# CLINICAL TRIAL 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 medicine 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:** 20-valent Pneumococcal Conjugate Vaccine (diphtheria $CRM_{197}$ protein), Compound Number: PF-06482077

**Protocol Number:** B7471008

**Dates of Trial:** 14 February 2019 to 9 October 2019

**Title of this Trial:** Trial to Evaluate the Safety and Immunogenicity of 3 Lots of 20-valent Pneumococcal Conjugate Vaccine in Pneumococcal Vaccine-Naïve Adults

[Final Report: A Phase 3, Randomized, Double-Blind Trial to Evaluate the Safety and Immunogenicity of 3 Lots of 20-valent Pneumococcal Conjugate Vaccine in Pneumococcal Vaccine–Naïve Adults 18 Through 49 Years of Age]

**Date of this Report:** 26 August 2020

# *– Thank You –*

Pfizer, the Sponsor, would like to thank you for your participation in this clinical trial and provide you a summary of results representing everyone who participated. If you have any questions about the study or results, please contact the doctor or staff at your study site.

# WHY WAS THIS STUDY DONE?

*Streptococcus pneumoniae* is a bacteria that can cause serious diseases, including infections of the lung (pneumonia), brain lining (meningitis), blood (bacteremia), or ear (otitis). These infections may be very serious in young children and older adults. *Streptococcus pneumoniae* is also known as *S. pneumoniae.* There are 100 types of *S. pneumoniae.*

This study is about a vaccine called the "20-valent pneumococcal conjugate vaccine", or 20vPnC. A vaccine is used to help prevent infection by helping the body to fight off germs. 20vPnC may help to prevent infections caused by *S. pneumoniae.* It is called "20-valent" because 20vPnC prevents 20 of the most common types of *S. pneumoniae.*

20vPnC 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 *S. pneumoniae,* although studies are ongoing to assess how well 20vPnC works.

After a vaccine is injected into a person's body, the body responds to help fight infections and prevent diseases. The response to vaccines includes making "antibodies", which are proteins that fight infections and help to prevent diseases.

In the United States, the "13-valent pneumococcal conjugate vaccine", or 13vPnC, is currently approved for preventing *S. pneumoniae* diseases in children and adults. 13vPnC is made up of components to prevent diseases caused by 13 types of *S. pneumoniae.* 20vPnC has the same components found in 13vPnC, plus 7 additional components that may widen protection.

The purpose of this study was to learn about the safety of 20vPnC and about the body's antibody response to 3 different batches, or "lots", of 20vPnC. These 3 different lots contained the same components and were made in the same way. The researchers needed to compare 3 different lots of vaccine to be sure that the vaccines worked the same way and were safe to use.

To learn about the body's antibody response, researchers asked this question:

- Did 20vPnC produce similar antibody responses in participants when it was manufactured in 3 different lots?

To answer this question, the researchers measured the amount of antibodies in participants' blood 1 month after being vaccinated.

To learn about the safety of 20vPnC, researchers asked these questions:

- What was the percentage of participants that had redness, swelling, or pain at the injection site within 10 days after being vaccinated with 20vPnC?
- What was the percentage of participants that had fever, headache, tiredness, muscle pain, or joint pain within 7 days after being vaccinated with 20vPnC?
- What medical problems did participants have within 1 month after being vaccinated with 20vPnC?
- Did participants have any serious medical problems or any newly diagnosed chronic medical problems within 6 months after being vaccinated with 20vPnC?

## WHAT HAPPENED DURING THE STUDY?

This study compared 3 groups of participants to learn about the body's antibody response to 20vPnC. The information from the combined 20vPnC groups and a "control group" that received 13vPnC were used to learn about safety. A control group is a group of participants that do not receive the vaccine being studied. In this study, 13vPnC was used as the control because it is commonly used for preventing *S. pneumoniae* diseases.

Participants were checked (screened) to make sure they were a good fit for the study. This study included adult men and women who:

- Were between the ages of 18 and 49 years
- Were considered to be healthy or with stable chronic disease by the study doctors

- Did not have a disease or take medicine that would be associated with a weakened immune system
- Had never received any vaccine for *S. pneumoniae*

This was a "randomized" study, which means that participants were assigned to groups based on chance alone. Randomization is done to make the groups similar so that differences in antibody response or safety are most likely due to the different vaccines people received.

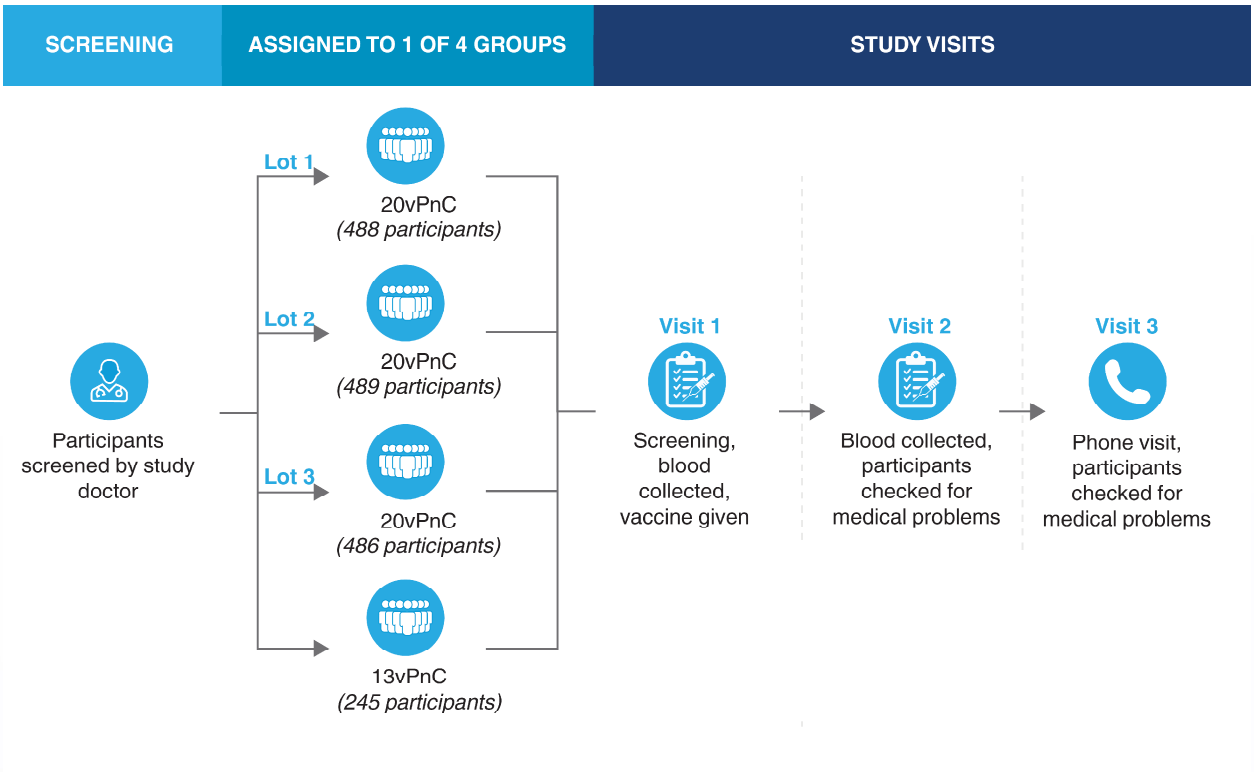
This study was also "double-blinded". This means that participants and study staff members who administered the vaccine did not know who was given which vaccine. This was done to make sure that the study results were not influenced in any way.

Participants who were a good fit for the study were assigned by chance alone to receive 1 of 4 vaccines:

- 20vPnC, Lot 1 (488 participants)
- 20vPnC, Lot 2 (489 participants)
- 20vPnC, Lot 3 (486 participants)
- 13vPnC (245 participants)

Participants were expected to participate in 3 study visits. At the first visit, blood samples were collected, and the participants received the vaccine. The second visit was done about 1 month after the first visit. Blood samples were collected, and participants were checked for any medical problems. The third visit was done over the phone at the end of the study, and participants were asked about any medical problems.

The figure on the following page shows what happened during the study.




While participants were in this study for about 6 months, the entire study took about 9 months to complete since not all participants entered the study at the same time. The Sponsor ran this study at 21 locations in the United States. It began 14 February 2019 and ended 9 October 2019. 593 men (35%) and 1115 women (65%) participated. All participants were between the ages of 18 and 49 years.

Of the 1708 participants who joined the study and received vaccine, 1635 (96%) finished it. A total of 73 participants (4%) left the study early by their choice or because a doctor decided it was best for them to stop the study.

Throughout the course of the study, the Sponsor reviewed the data. When the study ended in October 2019 and after antibody testing was completed, the Sponsor then created a report of the results. This is a summary of that report.

# WHAT WERE THE RESULTS OF THE STUDY?

## Did 20vPnC produce similar antibody responses in participants when it was manufactured in 3 different lots?

To answer this question, the researchers measured the amount of antibodies in participants' blood 1 month after being vaccinated. They looked to see if the amount of antibodies that the body produced for each of the 20 vaccine components was similar in participants who received vaccines from Lot 1, Lot 2, and Lot 3.

The researchers found that antibody levels for each of the 20 vaccine components were similar in participants who received vaccines from Lot 1, Lot 2, and Lot 3. Based on these results, the researchers have decided that the results are not likely the result of chance. These results indicate that the Sponsor can produce 20vPnC consistently so that antibody levels do not vary from one batch to the next.

These are just some of the main findings of the study, and more information may be available at the website listed at the end of this summary.

# 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 study vaccine or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By looking at medical problems across many treatment groups in many studies, doctors try to understand what the side effects of an experimental drug (in this case experimental vaccine) might be.

## What was the percentage of participants that had redness, swelling, or pain at the injection site within 10 days after being vaccinated with 20vPnC?

The percentage of participants with redness, swelling, or pain at the injection site within 10 days after being vaccinated was similar for those receiving a dose of 20vPnC or 13vPnC. The table below shows the number of participants with these reactions.

| Participants With Redness, Swelling, or Pain at Injection Site Within 10 Days After Being Vaccinated | | |
|---|---|---|
| | 20vPnC (1456 Participants) | 13vPnC (243 Participants) |
| Pain at injection site | 1146 (79%) | 184 (76%) |
| Swelling at injection site | 124 (9%) | 21 (9%) |
| Redness at injection site | 102 (7%) | 15 (6%) |

## What was the percentage of participants that had fever, headache, tiredness, muscle pain, or joint pain within 7 days after being vaccinated with 20vPnC?

The percentage of participants with fever, headache, tiredness, muscle pain, or joint pain within 7 days after being vaccinated was similar for each vaccine group. The table on the following page shows the number of participants with these reactions.

| Percentage of Participants With Fever, Headache, Tiredness, Muscle Pain, or Joint Pain Within 7 Days After Being Vaccinated | | |
|---|---|---|
| | 20vPnC (1456 Participants) | 13vPnC (243 Participants) |
| Muscle pain | 904 (62%) | 147 (60%) |
| Tiredness | 693 (48%) | 106 (44%) |
| Headache | 527 (36%) | 92 (38%) |
| Joint pain | 245 (17%) | 34 (14%) |
| Fever | 18 (1%) | 2 (1%) |

## What medical problems did participants have within 1 month after being vaccinated with 20vPnC?

113 out of 1708 (7%) participants in this study had at least 1 new or worsening medical problem within 1 month after being vaccinated, including 100 out of 1463 participants (7%) who received 20vPnC and 13 out of 245 participants (5%) who received 13vPnC. A total of 7 participants (less than 1%) had a medical problem that the doctor thought was related to the study vaccine, including 5 participants (less than 1%) who received 20vPnC and 2 participants (1%) who received 13vPnC. The other related medical problems happened in 1 participant each. No participants left the study because of one of these medical problems.

# WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

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

## Did participants have any serious medical problems or any newly diagnosed chronic medical problems within 6 months after being vaccinated with 20vPnC?

10 out of 1463 participants who received 20vPnC (1%) had serious medical problems within 6 months after being vaccinated. None of these serious medical problems were thought to be related to the study vaccine by the study doctors. No participants who received 13vPnC (0%) had serious medical problems within 6 months after being vaccinated.

20 out of 1708 participants in this study (1%) had newly diagnosed chronic medical problems within 6 months after being vaccinated. This included 15 out of 1463 participants (1%) who received 20vPnC and 5 out of 245 participants (2%) who received 13vPnC. None of these chronic medical problems were thought to be related to the study vaccine by the study doctors. No participants died during this study.

In summary, the researchers concluded from all of the above data on medical problems experienced by participants during the study that the safety of 20vPnC is similar to 13vPnc. They also concluded that the majority of medical problems reported in this study were not related to study 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 Use the study identifier **NCT03828617**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients. Further clinical trials with 20vPnC are planned.

Again, **thank you** for volunteering. We do research to try to find the best ways to help patients, and you helped us to do that!