

HOW A CLINICAL TRIAL GETS STARTED



Trial Protocol

Each clinical trial is carefully designed to answer specific research questions, and the trial protocol is the plan for how the clinical trial will do this. It answers who is eligible to be in the trial, how participants will be protected, what medication and doses will be administered, what the schedule for laboratory tests or procedures will be, and how long the trial will last. It also describes the goals of the trial and what information will be obtained to measure safety and effectiveness.



IRB Approval

The Institutional Review Board (IRB) is an independent committee that approves and monitors clinical trials. The board is responsible for ensuring that the trial is done ethically, poses minimal risks to participants, and that there is benefit (either to the individual or society) to doing the clinical trial.

Selecting Clinical Trial Sites

Clinical trials can be done at hospitals or medical clinics that are generally picked based on the availability of experienced healthcare professionals and patients. Geographic diversity of the trial sites helps to make sure that participants are representative of those who will benefit from and need the new drug.



Sponsors of the Trial

All trials are sponsored or funded by various organizations, companies, or individuals. Sponsors can include doctors, pharmaceutical companies, the National Institutes of Health, foundations, or medical institutions.



The Research Team

The research team is composed of a principal investigator, a trial coordinator, research nurses, and staff that are selected based on their scientific knowledge, training, and qualifications. This team will be with you throughout the duration of the clinical trial to monitor and care for your health.



Trial is Ready to Begin

Once a clinical trial team has confirmed their trial protocol, gained IRB approval, selected trial sites, identified the research team, and recruited patients, they are now ready to begin the participant screening and enrollment process. (See Various Steps of a Clinical Trial infographic for more information on what the clinical trial process looks like for participants).



Patient Recruitment

Each trial establishes different criteria for selecting participants based on the questions the researchers are trying to answer. The criteria can include gender, age, severity of IBD, previous treatments for IBD, and any other medical conditions that a person has. You can learn about clinical trials from the internet, radio ads, your doctor, foundations, or hospitals.

