

# What Are Clinical Trials Like Today?



## What is a clinical trial?

A clinical trial is a type of research study involving human volunteers. Clinical trials use traditional methods and may test a variety of new methods of screening, prevention, diagnosis, or treatment of a medical condition. Clinical trials (or “studies”) are intended to seek scientific answers to outstanding medical questions and gain knowledge about diseases, potentially leading to new or updated treatments. There are two main types of clinical studies: interventional studies (also called clinical trials) and observational (non-interventional) studies.

In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the investigators. These interventions may be medical products, such as drugs, biologics (e.g., vaccines and insulin), or devices (hardware and software-as-medical-device); procedures; or changes to participants' behavior, such as diet. Clinical trials may compare a new medical approach to an already-available approved treatment, to a placebo that contains no active ingredients, or to no intervention. Some clinical trials compare already-available approved treatments to each other. When a new product or approach is being studied, it is not usually known whether it will be helpful, harmful, or not different than available alternatives. The investigators try to determine the safety and efficacy of the intervention by measuring certain outcomes in the participants. For example, investigators may give a drug or treatment to participants who have high blood pressure to see whether their blood pressure decreases.



## How will I better understand what a clinical trial is about?

Before you can participate in a clinical trial or study, the study team must explain the purpose of the study and address any questions and concerns you may have before you begin participating in the study. The study team includes the study doctor, nurses, and others who work with the study doctor. The study team must ask for your permission to participate in the study and is required to have you sign (wet-ink or electronically) an Informed Consent Document before you undergo any study procedures. You must be given a copy of the Informed Consent Document that has been signed by you and the study team.



## If I'm considering enrolling in a clinical trial, what should I expect?

Some clinical trials involve visits to a study site, for evaluations by the investigator (e.g., doctor). Other studies may allow you to be monitored at home using telemedicine (telehealth), mobile/local healthcare providers (HCPs) and/or mobile (wearable and non-wearable) technologies.

If you are currently enrolled in a clinical trial, please refer to your clinical trial team for information about what to expect during your trial's processes. For general information regarding clinical trials, check out the following websites:

<https://clinicaltrials.gov/ct2/about-studies/learn>

<https://medlineplus.gov/clinicaltrials.html>

<https://medlineplus.gov/understandingmedicalresearch.html>



## Can I still see my current doctor?

Yes, you should continue to see your current doctor. The study doctor will oversee clinical trial care. For your safety, there could be overlap between your current doctor and your study doctor in your patient care if you encounter an adverse event.



## What support will be provided to me if I have questions about taking medication at home?

Clinical trial programs may deploy nurses, phlebotomists, or other licensed healthcare providers directly to your home to deliver treatments or collect samples if necessary. Sometimes the Primary Investigator (study doctor) will participate and/or oversee the visit via a telemedicine (telehealth) remote (virtual) meeting.



**Am I able to participate in a clinical trial if I don't live close to a trial site or cannot travel?**

Many clinical trial programs offer patients options for participating in a clinical trial remotely, i.e., away from the main investigational site. When patients must travel, most clinical trial programs cover travel and housing expenses. Other studies may not require patients to travel and may relieve such travel burdens by communicating and collecting patient data using electronic devices, applications on phones or desktop or tablet computers, as well as telemedicine (telehealth) videoconferences between patients and clinical trial doctors. The clinical trial program will determine the most feasible and accommodating options for their study participants based on the trial itself.



**What things could be done at my home for the trial?**

A home visit may be conducted by a health care professional other than your doctor (i.e., a nurse or nurse practitioner, a physician assistant, or healthcare technician). You could take a telemedicine (telehealth) call from your study doctor at home using a desktop or tablet computer or a smartphone. Again, this will depend on the study. Some studies may have you interact with the study doctor from your home, via a telemedicine (telehealth) visit over your computer or mobile device. Other studies may monitor you at home with a wearable sensor. Others may ask you to complete surveys or track certain symptoms using a mobile app on your phone. Still others might include a combination of these, along with visits to the study doctor at a clinic or hospital. While there are many ways to participate in a clinical trial at home, the clinical trial program conducting the study will identify the appropriate and available communication and measurement methods for your specific study.



**How will I get the study drug or intervention?**

You may be instructed to pick up the study drug at site, have it delivered to your home by a pre-specified courier or be instructed to go to a pharmacy and receive the study drug from a licensed pharmacist or pharmacy technician; this also will depend on the specific study.



**How are lab tests performed?**

As a clinical trial participant, you could be required to go to a clinical trial site, a local lab, or could have a health care practitioner visit your home.

Depending on the study, if there are lab tests required, you may be able to go to a lab close to our home. In other cases, you may go to the study clinic to have the lab tests performed by study staff. On other studies, you may be able to have a nurse or other trained staff visit you in your home to collect blood or other specimens for required lab tests.



**How will the clinical trial team communicate with me?**

This will vary by study, but the study staff will go over this with you at the outset of the study. It could involve regular visits to the investigational site, telemedicine (telehealth) visits, or other forms of communication via an app or phone calls. You may have a telemedicine (telehealth) visit using a digital device like a desktop or tablet computer, smartphone, or via a traditional landline phone.



**Will I get the results from my clinical trial?**

Under the law, "basic results" for certain clinical trials must be submitted and published on ClinicalTrials.gov, generally no later than 1 year after the study Completion Date. In many instances, study sponsors also share study results with participants via other mechanisms as well.

Please see the BIO Principles on Clinical Trials Data Sharing website for more information on how our member companies are and will continue to ensure a mutual exchange of knowledge gained from your participation in a clinical trial.