

UW Health: Moderna COVID-19 vaccine pediatric clinical trial to focus on ages 6 months to 5 years

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MADISON, Wis. – The KidCOVE phase three clinical trial at the University of Wisconsin School of Medicine and Public Health, which is evaluating the safety and effectiveness of the Moderna COVID-19 vaccine in children, has shifted focus to kids 6 months to 5 years old.

In August, enrollment for kids ages 5 to 11 years old closed just days after the nationwide trial opened at the Madison site thanks to a high volume of applicants. Data from that cohort are currently being analyzed by Moderna.

In Madison, dozens of kids ages 6 months to 5 years are participating in the clinical trial at American Family Children's Hospital. Due to incredible community response in August, study coordinators and researchers have the candidates they need and are not taking more participants. Those who applied previously will be contacted by the researchers if their child is chosen to participate.

On Oct. 26, the U.S. Food and Drug Administration granted emergency use authorization for the Pfizer/BioNTech vaccine for children ages 5 to 11 and the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices and CDC director recommended the Pfizer/BioNTech vaccine for this age group on Nov. 2. Moderna is expected to start the same process for its vaccine soon.

Researchers for the KidCOVE clinical trial have sought enrollment of approximately 4,000 children in North America in each group (vaccine or placebo), spread over 75 to 100 study sites in the United States and Canada. The Moderna vaccine is

administered in two doses, four weeks apart. Participation in the trial lasts 14 months with at least four follow-up appointments during that time.

This is a placebo-controlled trial, meaning participants will either get the vaccine or the placebo. Participants will not know which one they get. Approximately 80% of the participants in the trial in Madison are from underserved populations meaning they might face barriers based on race, ethnicity, income, geography and health outcomes, according to study leaders. ([More information on why clinical trial diversity is important.](#))

“This is the final frontier. Our very youngest children need to get the vaccine and we need to make sure they are safe,” said Dr. Bill Hartman, co-principal investigator of the KidCOVE clinical trial at UW-Madison. “The kids participating are heroes. They will be able to tell the story of how they helped save the world.”

Two of those heroes are four-year-old twin brothers Sam and Theo Rodriguez.

Video of Sam and Theo getting their shots is available, as well as recorded interviews with them, their mother Anne Rodriguez and Hartman.