

## #UECInsight

### Clinical Trials Q&A

#### ***What are clinical trials?***

Clinical trials are medical research studies that use volunteer subjects to test the safety and effectiveness of things that could potentially be used as an intervention for a disease or disorder. These interventions include drugs, drug delivery systems, vaccines, procedures, devices, treatment routines, diagnostic tests and strategies for prevention. Most medical research starts in a lab, and then it progresses to clinical trials.

#### ***What types of clinical trials may I participate in?***

There are four types of clinical trials.

- ***Phase I clinical trials.*** This type of trial tests a potential treatment in a small group of people. It's used to determine the optimal dosage and identify side effects.
- ***Phase II clinical trials.*** Here, the tests are opened to a larger group of volunteers with the aim of studying how an intervention impacts the body and how well it treats the condition.
- ***Phase III clinical trials.*** At this stage, hundreds and even thousands of people are part of the trial. These trials compare the new proposed treatment with existing treatments—and no treatment—to determine the true value of the intervention and secure approval from regulatory agencies.
- ***Phase IV clinical trials.*** This stage comes after the intervention is approved; it uncovers more about the treatment.

#### ***Can you walk me through how trials are conducted?***

Clinical trials are facilitated by two people; the **principal investigator** is in charge of the entire trial, and the person who coordinates your visits and walks you through the trial is the **clinic coordinator**. If you apply, your child will have to meet the eligibility criteria, which could require her/him to be within a particular age range, have a specific eye condition or have undergone a certain previous treatment. If s/he meet the requirements, you'll sign an informed consent form, which lays out the purpose of the study, what you need to do, the details of the treatment, the possible benefits and risks of the trials, and your/your child's rights. The doctors will create and follow a study protocol that sets standards for the trial. **Clinical trials are controlled, which means that it compares the proposed treatment with other modes of treatment.** To that end, your child will be randomly assigned to either the treatment group or the control group; children in the control group could receive standard treatment or no actual treatment at all (called a placebo or a sham treatment). If it's a nonmasked trial, both you and the doctor will know what group your child is in. In a masked trial, you won't know, but your doctor does. In a double masked trial, neither of you knows. This helps prevent either party from inadvertently influencing the outcome.

#### ***Are clinical trials for vision different than other types of trials?***

They can be! Because your child has two eyes, researchers have additional options when it comes to designing the trial. They could actually put one of your child's eyes in the treatment group, and the other in the control group to measure the impact of both in the same body.

#### ***What would I have to do as a volunteer?***

If you volunteer your child for a clinical trial that studies eyes, s/he will have to undergo several eye exams and other relevant testing. Depending on the intervention that is being tested, your child might

have to take a new medication or have a new surgical procedure. Some trials are short, while others may require your child to return for follow-up exams for years.

***Why should my child participate in clinical trials?***

On a personal level, your child could benefit from a promising new treatment before it becomes widely available. More broadly, your child's participation could help develop an intervention that prevents or even cures an eye condition that impacts millions of people.

***What are the risks?***

The intervention might not work, or, in some cases, it could even cause serious side effects.

***How is my child protected during clinical trials?***

**All human clinical trials must be approved by an independent institutional review board**, which ensures that it is both scientifically sound and designed to protect volunteers. Once the trial starts, the researchers and an outside group of experts will monitor your child closely to make sure the benefits continue to outweigh the risks.

***What rights do I have as a volunteer?***

If your child participates in a clinical trial, **you have a right to know the full benefits and risks, how long the study will last, what is expected of you and your child, any costs you will be responsible for and what information is shared outside the team of researchers**. You should also be able to talk directly to the doctors running the trial, ask questions, leave the trial, receive new information about the treatment that is discovered along the way, learn details of your child's treatment assignment at the conclusion of the trial and maintain your child's privacy both during and after the trial.