

SP0202 Project PNEUMOCOCCUS VACCINATION PEDIATRIC STUDY



EVALUATION OF AN
INVESTIGATIONAL VACCINE FOR
EARLY CHILDHOOD
IMMUNIZATION

What Is Pneumococcus Disease?

- Pneumococcus (pronounced: **noo-muh-kaa-kuhs**) disease is a bacterial infection that can cause various diseases, depending on the person exposed. The most frequent diseases caused by these bacteria are otitis media (ear infections) in young children and pneumonia in elderly populations.

Why Is Your Child's Doctor Involved?

- Our office is participating in a clinical research study to evaluate an investigational pneumococcus vaccine for pediatric immunization. A Pneumococcus vaccination is already a part of the U.S. Childhood vaccination schedule.
- The current vaccine marketed in the USA protects against the diseases caused by 13 types of pneumococcus. However, there are several types of pneumococcus responsible for diseases not covered by this vaccine.
- The SP0202 vaccine is being studied to protect against additional types of pneumococcus bacteria.
- Your participation may contribute to the development of a vaccine with the potential to prevent pneumococcus disease.

What Can You Expect After Your Child is Enrolled?

- This research study includes office visits for your child, with a telephone call between visits. Most of the office visits happen at the same time as the usual "well-child" visits that all children should have for checkups and vaccinations.
- You will need to keep the scheduled appointments, answer questions about your child's health, and follow the directions of the study staff
- At your first visit, the doctor or nurse will explain the research study to you and answer all of your questions. If you choose to have your child participate, you will be asked to sign a consent form and your child will be vaccinated. Also, a small amount of blood (a little more than half of a teaspoon) will be drawn at this time. You will complete an electronic diary right from your own smartphone, and you will receive a phone call from the study nurse or investigator to check on the health of your child.
- The other office visits are very much like the first visit. Your child will have a regular checkup and be vaccinated. Blood may be drawn at other visits.

Should You Volunteer To Enroll Your Child?

- In addition to the satisfaction of helping with the development of a new vaccine, there may be some benefits for you and your child
 - You will have access to medical assistance throughout the study
 - During the trial, your child will receive the other recommended childhood vaccinations that he/she needs without cost to you
 - You will not have to pay for your child's participation, and you will be reimbursed for your time and transportation costs.
 - Your Study Coordinator will discuss the reimbursement details with you.

Be part of this nationwide clinical study

YOUR CHILD'S PARTICIPATION CAN MAKE A DIFFERENCE!

For more information and to see if you qualify, please contact:

