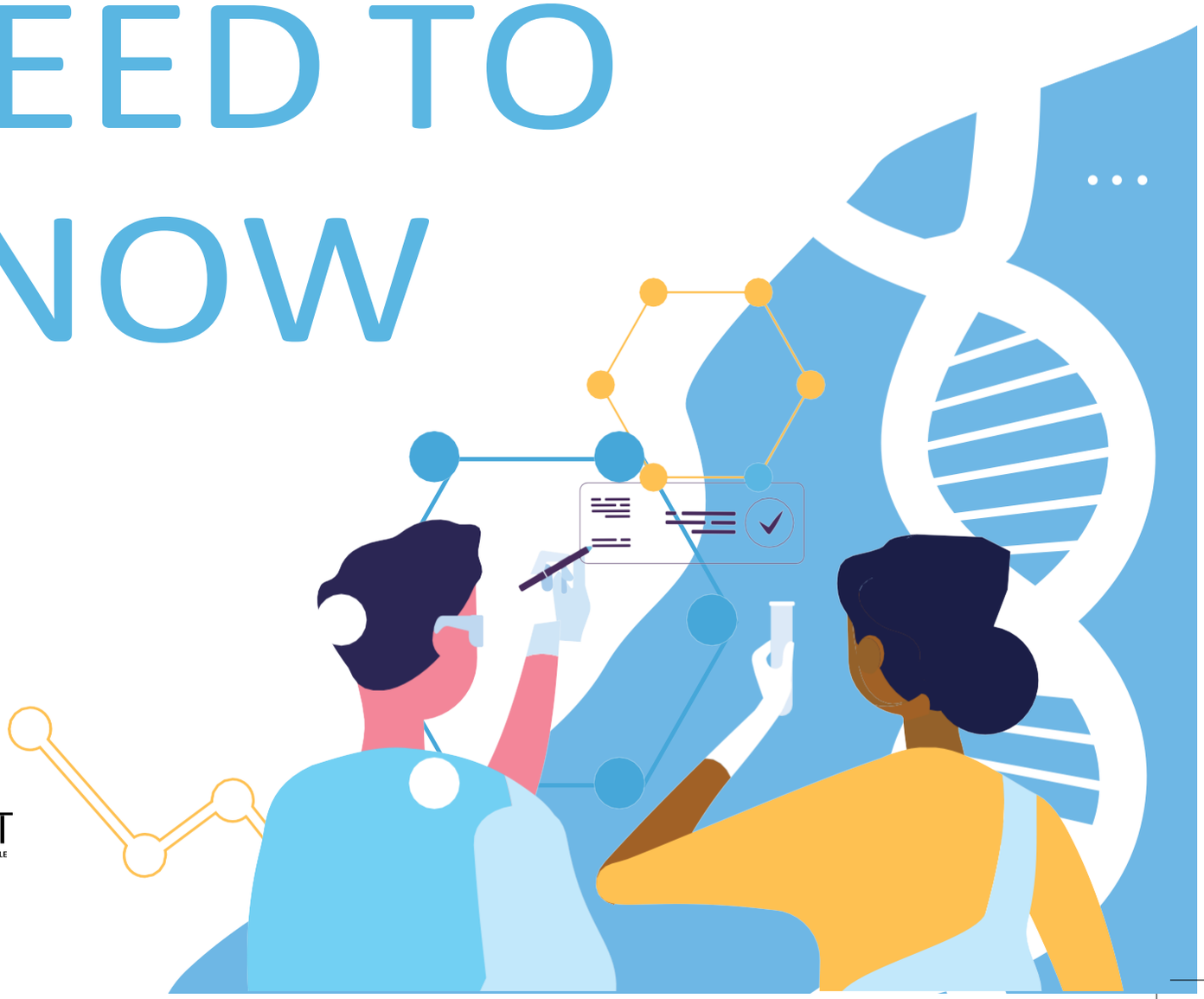
CLINICAL TRIALS: WHAT YOU NEED TO KNOW



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What are clinical trials and why do people participate?

A clinical trial is a type of research study that tests how well new medical approaches work in people. Laboratory research advances our knowledge of cancer and can lead to possible life-saving treatments. Clinical trials test whether these new treatments are safe, effective, and better than what is already available.

Clinical trials can study:

- New drugs or new combinations of drugs
- New ways to do surgery
- New medical devices
- New ways to use existing treatments
- New ways to change behaviors to improve health
- New ways to improve the quality of life for people with illnesses

Why would I want to take part in a clinical trial?

When you participate in a clinical trial, you help doctors and researchers learn more about diseases and how to improve health care for people in the future.

Reasons people take part in clinical trials:

- To help others and contribute to scientific progress
- To possibly receive the newest treatment
- To have a bigger cancer care team that includes clinical trial staff, doctors, and nurses
- To give hope to many people and a chance to help researchers find effective treatments for others in the future

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Why is diversity of participants important in clinical trials?

People may experience the same disease differently. People may also respond differently to treatments. That is why it is important that clinical trials include people with different living conditions, races, ethnicities, ages, genders, and sexual orientations. Knowing how treatments affect different populations can help guide doctors to make the best decisions with their patients.

How does the research process work?

The idea for a clinical trial starts in the lab. After researchers test new treatments in the lab and safely on animals, the best ones are moved into clinical trials with humans.
During the clinical trial, information is gained about the treatment: its safety, risks, and effectiveness.

What are clinical trial protocols?

Clinical trials follow a plan called a protocol. The protocol addresses the benefits and risks to participants and answers questions. It describes the following:

- The goal of the trial
- Who can participate in the trial
- How participants are protected from risks
- Details about tests, procedures, and treatments
- How long the trial will be
- What information will be collected

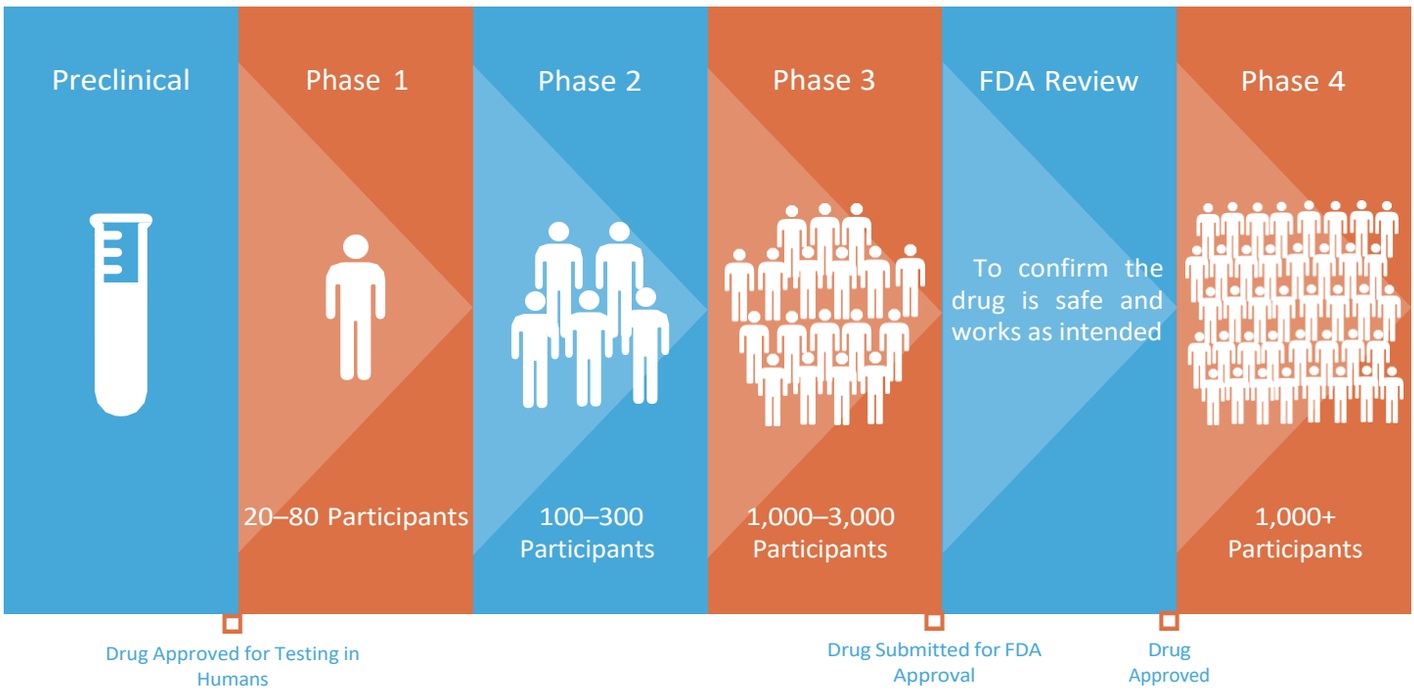
A clinical trial is led by a principal investigator, also known as the study PI. Members of the research team regularly monitor the participants' health to determine the trial's safety and effectiveness.

What are the phases of clinical trials?

Clinical trials are done in a series of steps called "phases." Each phase has a different purpose and helps researchers answer different questions.

- **Phase I trials:** The purpose is to study the drug or treatment to learn about its safety and identify side effects.
- **Phase II trials:** The new drug or treatment is given to a large group of people (100–300) to determine how well it works and to further study its safety.
- **Phase III trials:** The new drug or treatment is given to even larger groups of people (1,000–3,000) to confirm how well it works, track any side effects, and compare it with similar treatments.
- **Phase IV trials:** After a drug is approved by the FDA, a group responsible for protecting human health, the public can now use it. Researchers observe its safety in the general population and collect more information.

CLINICAL TRIALS



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CLINICAL TRIAL SPONSORS

Will start, manage, or finance the clinical trial, but will not perform the research

Sponsors may be:

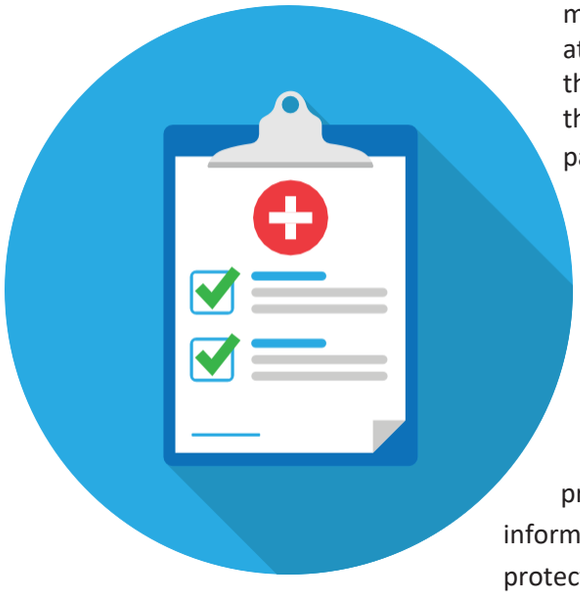
- Healthcare institutions and scientists
- Organizations
- Government agencies
- Pharmaceutical, biotech, and medical device companies

How is my safety protected?

Many people may have concerns about their safety when thinking about participating in a clinical trial. There are many measures in place now to ensure that medical research misconduct of the past are not repeated.

Institutional review board

An institutional review board (also called IRB) is a group of scientists, doctors, clergy, and patient advocates that is responsible for protecting the rights and safety of research participants. Every clinical trial is reviewed by an IRB before it can begin.



An IRB reviews and approves the detailed plan for a clinical trial. IRBs are meant to protect the people who take part in a clinical trial. There is an IRB at every healthcare facility that does clinical research. The IRB makes sure that the trial is well designed, legal, and ethical. The IRB also makes sure that the trial does not involve unneeded risks and that it includes a safety plan for patients.

Informed consent

Informed consent is a process in which you are given important information about a trial to help you decide if you want to participate. During this process, the research team gives you an informed consent form. An informed consent form is a document that includes details about the trial, such as its purpose, timeline, procedures, tests, possible risks and benefits, and important contact information. The informed consent form also tells how your privacy will be protected and how all your information will be kept strictly confidential.

During the informed consent process, you can ask any questions you may have about the clinical trial. It is your choice to sign the document and participate in the trial. If you do not understand English, the research team may provide a translator. While you are participating in the clinical trial, the researchers might learn new information that could affect your decision to participate. If this happens, you will be told and you may be asked to sign a second informed consent form.

Even if you sign the consent document agreeing to participate in a clinical trial, you can leave the study at ANY time by speaking with the study doctor so that you can be taken off the study safely. Taking part in a clinical trial is completely voluntary. There will be no impact to your future care and relationship with your doctor or medical team if you should decide to leave a clinical trial.

What are potential benefits and risks of clinical trials?

Like anything else in life, there are pros and cons to think about when deciding whether to participate in a clinical trial.

Clinical trials provide the opportunity to get a new or better treatment before it is available to everyone and to receive more frequent health checkups while on the trial. Some study participants experience complications that require medical attention. In rare cases, participants have been seriously injured or have died in clinical trials. The benefits and risks are described in the informed consent document. A member of the research team will explain the trial to you and answer all your questions. Carefully consider the benefits and risks before joining a clinical trial.

Potential benefits

- Help others get better treatment for their health problems in the future.
- Gain access to new research treatments before they are widely available.
- Receive the best standard of care available and frequent medical attention from a research team that includes doctors and other health professionals.

Potential risks

- There may be serious or even life-threatening side effects.
- The study may require more of your time and attention than standard treatment would, like extra visits, more blood tests, more procedures, hospital stays, or complex medication dose schedules. There is a risk that your personal information may be made public, but every effort will be made to protect your privacy and keep your information confidential.

What happens after a clinical trial is completed?

After a clinical trial is finished, the researchers carefully look at the information collected. Then, they look at the meaning of the findings and see if they need to do more testing. After a phase I or II trial, the researchers decide whether they will move on to the next phase or stop testing the treatment because it was not safe or effective. When a phase III trial is done, the researchers look at the information and decide whether the results have medical importance.

Results from clinical trials are usually published in journals and reviewed by other scientists (peers). Peer review is a process where experts review the report before it is published to make sure that the results are sound. If the results are important, they may be shown in the news and discussed at scientific meetings and by patient advocacy groups. Once a new approach has been proved safe and effective in a clinical trial, it may become new standard medical care.

What questions should I ask if offered a clinical trial?

If you are thinking about taking part in a clinical trial, you should feel free to ask any questions or bring up any issues concerning the trial at any time. The following suggestions may give you some ideas as you think about your own questions.

Preparing to talk to your doctor about a clinical trial

- Consider taking a family member or friend along for support and for help in asking questions or recording answers.
- Plan what to ask—but don't hesitate to ask any new questions.
- Write down questions in advance to remember them all.
- Write down the answers so that they're available when needed.
- Ask about bringing a tape recorder to make a taped record of what's said (even if you write down answers).

The study

- What is the purpose of the trial?
- How many people will be enrolled in this trial?
- Who will fund the trial?
- Why do researchers think the approach may be effective?
- How will the research team keep me safe during the trial?
- Will I be monitored for side effects?
- How long will the trial last?
- What will my responsibilities be if I take part?
- How are trial results being monitored?
- Who will tell me about the results of the trial, and how will I be informed?

Risks and possible benefits

- What are my possible short-term benefits?
- What are my possible long-term benefits?
- What are my possible short-term risks and side effects?
- What are my long-term risks?
- What other options are available?
- How do the risks and possible benefits of this trial compare with my other options?

Personal concerns

- How could being in this study affect my regular daily activities (such as work, family, hobbies)?
- How will being in this study affect my ability to attend special events?
- Can I talk to other people in the study?

Participation and care

- What kinds of therapies, procedures, and/or tests will I have during the trial?
- Will they hurt, and if so, for how long?
- How do the tests in the study compare with those I would have outside of the trial?
- Will I be able to take my regular medications while taking part in the clinical trial?
- Where will I have my medical care?
- Who will be in charge of my care?

Cost concerns

- Will I have to pay for any part of the trial such as tests or the study drug?
- If so, what will the charges likely be?
- What is my health insurance likely to cover?
- Who can help answer any questions from my insurance company or health plan?
- Will there be any travel or child-care costs that I need to consider while I am in the trial?
- Will the study accommodate my special needs or circumstances?

TERMS TO KNOW

Diversity: The state of including or involving people from a range of different social and ethnic backgrounds, genders, sexual orientations, and other characteristics.

Protocol: An official plan or system of rules that govern how the research is conducted.

Principal Investigator: The lead scientist; also called the "study PI." This individual is responsible for the preparation, conduct, and administration of a clinical trial.

For more information, contact DISRUPT Study Team Member Sylvia Lin and Erika Gonzalez at 646-984-3043

Institutional Review Board: Most clinical trials in the United States are approved and overseen by an institutional review board (also called IRB). IRBs are responsible for protecting the rights and safety of people who take part in research.

Placebo: An inactive substance (sugar pill) that looks like the drug or treatment being tested but contains no drug.

- Used only when there is no standard treatment for comparison. It is very rare that a cancer does not have a standard treatment

Randomization: The process where participants are assigned by chance, rather than by choice, to receive the usual treatment or the new treatment.

- Used to avoid the intentional selection of patients who may respond better to the new treatment

"Blinded" (or "Masked") Studies: Studies designed to prevent members of the research team and study participants from influencing the study results.

- In a single-blind study, you are not told what is being given, but the research team knows
- In a double-blind study, neither you nor the research team is told whether you are given the usual treatment or the new treatment; only the pharmacist knows

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