LET'S TALK TRIALS

Navigating conversations: How to talk about clinical trials

About this guide

People may be hesitant about participating in clinical trials. Empowering them to always ask questions and learn more can help dispel myths and encourage informed decision-making. Providing additional information may answer questions about safety and help build confidence in the clinical trial process.

Use this guide to engage potential clinical trial participants and offer additional materials, such as the infographic and brochure available on **LetsTalkClinicalTrials.com**, which provide individuals with something to review at their own pace.

This discussion guide provides information when talking to people about what clinical trials are and the importance of representation in clinical trials.

What are clinical trials?

- Clinical trials help researchers learn how our bodies respond to medicines and other treatments. They test new ways to help prevent, find, diagnose or treat diseases and whether investigational treatments or new uses for existing treatments are safe and effective. Investigational medicines and other treatments are first studied in clinical trials before they are approved for use in the general public.
- Clinical trials follow a detailed plan, or protocol, that clearly outlines:
  - Who can be in the study based on their disease, past medicines or other medical conditions they may have
  - The investigational treatment being studied
  - What people in the study will be asked to do
  - How long the trial will last
  - How outcomes will be monitored
- Clinical trial participants are partners in helping to advance medical research and have rights, including the right to withdraw from the clinical trial at any time.
- Clinical trials may take place in hospitals, universities, doctors' offices or community clinics.

Who can participate in a clinical trial?

- People must meet certain guidelines to join the study.
- Each trial has specific inclusion and exclusion criteria based on things like medical history, disease stage and prior medicines.
- If someone is interested in a trial, the team of physicians, nurses and trial coordinators will review their medical history and answer any questions they may have.

Updated September 2025

What is the importance of clinical trial participation?

- Clinical trial participation provides an opportunity to contribute to data that may help advance research and has the potential to help future generations.
- Health care institutions haven't consistently engaged all communities in the past. We can help build trust by advocating for inclusion and representation in clinical trials.
- Clinical trial participation can allow a person to take a more active role in their health journey and access relevant research.

Why does representation in clinical trials matter?

- Diseases can impact people differently based on their age, gender, weight, race, ethnicity and other factors. It's important that participants represent the population of people most impacted by the disease so the data generated from the research appropriately reflects the populations of patients medicines and vaccines are designed to help and protect.
- Only **24%** of clinical trial participants today are from communities of color, despite making up more than **40%** of the U.S. population and facing higher burdens of many diseases.[1]
  - In 2020, only **8%** of clinical trial participants were Black, despite making up **13.7%** of the U.S. population.[2,3]
  - Similarly, only **11%** of clinical trial participants in 2020 were Hispanic or Latino, despite making up **19.5%** of the U.S. population.[2,3]

What do people need to do if they decide they want to participate in a clinical trial?

- It is important that people understand the requirements of participation, as they are different for every trial. Questions to ask include:
  - What investigational medicine is being studied?
  - How long will the trial last?
  - How many in-person visits will there be?
  - What tests will there be?
  - What will I have to do at home?
  - Will I receive a placebo or investigational medicine?
- People who participate in a clinical trial may need to attend virtual or in-person doctor visits; write in a diary; fill out surveys; have tests such as blood tests, X-rays or others; and/or give urine or blood samples.
- Some trials compare investigational medicines to standard of care, others compare to placebos. Regardless of study design, if a placebo is involved, people who are considering participation are always informed of this possibility in advance, so they can decide if they're comfortable with it and want to continue to enroll in the study.

How can people make an informed decision about participation in a clinical trial?

- People may have questions like: What am I signing up for? What will happen to me? Am I putting myself at risk? Here's how you can help:
  - Provide clear, everyday language to explain clinical trials.
  - Reassure them that their rights and safety are protected.
  - Encourage them to ask questions and talk to their doctor (if that isn't you).
- Deciding to participate in a clinical trial is a personal choice, and having the right information is key.
  - Encourage people to ask questions: What will happen during the study? What are the possible risks? What support is available? What are my rights?
- The study team is there to answer any questions so people who participate can make the best decision for themselves.
- Talking with a doctor and loved ones can help people weigh their options and ensure the decision aligns with their personal health goals.

How are clinical trial participants protected?

- Clinical trials follow strict safety guidelines and are closely monitored by experts who are not part of the trial.
- Before a clinical trial can start, it must be approved by a committee called the Institutional Review Board (IRB) to make sure the risks are as low as possible and worth any possible benefits. The committee includes doctors, data experts, community advocates and others who help ensure that a trial is done in an ethical way and the rights of participants are protected.
- Informed consent is the process in which researchers talk with people who are thinking about enrolling, or have enrolled, in a clinical trial. They will have you read an informed consent form (ICF) that describes the possible benefits and risks of taking part. It tells you that taking part in the trial is voluntary and that you may leave the trial at any time.
- The informed consent process is to protect the participants who enroll in clinical trials. The informed consent process starts when a possible participant first asks for information about a trial and continues until the trial ends.
- During the clinical trial, researchers report the results to the IRB and government agencies. If problems such as severe side effects happen during a trial, it may be stopped or paused to protect participants.
- Details about how participants are monitored throughout the trial should be shared through the informed consent process.
- Participating in a clinical trial is voluntary and people may leave a trial at any time, for any reason. It will not affect your medical care.

What happens after the trial ends?

- Once the trial is complete, the research team may require follow-up phone calls or visits to check on the health of the person who participated or ask them to write down any changes that may have happened. The research team will tell them before they participate in the trial if they will need to do any follow-up.
- As every clinical trial is different, it's important to encourage people to ask the study coordinator questions about a specific trial.

Let's talk together

Visit **LetsTalkClinicalTrials.com** for more resources and information that can help you start the conversation about clinical trial participation.

1. Peters U, Turner B, Alvarez D, et al. Considerations for embedding inclusive research principles in the design and execution of clinical trials. *Ther Innov Regul Sci.* 2023;57(2):186-195. doi:10.1007/s43441-022-00464-3.
2. QuickFacts: United States. United States Census Bureau. Published July 1, 2024. Accessed September 2025. https://www.census.gov/quickfacts/fact/table/US.
3. Cavazzoni P, Anagnostiadis E, Lolic M. *2020 Drug Trials Snapshots Summary Report*. U.S. Food and Drug Administration; 2021:3.

MERCK