



# CLINICAL TRIAL RESULTS

**Sponsor:** Pfizer, Inc.

**Medicine(s) Studied:** Pneumococcal 13-Valent Conjugate Vaccine (Diphtheria CRM<sub>197</sub> Protein)

Compound Number: PF-06414256

**Protocol Number:** B4671001

**Dates of Trial:** 09 January 2014 to 01 September 2014

**Title of this Trial:** Testing the safety and effectiveness of a vaccine that protects people from a certain kind of infection (pneumococcal disease) after adding a preservative to the vaccine

[Final Infant Series Report: A Phase 3, Randomized, Open-Label Trial to Evaluate the Safety, Tolerability, and Immunogenicity of 13-valent Pneumococcal Conjugate Vaccine Formulated in Multi-Dose Vials Given With Routine Pediatric Vaccinations in Healthy Infants]

**Date of this Report:** 18 May 2017

– *Thank You* –

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

This summary only represents the results from a single study.

## WHY WAS THIS STUDY DONE?

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A certain kind of germ called *Streptococcus pneumoniae* (also called the “pneumo” germ) can cause serious diseases including infection of the lung (pneumonia), brain lining (meningitis), blood (bacteraemia), and ear (otitis). These infections can be very serious in children less than 2 years old.

This study is about Prevenar 13, a vaccine that is also called 13vPnC. A vaccine is a kind of medicine that helps a person’s body fight an infection. The Prevenar 13 vaccine helps people fight infections caused by the “pneumo” germ. The Prevenar 13 vaccine is part of the nurse’s injection that every infant in The Gambia gets when they are 2, 3, and 4 months old.

Usually, each injection of the vaccine is in its own single-dose syringe or in a single-dose vial. Another way to provide the vaccine is to put enough vaccine for several injections into 1 vial. This is called a multi-dose vial. When the vaccine is needed, a single dose is taken from the multi-dose vial and put into a syringe. Putting the vaccine into a multi-dose vial can make the vaccine less expensive and easier to send to the people who need it. But the multi-dose vaccine must be handled carefully between uses to make sure that the vaccine is safe.

A preservative was added to the multi-dose vial of Prevenar 13 to keep the vaccine from going bad between uses. This preservative is already used in several other vaccines. The Sponsor needed to compare the vaccines from the multi-dose vial and the single-dose syringe. They needed to be sure that the vaccines worked the same way and were both safe to use.

## **There were four questions that the Sponsor wanted to answer:**

1. Did the vaccine from the multi-dose vial work as well as the vaccine from the single-dose syringe?
2. There are many types of “pneumo” germs. Prevenar 13 helps protect people from 13 types of the germ. Did the vaccine from the multi-dose vial work as well as the vaccine from the single-dose syringe for each of these types of “pneumo” germs?
3. Any medical treatment can cause health problems. What medical problems did infants have during the study?
4. Were there any serious health problems?

## **WHAT HAPPENED DURING THE STUDY?**

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This study included 500 infants in The Gambia. The infants who took part in this study were healthy and were between 6 and 10 weeks old when the study started. The study was explained to the parents, and each of the parents could choose whether they wanted their infant to be part of the study.

The infants received all other vaccines that were recommended for them in The Gambia. In addition, 250 of the infants received Prevenar 13 from a single-dose syringe, and the other 250 infants received Prevenar 13 from a multi-dose vial. All of the infants received their first dose of Prevenar 13 at about 2 months of age.

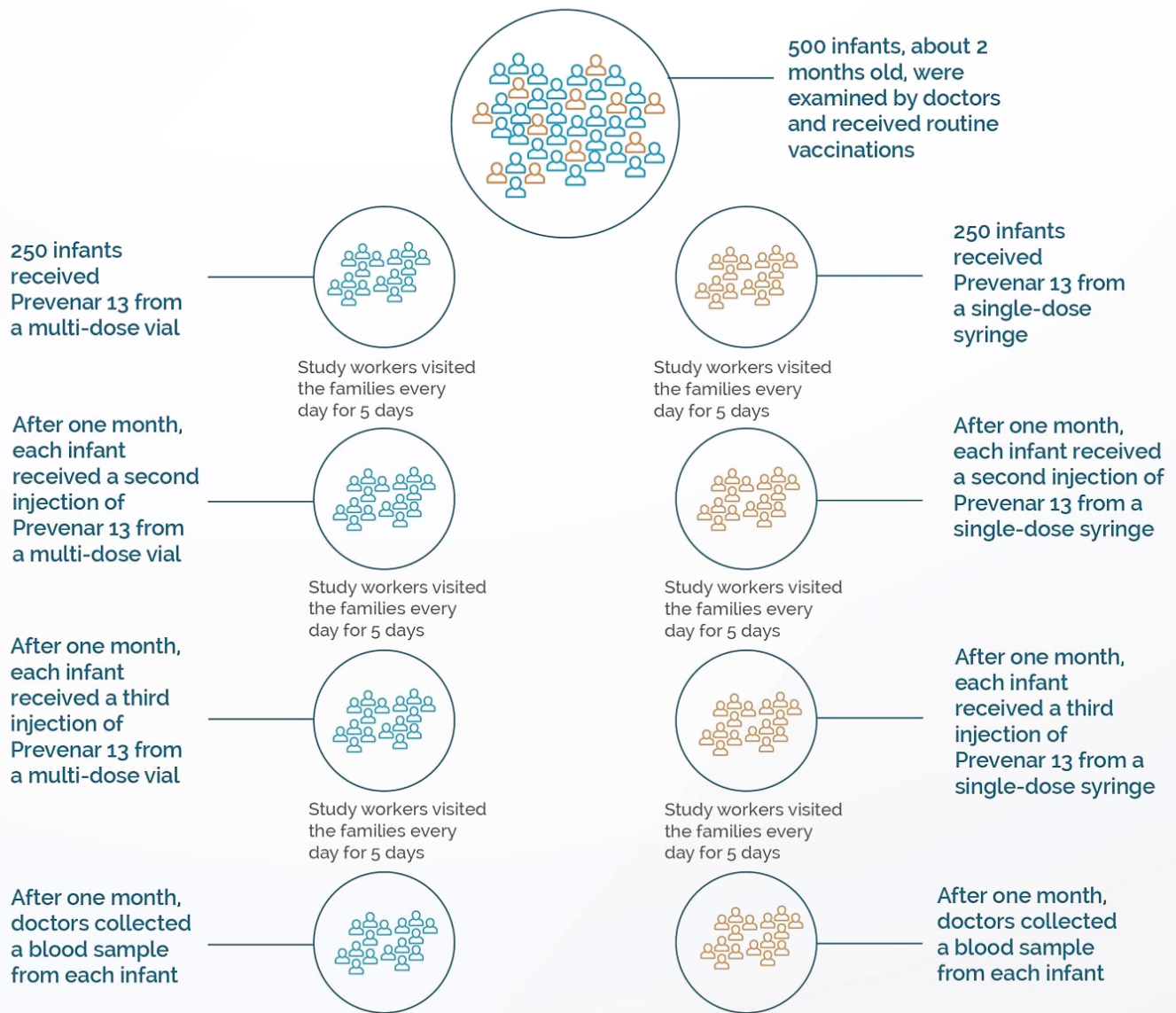
Each infant received another injection of Prevenar 13 when he or she was about 3 months old, and another when he or she was about 4 months old. After each injection, people working on the study went to visit the parents’ home every day for 5 days. They asked the parents about any health problems that the infants might be having, and they wrote down all of this information.

When each infant was about 5 months old, the family met with the study doctors for the last time. The study doctors asked about any health problems that the infant might be having. They also collected a small amount of blood, about 1 teaspoon, from the infant. Tests were performed on the blood to find out how well the vaccine worked.

Each infant was part of the study for about 3 months. Because the study included 500 infants, it took about 8 months to finish the whole study. It started on 09 January 2014 and finished on 01 September 2014.

Of the 500 infants who started the study, 489 finished the study. 11 infants left the study before it was over. The most common reason why infants left the study was that their parents decided that they did not want their infant to be part of the study anymore.

This diagram shows what happened to the infants during the study.



## **WHAT WERE THE RESULTS OF THE STUDY?**

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### **Did the vaccine from the multi-dose vial cause the same effect as the vaccine from the single-dose syringe?**

**Yes**

Doctors tested the blood samples from the infants to find out how the infants' bodies responded to the vaccine. More than 95 out of every 100 infants who received the vaccine from the single-dose syringe responded to the vaccine. More than 95 out of every 100 infants who received the vaccine from the multi-dose vial also responded to the vaccine. The Sponsor decided that there was no important difference in the number of infants who responded to each type of vaccine.

### **Did the vaccine from the multi-dose vial work as well as the vaccine from the single-dose syringe for each type of “pneumo” germ?**

**Yes**

There are many types of “pneumo” germs. Prevenar 13 helps to protect people from 13 types of the “pneumo” germ. The Sponsor wanted to make sure that the vaccine from the multi-dose vial helped to protect people from all 13 of these types. They tested the blood from the infants to compare the response caused by the vaccine from the multi-dose vial and the single-dose syringe.

There were some small differences between the responses caused by the vaccine from the multi-dose vial and the vaccine from the single-dose syringe. The vaccine from the multi-dose vial caused a slightly bigger response to 2 types of “pneumo” germs. The vaccine from the single-dose syringe caused a slightly bigger response to a different type. The Sponsor decided that there was no important difference between the ways the infants' bodies responded to the vaccine from the multi-dose vial compared to the vaccine from the single-dose syringe.

## WHAT MEDICAL PROBLEMS DID INFANTS HAVE DURING THE STUDY?

The researchers recorded any medical problems the infants had during the study. Infants 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 have been caused by a study treatment, or by another drug the infant 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 the side effects of an experimental drug might be.

1 infant left the study due to medical problems. 249 out of 500 of the infants in this study had at least 1 non-serious medical problem. The most common are listed below.

### Most Common Non-Serious Medical Problems (Reported in More Than 5% of Infants)

Medical Problem	Vaccine From a Multi-Dose Vial (250 Infants Treated)	Vaccine From a Single-Dose Syringe (250 Infants Treated)
Infection of the nose or throat	58 (23%)	50 (20%)
Diarrhea caused by a virus	19 (8%)	30 (12%)
Infection of the skin	15 (6%)	22 (9%)

Any vaccine injection can cause a reaction in the part of the body where the injection was placed. In this study, some of the infants had redness, swelling, or tenderness where the vaccine was injected. These reactions were usually not serious, and they usually did not last more than 3 days. The vaccine from the multi-dose vial and the vaccine from the single-dose syringe caused about the same number of these kinds of problems.

Some of the infants had other non-serious medical problems like a mild fever, sleeping more than usual, being irritable, or not eating as much as usual. The vaccine from the multi-dose vial and the vaccine from the single-dose syringe caused about the same number of these kinds of problems.

## **WERE THERE ANY SERIOUS MEDICAL PROBLEMS?**

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

Out of the 500 infants who received vaccinations in this study, 1 had a serious medical problem. The infant died due to Sudden Infant Death Syndrome 20 days after the third injection of Prevenar 13 from a multi-dose vial. The study doctors and the Sponsor decided that the vaccine did not cause the infant’s death.

## **WHERE CAN I LEARN MORE ABOUT THIS STUDY?**

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If you have questions about the results of your study, please speak with the doctor or staff at your study site.

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

[www.clinicaltrials.gov](http://www.clinicaltrials.gov)

Use the study identifier **NCT01964716**

[www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu)

Use the study identifier **2012-000482-21**

[www.pfizer.com/research/research\\_clinical\\_trials/trial\\_results](http://www.pfizer.com/research/research_clinical_trials/trial_results)

Use the protocol number **B4671001**

Please remember that researchers look at the results of many studies to find out which medicines work best and are safest for patients.

**Again, thank you** for allowing your infant  
to be a part of this study.

**We do research to try to find the  
best ways to help patients,  
and you helped us to do that!**