



Clinical Study Results

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 medication 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.

Medicine(s) Studied: Respiratory Syncytial Virus (RSV) Stabilized Prefusion F Subunit Vaccine (RSVpreF; PF-06928316)

Protocol Number: C3671003

Dates of Study: 07 August 2019 to 30 September 2021

Title of this Study: Safety of a Respiratory Syncytial Virus (RSV) Vaccine in Pregnant Women and their Infants

[Final Report: A Phase 2b, Randomized, Placebo-Controlled, Observer-Blinded Trial to Evaluate the Safety, Tolerability, and Immunogenicity of a Respiratory Syncytial Virus (RSV) Vaccine in Pregnant Women 18 Through 49 Years of Age and Their Infants]

Date(s) of this Report: 26 May 2022

— Thank You —

If you and your child participated in this study, Pfizer, the Sponsor, would like to thank you both for your participation.

This summary will describe the study results. If you have any questions about the study or the results, please contact the doctor or staff at your study site.

Why was this study done?

What is respiratory syncytial virus?

Respiratory syncytial virus (RSV) is a virus that can cause an infection in people of all ages, usually with signs or symptoms that are similar to a bad cold, such as cough, runny nose, and fever. However, RSV infection can be very serious in infants and young children as well as in older adults and in people who already have chronic medical problems. People with serious RSV infection may have trouble breathing and may need to be hospitalized.

What is the respiratory syncytial virus stabilized prefusion F subunit vaccine, or RSVpreF?

This study is about a vaccine called the respiratory syncytial virus stabilized prefusion F subunit vaccine, or “RSVpreF”. A vaccine is used to help the body’s immune system fight infections and prevent disease.

RSVpreF is an investigational vaccine, which means that it has not been approved for general use and it is not yet known if it will protect against disease caused by RSV. The RSVpreF used in this study contains either the RSVpreF vaccine on its own or RSVpreF with aluminum hydroxide. Aluminum is an ingredient that is sometimes included in vaccines to help boost the body’s response to the vaccine.

The Sponsor of this study is developing RSVpreF for use in pregnant women. After vaccination, the mother’s immune system will make antibodies, which are special disease fighting proteins. Pregnant women naturally pass antibodies to their infants while they are still in the womb. These antibodies can then help protect infants from disease after they are born. Pregnant women vaccinated with RSVpreF may be able to pass RSV-fighting antibodies to their infants using this natural process. If so, this may help to prevent infections caused by RSV in infants.

What was the purpose of this study?

The researchers did this study to mainly learn more about the safety of the RSVpreF vaccine. They did this by looking at “local reactions” and “systemic events.” Local reactions include redness, swelling, and pain where the vaccine was given. Systemic events include fever, fatigue, headache, nausea, muscle pain, joint pain, vomiting, and diarrhea. Both local reactions and systemic events are reactions that a person can have to a vaccine. The researchers also wanted to find out more about the safety of the RSVpreF vaccine and see if participants vaccinated with RSVpreF developed antibodies.

Researchers wanted to know if participants vaccinated with RSVpreF had:

- Any local reactions or systemic events within 7 days after vaccination?
- Any medical problems within 1 month after vaccination?
 - Any serious medical problems during the study (eg, life-threatening, needs hospital care, or causes lasting problems)?
- Any medical problems during the study that prompted the participant to see a doctor?
- Any complications during pregnancy and/or childbirth?
 - Antibodies made in response to the RSVpreF vaccine?

What happened during the study?

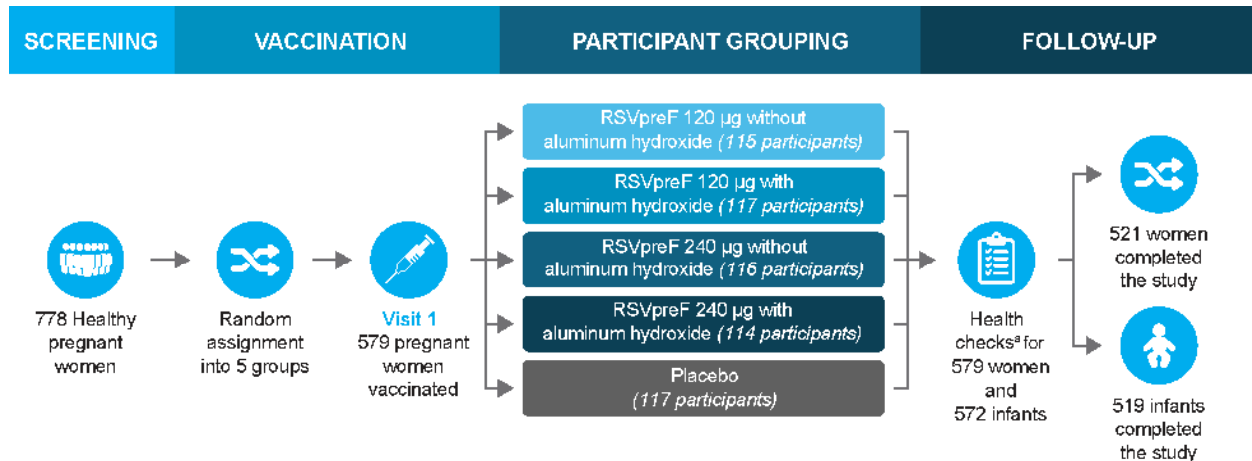
How was the study done?

Researchers tested the RSVpreF vaccine on groups of pregnant women to find out if participants given this vaccine had local reactions or systemic events within 7 days after vaccination. The researchers also wanted to know about medical problems within 1 month after vaccination, if there were any complications during pregnancy and/or childbirth, if there were any serious medical problems or medical problems that prompted the participant to see a doctor during the study.

Researchers also wanted to see what happened if participants were given a placebo vaccine instead of the RSVpreF vaccine. A placebo vaccine does not have any active ingredients in it, but it is given as an injection in the same way as the RSVpreF vaccine. The RSVpreF vaccine was given as an injection at 2 different doses. These doses were either 120 micrograms (written as 120 µg) or 240 micrograms (written as 240 µg). Some of the RSVpreF vaccines also contained aluminum hydroxide. Blood samples were also collected during the study to see if participants developed RSVpreF antibodies after the vaccination. The researchers then compared the results between participants vaccinated with RSVpreF and placebo.

Participants were assigned to each group by chance alone. Only the person who prepared the injections knew what vaccine each pregnant woman was given. This is known as an “observer blinded” study and this is done to make sure that the study results were not influenced in any way. The participants and researchers did not know who was given each type of RSVpreF vaccine and who was given placebo.

During the study, participants were asked to record information about local reactions and systemic events in a study diary. The health of participants and their infants, including collecting information about new medical problems, was checked regularly by staff at the study center throughout the study.



* Study visits for the vaccinated women were 2 weeks and 1 month after vaccination, after childbirth, and then at 1, 6 and 12 months after childbirth. Infant health checks were conducted when the infant was 1, 2, 4, 6, and 12 months of age.

Where did this study take place?

The Sponsor ran this study at 61 locations in 4 countries (Argentina, Chile, South Africa, and the United States).

When did this study take place?

It began 07 August 2019 and ended 30 September 2021.

Who participated in this study?

The study included participants who were healthy pregnant women and their infants once born.

- A total of 579 women participated and were vaccinated
- A total of 572 infants were born to women in the study
- All women were between the ages of 18 and 42 years
- It was planned that infants would stay in the study from birth to 12 months of age

Of the 778 participants who were screened to see if they could join the study, 581 women were randomized, and 579 were given a single vaccination; 572 infants were born during the study. Out of the original 579 participants, there were

521 women and 519 infants who completed the study. Most of the women participants and their infants who did not finish the study were lost to follow-up or no longer wanted to continue in the study. Lost to follow-up means the study center was not able to contact the participants to check on their health or the health of the infant.

How long did the study last?

Study participants were in the study for up to 17 months (depending on when they were vaccinated during the pregnancy and for approximately 12 months after childbirth). The entire study took almost 26 months or a little longer than 2 years to complete.

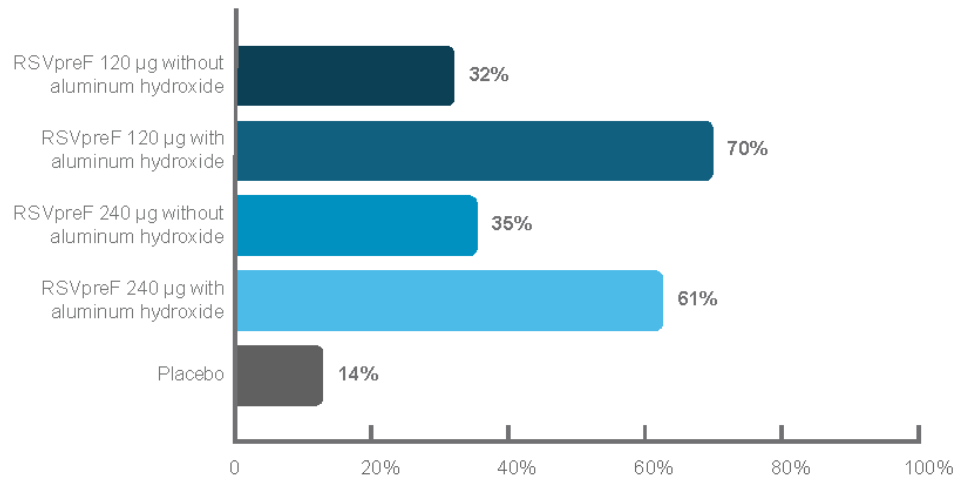
When the study ended in September 2021, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

What were the results of the study?

What percentage of participants had local reactions within 7 days after vaccination?

Overall, local reactions, which included redness, swelling, and pain where the vaccine was given, were reported more frequently in participants given RSVpreF than placebo: 228 out of 459 (50%) participants given RSVpreF had local reactions while 16 out of 117 (14%) given placebo reported local reactions. These local reactions were seen in between 32% and 70% of participants given RSVpreF compared to 14% given placebo as shown in the following figure.

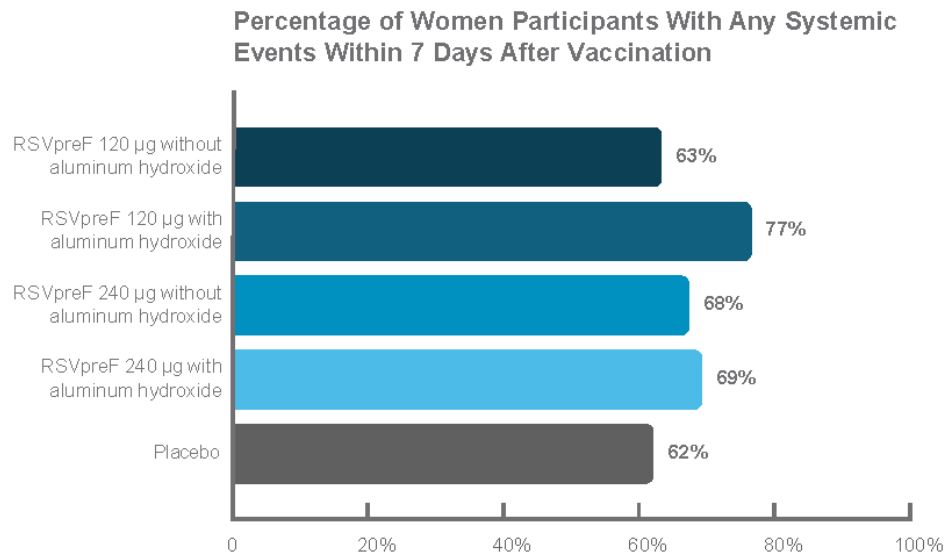
Percentage of Women Participants With Any Local Reaction Within 7 Days After Vaccination



Note: Diary data for local reactions were not available for 3 participants: 1 participant given RSVpreF 120 µg without aluminum hydroxide and 2 participants given RSVpreF 120 µg with aluminum hydroxide).

What percentage of participants had systemic events within 7 days after vaccination?

Overall, systemic events, which included fever, fatigue, headache, nausea, muscle pain, joint pain, vomiting, and diarrhea, were reported by a similar number of participants given RSVpreF and placebo: 319 out of 459 (69%) participants given RSVpreF had systemic events while 73 out of 117 (62%) given placebo reported systemic events. These systemic events were seen in between 63% and 77% of participants given RSVpreF compared to 62% given placebo as shown in the following figure.



Note: Diary data for systemic events were not available for 3 participants: 1 participant given RSVpreF 120 µg without aluminum hydroxide and 2 participants given RSVpreF 120 µg with aluminum hydroxide).

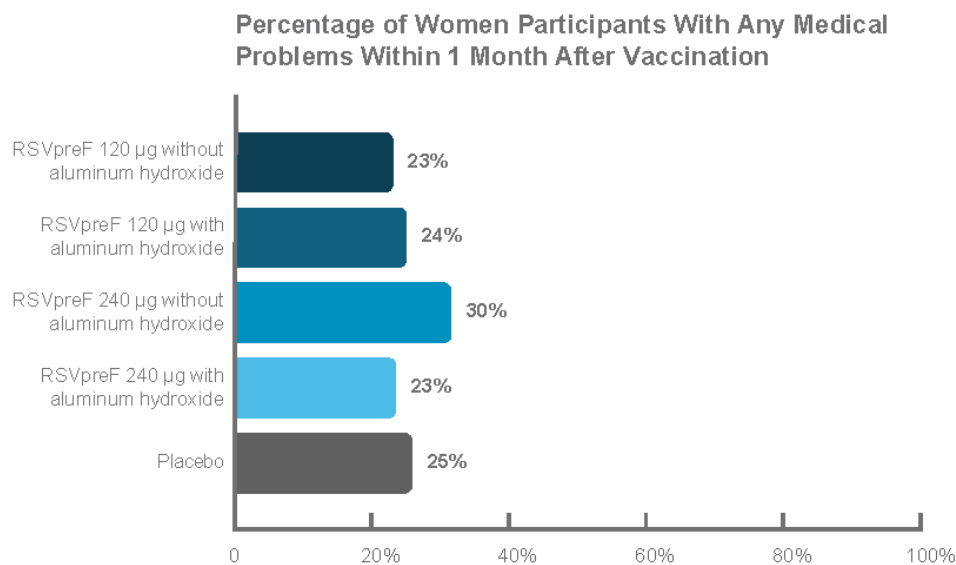
This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies with the RSVpreF vaccine may have different results.

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 treatment 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 medication might have on a participant.

The number and percentage of women participants with medical problems after vaccination was similar between participants given the RSVpreF and placebo (see

figure below). There were 144 out of 579 (25%) participants in this study who had at least 1 medical problem.



The most common medical problems – those reported by more than 3% of women participants – are described below.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were commonly reported during the study. All medical problems reported by more than 3% of participants are listed.
- The **2nd** column tells how many of the 115 participants given RSVpreF 120 µg without aluminum hydroxide reported each medical problem. Next to this number is the percentage of the 115 participants given RSVpreF 120 µg without aluminum hydroxide who reported the medical problem.

- The **3rd** column tells how many of the 117 participants given RSVpreF 120 µg with aluminum hydroxide reported each medical problem. Next to this number is the percentage of the 117 participants given RSVpreF 120 µg with aluminum hydroxide who reported the medical problem.
- The **4th** column tells how many of the 116 participants given RSVpreF 240 µg without aluminum hydroxide reported each medical problem. Next to this number is the percentage of the 116 participants given RSVpreF 240 µg without aluminum hydroxide who reported the medical problem.
- The **5th** column tells how many of the 114 participants given RSVpreF 240 µg with aluminum hydroxide reported each medical problem. Next to this number is the percentage of the 114 participants given RSVpreF 240 µg with aluminum hydroxide who reported the medical problem.
- The **6th** column tells how many of the 117 participants given placebo reported each medical problem. Next to this number is the percentage of the 117 participants given placebo who reported the medical problem.
- Using these instructions, you can see that 4 out of the 116 participants given RSVpreF 240 µg without aluminum hydroxide reported stomach pain. There were no other participants in the other RSVpreF groups (115, 117, and 114 participants) or the placebo group (117 participants) who reported stomach pain.

Table 1. Commonly reported medical problems by study participants within 1 month after vaccination

Medical Problem	RSVpreF 120 µg Without Aluminum Hydroxide (115 Participants)	RSVpreF 120 µg With Aluminum Hydroxide (117 Participants)	RSVpreF 240 µg Without Aluminum Hydroxide (116 Participants)	RSVpreF 240 µg With Aluminum Hydroxide (114 Participants)	Placebo (117 Participants)
Stomach pain	0 out of 115 participants (0%)	0 out of 117 participants (0%)	4 out of 116 participants (3%)	0 out of 114 participants (0%)	0 out of 117 participants (0%)
Nausea	1 out of 115 participants (1%)	1 out of 117 participants (1%)	4 out of 116 participants (3%)	1 out of 114 participants (1%)	1 out of 117 participants (1%)
Premature childbirth	2 out of 115 participants (2%)	2 out of 117 participants (2%)	4 out of 116 participants (3%)	1 out of 114 participants (1%)	2 out of 117 participants (2%)

The medical problems seen in infants were events that are commonly seen from birth through 12 months and were similar between groups.

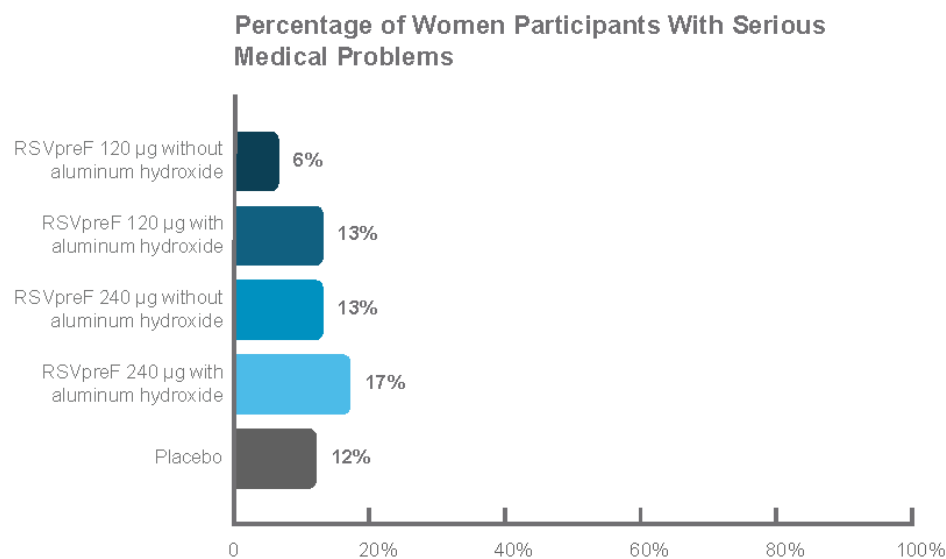
None of the participants left the study because of medical problems within 1 month after vaccination. There was a single infant who left the study because of severe heart and lung problems. This infant’s mother had received the placebo vaccine.

There was only a single medical problem of dizziness that was considered related to the vaccination in the women participants (1 out of a total of 144 medical problems reported, or less than 1%). None of the medical problems reported by infant participants were considered related to the vaccination.

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.

In total, 70 out of 579 (12%) participants had serious medical problems during this study. The serious medical problems were similar between participants given RSVpreF and placebo. These serious medical problems were mostly like the problems that can happen during pregnancy. None of the serious medical problems were thought to be related to the study vaccines. One (1) of the women had an infant who was stillborn during the study. This woman had been given the placebo vaccine.

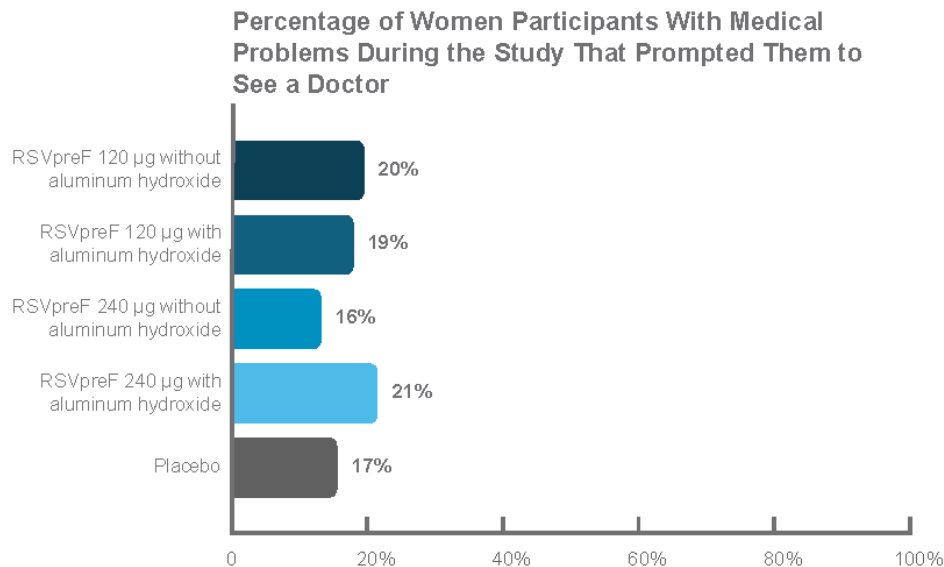


The serious medical problems seen in infants were events that are commonly seen from birth through 12 months and were similar between groups.

None of the women or infant participants died during this study.

What percentage of participants had medical problems during the study that prompted the participant to see a doctor?

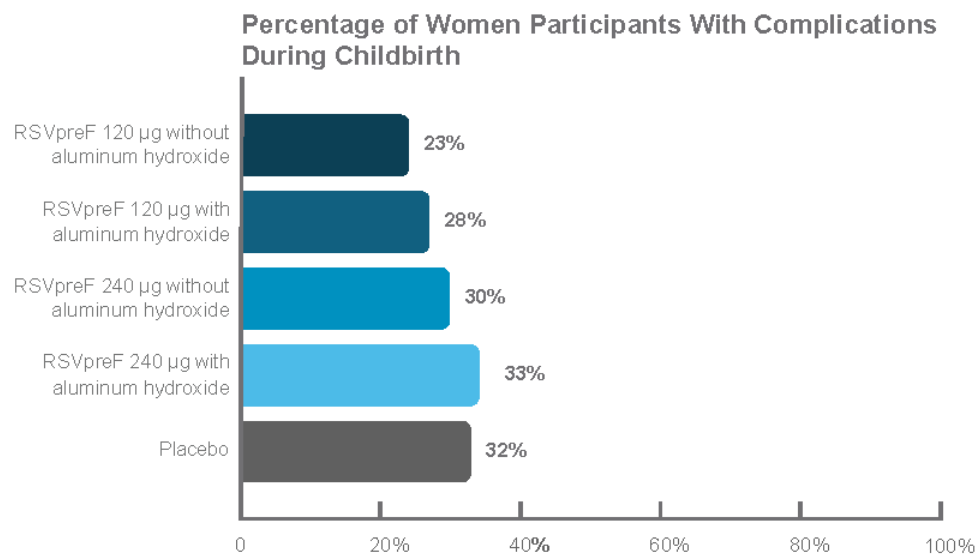
In total, 107 out of 579 (18%) participants had medical problems during the study that prompted them to see a doctor. This was similar between participants given RSVpreF and placebo as shown below:



For infants, medical problems during the study that prompted the participant to see a doctor were similar between groups.

How many participants complications during pregnancy and/or childbirth?

Most participants had no problems during their pregnancy and had their infants via the vaginal route at the expected time (ie, about 39 to 40 weeks of pregnancy). Complications during childbirth were seen in similar numbers of women participants given the RSVpreF vaccine and placebo. Specific birth complications in infants were similar between groups.



Did participants in the study develop antibodies after vaccination with RSVpreF?

By looking at antibody levels in blood, the researchers could see that women participants vaccinated with RSVpreF developed antibodies against RSV. The amount of antibody detected was well above the level seen before vaccination and remained high for around 6 months after childbirth.

Antibodies against RSV were also identified in blood samples collected from the infants born to women who were vaccinated with the RSVpreF vaccine.

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.clinicaltrials.gov

www.pfizer.com/research/

[research_clinical_trials/trial_results](http://www.pfizer.com/research/clinical_trials/trial_results)

Use the study identifier **NCT04032093**

Use the protocol number C3671003

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 and your child 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!