

# Lyme Disease Vaccine Study

Protocol: C4601012



*Subject line:*

**Physicians: Please speak with families in your practice about a pediatric Lyme vaccine study**

*Preview text:*

The Pfizer C4601012 study is now enrolling children and teens 5 to 17 years of age. You can help by referring eligible patients.

Dear Pediatric Health Network Colleagues:

I am pleased to share our involvement in Pfizer Study C4601012, 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. We are establishing relationships with doctors who may be able to refer patients for this study and invite you to consider referring potential candidates to us.

Your patients may be eligible if they:

- Are 5 to 17 years old
- Are generally healthy or have certain stable chronic medical conditions
- Have not been diagnosed with Lyme disease in the past 3 months

About 3,000 participants will be enrolled in the United States. Participants will be randomized 3:1 to receive 4 total doses of the study vaccine or placebo. Participants will be enrolled for about 2 years and will need to attend 6 planned in-office visits and 2 follow-up phone calls. Participants will complete eDiary entries to document reactions occurring in the week after vaccination, but there are no blood draws or other planned procedures. Any of your patients who take part in this research study will remain under your medical care for all non-study-related needs, including if they acquire Lyme disease during the study.

As their trusted healthcare provider, we appreciate you taking the time to have open discussions with patients and families who may be interested in contributing to research. If you would like more study-specific information to help inform conversations with your patients, please let us know. Your patients are welcome to contact my research team using the information provided below, or they can visit [Lyme Vaccine Study for Kids and Teens \(lymekidstudy.com\)](https://www.lymekidstudy.com) to learn more.

Thank you for your time and consideration.

Sincerely,

Alexandra Yonts, MD and Claire Boogaard, MD MPH

Co- Investigators for the Pfizer C4601012 Lyme Vaccine Clinical Trial, Site 1064

Children's National Hospital

[ayonts@childrensnational.org](mailto:ayonts@childrensnational.org) | 202-476-3753 (Emily Ansinha, Lead Clinical Research Coordinator)