

WHAT TO EXPECT

Your child will be randomly assigned (by chance) to receive either the COVID-19 study vaccine or placebo (injection with no active ingredient). This assignment will be made by a computer and not by the study team. Neither you nor the study doctor will know if your child is receiving the study vaccine or a placebo.

Two thirds of the participants will receive the COVID-19 study vaccine, and one third will receive the placebo. Your child will receive 2 injections about 3 weeks apart. You will learn 6 months after the vaccination whether your child received the COVID-19 vaccine or placebo. Over the course of the 2 years, your child will have between 6 and 11 planned visits.

You will also be asked to record and report any changes to your child's health over time, including any symptoms of COVID-19 or related complications. To make recording of symptoms easier, you will be provided with:















- An electronic diary (e-diary – a device or app on your phone)
- A digital thermometer
- A caliper (a device to measure any redness and swelling at the injection site)







The study team will show you how to use these.

STUDY VISITS

All participants will initially follow the study visit schedule below.

INITIAL STUDY VISIT SCHEDULE: For All Participants







VACCINATION		FOLLOW UP		
VISIT 1	VISIT 2	VISIT 3	VISIT 4	VISIT 5
Day 1 (Dose 1)	3 weeks (Dose 2)	1 week after Dose 2	1 month after Dose 2	6 months after Dose 2
 	 	 Visit not applicable for all participants	  Blood Collection for first ~ 450 participants only	  
POTENTIAL ILLNESS VISITS				
These visits can occur at any point during 2 years of study participation				
  Potential COVID-19/MIS-C Illness Visit			  Potential COVID-19/ MIS-C Convalescent Visit	

 = Vaccination  = Nasal Swab Test  = Blood Collection  = Unblinding Occurs
 = Potential COVID-19/MIS-C Symptoms Check  = Follow Up



- At each visit, the study team will ask about your child’s general health and complete study activities.
- In between visits, you will complete the e-diary to help monitor your child’s health and track signs or symptoms of potential COVID-19 or complications of COVID-19 known as Multi-Inflammatory Syndrome in Children (MIS-C). You will be asked to complete the e-diary once a day for 7 days after your child receives each injection. Thereafter, you will complete the e-diary weekly for the duration of the study.
- It is important that you contact the study team right away if your child has any symptoms you think may be caused by COVID-19/MIS-C. They will advise you if your child needs to take a COVID-19 test.
- You will be reimbursed for expenses (such as parking, meals, travel) and time related to completing the e-diary.
- At your child’s 6 month follow up visit, you will learn if they received the placebo or the COVID-19 study vaccine (called unblinding). If your child received the placebo, they will be offered the COVID-19 study vaccine at this time.

After the unblinding occurs, participants may follow one of two visit schedules for their remaining visits, depending on if they originally received the placebo or the COVID-19 study vaccine.

REMAINING STUDY VISIT SCHEDULE: For Participants Who Originally Received Placebo and Choose to Receive the COVID-19 Study Vaccine

VACCINATION		FOLLOW UP			
VISIT A	VISIT B	VISIT C	VISIT D	VISIT E	VISIT F
6 month (Dose 3)	3 weeks after Dose 3 (Dose 4)	1 month after Dose 4	6 months after Dose 4	12 months after Dose 4	18 months after Dose 4
					

REMAINING STUDY VISIT SCHEDULE: For Participants Who Originally Received the COVID-19 Study Vaccine

FOLLOW UP	
VISIT X	VISIT Y
12 months after Dose 2	24 months after Dose 2
 Blood Collection not applicable to all participants	 Blood Collection not applicable to all participants