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-07307405

Protocol Number: C4601012

Dates of Study: 12 December 2022 to 21 July 2025

Title of this Study: Safety Study of a Lyme Disease Vaccine in Healthy Children

[A Phase 3, Randomized, Placebo-Controlled, Observer-Blinded Trial to Evaluate the Safety of a 6-Valent OspA-Based Lyme Disease Vaccine (VLA15) in Healthy Children 5 Through 17 Years of Age]

Date of this Report: 09 January 2026

Pfizer

– Thank You –

If your child 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 child's study site.

Why was this study done?

What is Lyme disease?

In the United States (US), Lyme disease is caused by *Borrelia burgdorferi* (a type of bacteria). Lyme disease bacteria are spread to humans through the bite of infected ticks. Common signs and symptoms of Lyme disease include fever, headache, tiredness, and a skin rash.

Most people with Lyme disease can be treated with medicines called antibiotics. If Lyme disease is not fully treated with antibiotics or left untreated, the bacteria can spread through the bloodstream and cause serious problems in the heart, brain, or joints.

People of any age can get Lyme disease, but it is most common in children 5 through 15 years of age and in adults older than 50 years old.

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What is PF-07307405 (also known as "LB6V")?

LB6V ("6-valent OspA-based Lyme disease vaccine") is also called VLA15. LB6V is an injectable study vaccine being developed by the Sponsor (Pfizer) and another company called "Valneva". Researchers think that LB6V may help protect people against Lyme disease.

LB6V targets the **o**uter **s**urface **p**rotein **A** (**OspA**) of 6 types of Lyme disease bacteria present in a tick. Targeting OspA can block the bacteria's ability to leave the tick and infect humans.

What was the purpose of this study?

The goal of this study was to get more information about the safety of LB6V in children 5 through 17 years of age. LB6V had been given in earlier studies to children and adults (from 5 years of age and older). This study focused on children 5 through 17 years of age.

Researchers wanted to know:

Is LB6V safe in children 5 through 17 years of age?

What happened during the study?

How was the study done?

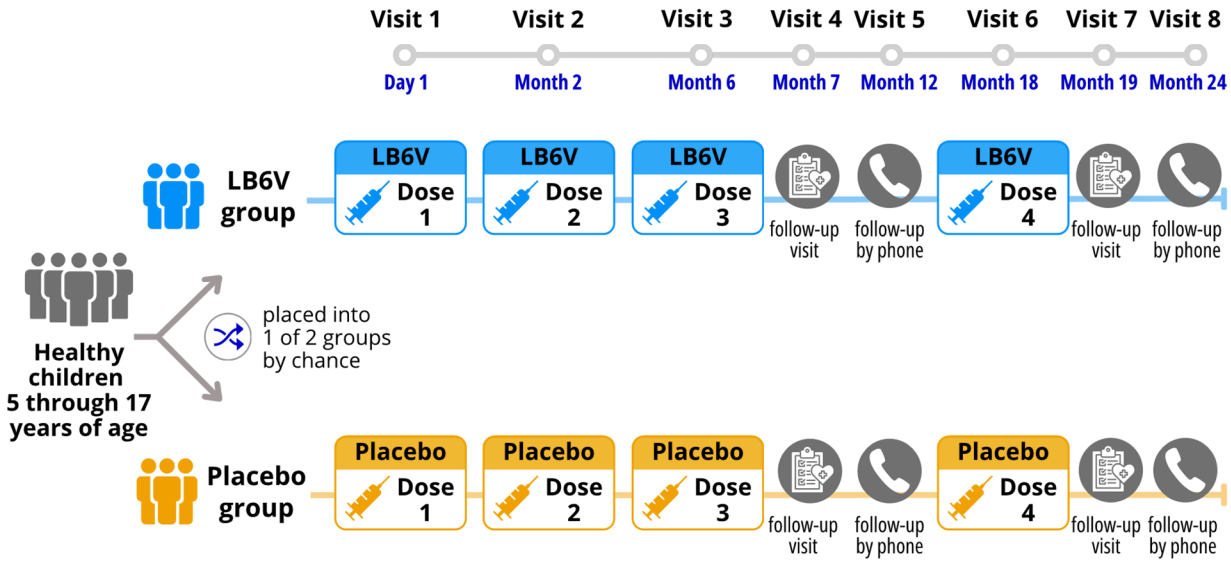
Participants were randomly placed into 1 of 2 groups: **LB6V** or **placebo**. A **placebo** contained saltwater only and did not have any medicine in it. For every 4 participants, 3 had a chance of being placed into the LB6V group and 1 had a chance of being placed into the placebo group.

Participants got each vaccination (“shot”) by an injection in the arm across 4 visits:

- The **LB6V group** got 1 shot of LB6V at each of the 4 visits (total of 4 shots).
- The **placebo group** got 1 shot of placebo at each of the 4 visits (total of 4 shots).

Figure 1 below shows the participants’ vaccination and follow-up schedule. During the study, researchers checked the participants’ health and asked them how they were feeling.

Figure 1. How was the study done?



During the study, participants, their parents/guardians, and researchers did not know whether participants got LB6V or placebo.

Researchers compared the results of participants in the LB6V group to the results of participants in the placebo group.

Where did this study take place?

This study ran at 57 locations in the US.

When did this study take place?

It began on 12 December 2022 and ended on 21 July 2025.

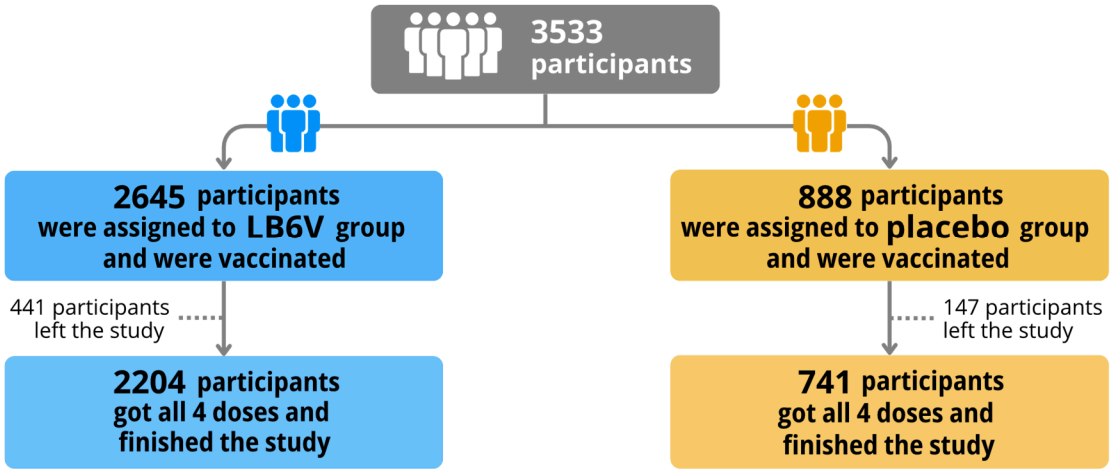
Who participated in this study?

The study included healthy children. When they joined this study, they:

- must have been 5 through 17 years of age,
- have not had Lyme disease in the last 3 months before the start of the study or ever had Lyme disease that spread to their heart, brain, or joints, and
- have not gotten a vaccine for Lyme disease before.

Figure 2 below shows how many participants took part in the study. Out of 3533 participants vaccinated in this study, there were 1645 girls (47%) and 1888 boys (53%). All participants were between the ages of 5 years and 17 years.

Figure 2. How many participants took part in the study?



Some participants left and did not finish the study after vaccination (see Figure 2 above). The most common reasons they did not finish the study were because they or their parent/guardian:

- could not be contacted for follow-up or
- chose to stop taking part in the study.

How long did the study last?

Study participants were in the study for about 2 years. The entire study took about 2 years and 7 months to complete.

When the study ended in July 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?

Is LB6V safe in children 5 through 17 years of age?

Researchers found that:

LB6V was safe and well tolerated in participants 5 through 17 years of age.

The sections below show more information on the safety results of LB6V.

Local Reactions and Systemic Events

Participants (or their parents/guardians) were asked to complete their electronic diary (e-diary) each night for 7 days after each vaccination. They answered questions in their e-diary about how the participants were feeling.

Researchers looked at the participants' e-diary to see if they had any discomforts listed below.

- **Local reactions** are the body's response at the injection site (spot in the arm where LB6V or placebo was injected). These are **injection site pain**, **redness**, or **swelling**.
- **Systemic events** are symptoms that affect the whole body or a part of the body like the head or joints. These are **fever**, **tiredness**, **headache**, **muscle pain**, or **joint pain**.

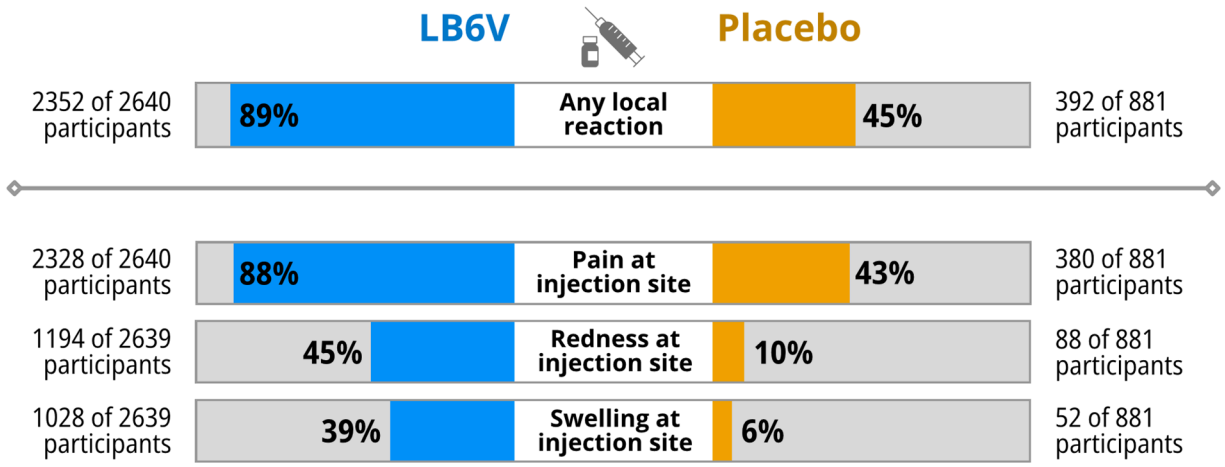
Local Reactions – Within 7 Days After Any Vaccination

> **"Within 7 days after any vaccination"** means on any day from Day 1 through Day 7 after **any dose** (Dose 1, 2, 3, or 4) of LB6V or placebo.

Figure 3 below shows that more participants in the LB6V group (89%) had local reactions within 7 days after any vaccination compared to the placebo group (45%). Injection site pain was the most common local reaction in both groups.

Most local reactions lasted for 1 to 3 days and were not severe.

Figure 3. How many participants had local reactions within 7 days after any vaccination (Dose 1, 2, 3, or 4)?

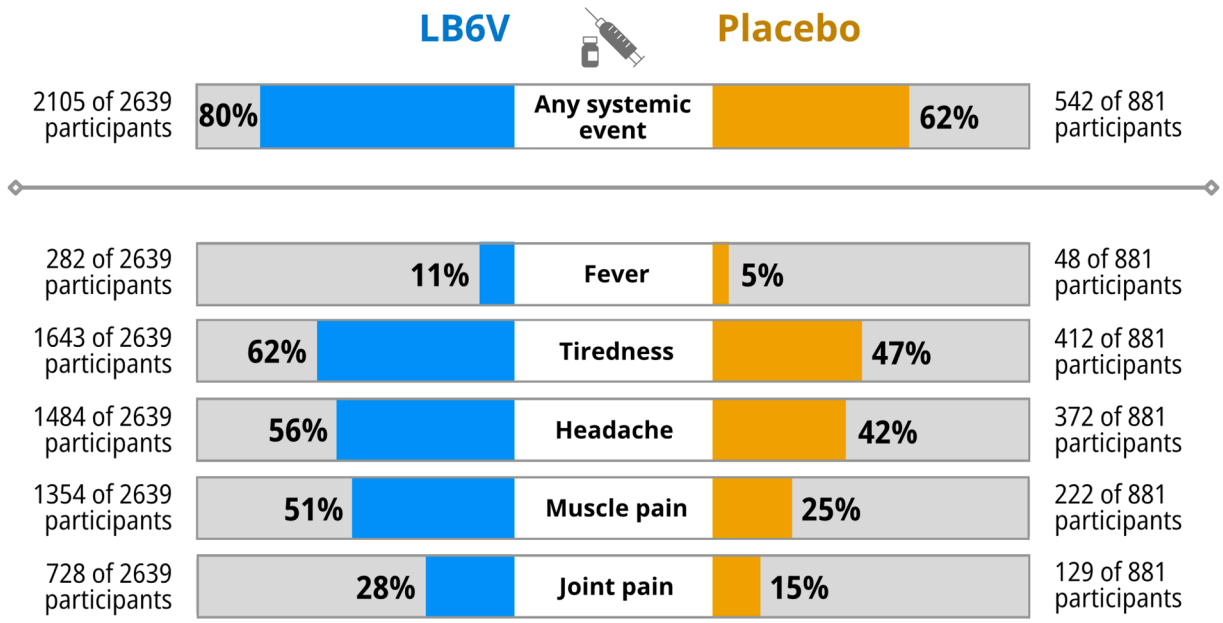


Systemic Events – Within 7 Days After Any Vaccination

Figure 4 below shows that more participants in the LB6V group (80%) had systemic events within 7 days after any vaccination compared to the placebo group (62%). Tiredness and headache were the most common systemic events in both groups.

Most systemic events lasted for 1 to 2 days and were not severe.

Figure 4. How many participants had systemic events within 7 days after any vaccination (Dose 1, 2, 3, or 4)?



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 unknown 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.

Medical Problems – Within 1 Month After Any Vaccination

> **"Within 1 month after any vaccination"** means on any day from Day 1 through Day 31 after **any dose** (Dose 1, 2, 3, or 4) of LB6V or placebo.

A similar percentage of participants in the LB6V group (12%) and placebo group (10%) had at least 1 medical problem within 1 month after any vaccination. Figure 5 below shows the results.

Figure 5. How many participants had medical problems within 1 month after any vaccination (Dose 1, 2, 3, or 4)?

The medical problems reported in the study are commonly seen in this age group. The most common medical problems within 1 month after any vaccination – those reported by at least 1% of participants in either group – are listed below.

- "Strep throat" – a bacterial throat infection called "streptococcal pharyngitis"
- "Upper respiratory tract infection" – an infection of the upper portion of the airway (from the nose to the voice box); an example is the common cold

Researchers also collected information on the participants' health from Dose 1 of vaccination to the end of the study.

> **"From Dose 1 to the end of the study"** means on any day from Day 1 (Dose 1) of LB6V or placebo until the last day in the study.

Left the Study Because of Medical Problems – From Dose 1 to the End of the Study

From Dose 1 to the end of the study, a similar percentage of participants in the LB6V group (1%) and placebo group (1%) left the study because of a medical problem. Figure 6 below shows the results.

Figure 6. How many participants left the study because of medical problems reported from Dose 1 to the end of the study?

New Long-Term Medical Conditions – From Dose 1 to the End of the Study

Figure 7 below shows a similar percentage of participants in the LB6V group (3%) and placebo group (3%) had a new long-term medical condition diagnosed from Dose 1 to the end of the study.

Figure 7. How many participants had new long-term medical conditions diagnosed from Dose 1 to the end of the study?

The types of new long-term medical conditions reported in the study were similar between the LB6V and placebo groups and were commonly seen in this age group. The most common new long-term medical condition reported in this study was ADHD. This was seen in 25 of 2648 participants (1%) in the LB6V group and 12 of 885 participants (1%) in the placebo group.

> **ADHD** ("attention-deficit/hyperactivity disorder") is a brain condition that affects how a person focuses, sits still, and behaves.

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.

Serious Medical Problems – From Dose 1 to the End of the Study

A similar percentage of participants in the LB6V group (2%) and placebo group (2%) had a serious medical problem reported from Dose 1 to the end of the study. Figure 8 below shows these results.

Figure 8. How many participants had serious medical problems reported from Dose 1 to the end of the study?

There were no common serious medical problems seen throughout the study. Each serious medical problem was reported by less than 1% of participants in either group.

Overall, 1 participant died during the study. This participant was part of the placebo group and died from “sepsis” (the body’s extreme response to an infection).

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 **C4601012**

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

www.clinicaltrials.gov	Use the study identifier **NCT05634811**
https://euclinicaltrials.eu	Use the study identifier **2025-000441-15**

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 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!

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