ABOUT THE DIFFERENT TYPES OF CLINICAL STUDIES

What is a clinical study?

Clinical studies explore whether a treatment is safe and effective and works as intended for humans.

In the U.S. and other countries, a new treatment, or a new use for an existing treatment, must follow a carefully established process to demonstrate that the treatment can be approved for use with patients. Data from the studies must be submitted to the appropriate government agency, which in the U.S. is the Food and Drug Administration (FDA), where the data is closely reviewed to determine whether the treatment will be approved. The process from initial discovery of a potential new treatment to its approval can take years and be very expensive, to help ensure that patients have access to effective and safe drugs, and that any potential negative effects of the drug are known.

Clinical studies may help us to understand which medical approaches work best for certain illnesses or groups of people. In a clinical study, volunteers receive a treatment in line with the study protocol. The protocol is a detailed document that describes the study design in detail and acts as the blueprint for the conduct of the clinical study. Clinical studies may compare new possible treatments to routine care that is already available, or use a placebo comparison to establish whether the treatment is providing benefits to a patient.

A placebo is a substance made to look like a treatment, but it provides no medicinal effect and helps to assess any psychological effects a treatment may have. Studies can be blinded so that neither the patient, doctor nor research team knows the treatment assigned to an individual patient, to prevent any favoritism towards a treatment or a placebo. This helps to truly demonstrate the benefits of the treatment during the data analysis stages of the study. A placebo may also help to determine if other factors are contributing to the patients' health as opposed to the treatment under investigation for example whether the patient's own state of mind can influence response to the disease or condition. This helps to get a true understanding of the benefits of a drug on the health of a patient,

What types of studies are there?

Studies are normally grouped into four different phases, based on the objectives of the study.

Phase I studies are usually conducted in healthy volunteers with the goal of checking whether the treatment is safe to give humans, and what side effects it might cause. Doses of study medication are normally given to groups in small steps to establish the best dosing strategy for patient's in future clinical studies. These studies help researchers to understand if there are any common side effects and how often these may occur. The studies also help the researchers to

understand what happens when a new drug enters the body, such as where it reaches and how long it stays in the body. Volunteers may receive financial payment for their participation.

Phase II studies normally involve patients who are living with the specific disease or condition that the treatment is targeting. These types of studies help researchers to understand the effectiveness of the treatment. Safety is monitored closely during these studies and, similarly to Phase I, side effects are tracked and investigated.

A Phase III study often involves a large number of patients and supports researchers in gathering increased information about the treatment, its safety and success in different groups of people, appropriate dosages, and how it acts when used in combination with other drugs, which could either boost effectiveness or cause additional side effects. This is the final step before the results will be submitted to regulatory authorities for approval.

Phase IV studies occur after a treatment has been granted approval for public use by the FDA or other applicable regulatory agency. These studies include a larger number of patients than Phase I-III studies. Phase IV studies help to monitor long-term drug safety, how well the treatment works, and the best way to use the drug in the treatment of patients. Interaction with other drugs is also an important subject of Phase IV studies.

Who can take part in clinical studies?

Every study has criteria set in the protocol outlining who is able to take part. These criteria are called 'eligibility criteria'. Examples of criteria could include gender (male/female), age, stage or type of disease or illness, previous treatments or other medical conditions.

Interested in learning more about Phase I / healthy volunteer studies?

Phase I studies are run by specialized clinics. For example, Covance has clinics located in the following cities in the United States: Dallas, Texas; Daytona Beach, Florida; and Madison, Wisconsin. To learn more about participating in a Covance-led Phase I trials, click the link below.

https://www.covanceclinicaltrials.com/en-us/clinical-research.html

How can I get involved in supporting clinical studies?

LabCorp's mission is to improve health and improve lives. Helping to bring innovative medicines to patients faster is an important part of that mission. LabCorp has opportunities for people to participate in research that can improve the quality of their lives and the lives of others. The research can take many forms, including clinical studies, and other types of research to develop new health care solutions. To express your interest in participating, you can register

via your LabCorp Patient™ portal account. Alternatively, websites like www.clinicaltrials.gov provide full listings of research studies with a searchable function by condition and country.

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