WHAT IS A CLINICAL STUDY?

Thank you for your interest in learning more about clinical studies through LabCorp. Here we describe how clinical studies work and cover the basics of research study participation.

The purpose of clinical studies
The U.S. National Institutes of Health* provides information about clinical studies. Clinical studies are generally medical research studies that explore whether a medical strategy, treatment or device is safe and effective for humans, and that determine whether the medical strategy can eventually be made available to the public. Sometimes referred to as a clinical trial, these clinical studies help find new ways to prevent, diagnose, treat and better understand diseases in humans.

Participation in the study will take place in a hospital, clinic or doctor's office. Participation can include using new medications, existing medications used in different ways, new combinations of drugs, surgical interventions or even medical devices. Testing to determine how patients are responding to the drugs or other interventions are also done, usually at the study site, but they can sometimes be done in other locations that might be more convenient.

The reasons to participate in a clinical study
The choice to participate in a clinical study can be very personal. Some patients may wish to help others suffering from the same disease. Others would like to have access to the latest treatments, while some participants may wish to help advance science or have access to any additional care available from site staff. Each reason is unique to the participant, but participation ultimately helps support medical research.

Safeguards within a clinical study
By the time a treatment or drug reaches the phase of clinical research, it has been through several years of scientific evaluation. But researchers still need to know what does and doesn't work in people, so they run a clinical study.

Every clinical study has a plan called a protocol, which clearly defines how the research study will be run. A protocol defines who can participate in the study, details of all the tests and diagnostic procedures, the length of the study and any information that will be recorded.
Each study protocol is reviewed by an expert regulatory board and/or an independent ethics committee to assess the protocol's safety and to help ensure that any potential risks to a study participant are outweighed by the potential benefits.

Making an informed choice as a study participant
All participants looking to join a clinical study are asked to review an informed consent form. This form helps the participant understand the key procedures involved in the study, the potential benefits and the potential risks, in addition to any specific requirements for a particular study, such as the expected time commitment, where study sites are located, or the need to spend extended time in a clinic for the study.

Research staff in a study will discuss the informed consent process and then describe the study to help each participant fully understand the study and decide what is best for them. Then, the participant can make an informed choice to join the study or decline to participate. Even after joining, participants in a study are free to leave at any time they wish.

Potential benefits versus risks
Participating in a research study has benefits and risks, just as people experience benefits and risks in routine medical care and their daily routines.

The potential benefits of participating in a study can include access to breakthrough medications that are not widely available, receiving additional medical attention and contributing to medical research that may help others.

The study may also involve additional time and tests above the typical standard of care, including travel to specific trial locations and in some cases overnight or longer stays in a clinic to allow for closer monitoring. These additional requirements will be explained as part of the informed consent process.

The potential risks of participating in a study can include side effects, which are secondary to the intended effect of the treatment. Although side effects can sometimes be beneficial, the potential risk is that a side effect will be adverse, or negative. Side effects can occur in medical treatments of any kind, even those that were previously tested, and may only affect certain people. They can range from minor and short-term to serious and long-term. Depending on where the study falls in the development timeline, more or less information about the potential side effects may be known. Identifying and managing side effects is a particular focus in each study's protocol, and research staff will discuss the potential side effects in detail as part of the informed consent process.

Clinical studies and comparison groups
Most clinical studies are designed with comparison groups, meaning that some of the participants receive one type of medical strategy, while another group gets a different medical strategy. This allows researchers to compare the results between groups to determine which has better outcomes.

A placebo is an inactive product that looks like a test product. A placebo may be used to compare a treatment and assess its effectiveness. A research study participant would never be assigned a placebo if this would possess a risk to their health, such as those participants with a serious illness. Participants will be told if their study includes a placebo before they agree to join the study.

Learn more about clinical studies
Your personal physician may be a great resource to learn more about clinical studies. Additionally, clinicaltrials.gov can provide more educational information, as well as a complete listing of many active and upcoming clinical studies.

By opting in and consenting to receive more information through Research to Improve Lives, you may hear about clinical studies being run by Covance, the drug development business of LabCorp.

References*

https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics

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