common medical problems – those reported by more than 2 participants in either group – were inflammation of the nose and throat seen in 4 out of 263 participants (2%) in Group 2, swelling and pain in the joints seen in 3 out of 263 participants (1%) in Group 2, and a fall reported by 3 out of 260 participants (1%) in Group 1 and 2 out of 263 participants (1%) in Group 2.

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.

Ten (10) out of 260 participants (4%) in Group 1 and 6 out of 263 participants (2%) in Group 2 had serious medical problems.

Two (2) participants in Group 1 had a serious medical problem of kidney damage. No other serious medical problem was reported by more than 1 participant in Group 1. None of the serious medical problems were reported by more than 1 participant in Group 2.

One (1) participant from Group 1 died during the study.

Researchers do not believe any of the serious medical problems reported by participants, or the death of the participant in Group 1, were related to the study vaccines.

090177e1a70c2fdf\Approved\Approved On: 22-Sep-2026 20:58 (GMT)

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 **C3671058**

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

www.clinicaltrials.gov

Use the study identifier **NCT06890416**

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!

090177e1a70c2fdf\Approved\Approved On: 22-Sep-2026 20:58 (GMT)

Pfizer