What is a Clinical Research Study?

Transcript

* *this transcription has been done with the help of AI.*

What is a clinical research study? For many of us, being diagnosed with a serious life changing illness can mean starting a stage in life filled with new doctors, nurses, tests, procedures, treatment regimens, and plenty of confusion.

And on top of everything else, you may be asked about, considering clinical research or clinical trial. Clinical study or research study. And that’s where we come in. Let’s start by explaining what these terms mean.

Clinical study, clinical trial and research study mean the same thing. Studies are what doctors create to find out if a potential study drug works and is safe.

Some of these potential drugs may be new in development, and other drugs may have been around for a while but are being studied in different illnesses. Every drug from your common painkiller to a leading cancer medicine has been through a clinical study.

These studies answer questions like what side effects does a new drug have? Does it stop or slow down the illness it is designed to treat?

Does it work better than current treatments? And can it be given alongside other drugs? That are used for the same

illness.

In each case, the answers must come in the form of scientific data or facts, not the opinions of the doctors, patients, or families involved, but the actual results that are collected and monitored during a clinical study.

It’s important to have patients of every race and ancestry included in studies to better understand how the study drug works in every patient population.

All potentially eligible patients are invited to consider a study regardless of race, ancestry, sexual orientation, gender identity or disability status.

Diverse representation matters, and studies to understand if results differ in different populations.

Every study participant receives the same care, the same tests, scans, procedures, study visits and follow up.

Plus, there are always safety procedures in place to monitor the well-being of every patient at every stage of every study. Because of this diligent monitoring, patients get personalized care from doctors and nurses, while in clinical research.

Studies are designed to remove bias. Some studies are comparative, meaning that some patients will get the standard treatment plus the study drug, while others will get only the standard treatment plus a placebo.

Comparative studies are often done under double-blind conditions. This means that neither the patients nor the doctors know who is getting the study drug or the placebo.

A placebo is a substance that looks like the study drug but contains no active components. If there is no standard treatment approved for an illness, a patient may only get the study drug or the placebo.

Patients can also be randomized to different groups in a study, meaning they are randomly assigned, like flipping a coin into a particular group.

Always remember it is up to you to decide whether a study is right for you. Study participation is voluntary and requires your informed consent or permission from start to finish. And of course, patients have the freedom to leave any study at any time.

Not every patient is eligible for a study though. Enrollment is based on meeting certain entry requirements.

For example, most studies require that patients are over 18 years old and have moderate to severe illness.

If you meet all entry requirements and you decide to participate, your informed consent is required before any study procedures can be done.

A well-designed study can help answer whether a drug works and if it is safe, whether the outcome is better or worse than standard therapy, whether your illness responds to the drug or not, and all studies give researchers and doctors information about what to do next.

So the next time a doctor or nurse mentions clinical research, hopefully this information has helped you understand what that means. Talk to your doctor and nurse to find out more about the benefits and risks of a clinical study. Ultimately, you decide what is right for you.

***Intended audience for the video:** EUPATI supports the publication of this video for all stakeholders aiming to interact with patients on medicines research and development (R&D) in clinical studies or clinical trials. The video is informational, for education purposes and is intended for the general US population. Different terminology and definitions exist between the US and the European Union (EU), and this

should be kept in mind when viewing the video (Further information on the definition of clinical studies/clinical trials in the EU can be found in Regulation (EU) No 536/2014 (Article 2) [glossary_exclude](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02014R0536-20140527). [/glossary_exclude]The presented information is aimed at raising awareness of clinical studies/clinical trials and what it means to participate in clinical trials.

This video is not intended to be prescriptive. The video should be adapted for individual requirements using best professional judgment. If formal advice is required, involved stakeholders should consult their respective legal department if available, or seek legal advice from competent sources.

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You can find more information about clinical trials at the[glossary_exclude] EUPATI Open Classroom.[/glossary_exclude]