A Guide on the Importance of Diversity in Clinical Trials

Finding Treatments Together

What are clinical trials?

Clinical trials are the best way to find out if new treatments or vaccines work and how safe they are. If you have ever taken medicine or gotten a vaccine, then you have benefited from clinical trials.

Who takes part in clinical trials?

People who participate in a trial may have a specific disease or condition. But, trials can also include healthy volunteers who help researchers learn how a new treatment acts in the body.

All trial participants play an important role in helping to advance our knowledge about human health and disease.

Federal laws protect the safety of clinical trial participants. Clinical trials must:

- Follow laws and guidelines that make sure trials are ethical
- Include a process called informed consent to fully inform people about a trial before they can agree to be in it
- Be approved by an expert group called an institutional review board (IRB) that helps make sure the trial is as fair and as safe as possible

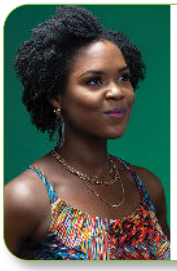
When you sign an informed consent form to participate in a trial, you are not signing your rights away. Being in a trial is optional. **You can stop at any time and for any reason**. The trial staff will help you do this safely.

You can talk to the trial staff or the IRB anytime you have concerns.

Why should clinical trials have diverse participants?

People respond to treatments in different ways

Clinical trials help us learn how well a treatment or vaccine works and if it is safe. If trials do not include diverse participants, we cannot know if treatments work for everyone who needs them. But, trials only tell researchers how something works in the participants of that trial. Treatments work differently depending on race and ethnicity.



"Due to a lack of participation by women of color in a lot of these trials, [researchers] were not able to actually track if it worked for us. There's only one way to find out if it works. It meant a lot to be able to do so."

Shanelle Gabriel, lupus awareness advocate

Improve the representation of people from different communities

Clinical trials sometimes do not include a group of participants that is as diverse as the full population of patients who might use a new treatment or vaccine. People who are White are often represented more than people from other racial and ethnic backgrounds, including people who are Asian, Black, African American, Hispanic, Latino, or Native American.

Diversity in trials is the only way to know whether a treatment will work and be safe in all the people who might receive it.

"This has become a coming-of-age story – I realized I didn't have to be ashamed of having this disease. I wasn't disrespecting my elders because I was treating this disease. This is my body and this is my life and I have to pay that respect to myself as well. I don't want anyone else to suffer, and that's why I talk about clinical research and educate others on its importance."

Tina Aswani Omprakash, Crohn's disease advocate

Improve access to treatments

For some people, participation in a clinical trial is a way to access other treatment options for their disease. Cancer is an example of such a disease. Improving diversity in cancer trials and trials for other life-threatening diseases is one way to improve equal access to new treatments.

Improve fair treatment in health care

Diverse trials can help doctors learn which treatments are appropriate for patients from different communities. This can help pave the way for fairer health care for people who have been underrepresented in trials.

What is being done to improve diversity in clinical trials?

Some people are hesitant to participate in clinical trials due to mistrust of clinical research or the healthcare system, lack of access to sites where trials take place, and lack of access to information about trials. While there is still work to be done, steps are being taken to address these concerns.

Government guidelines and programs

Across the world, guidelines and regulations are being put in place to protect the safety of trial participants and to make sure they are treated fairly.

Government programs from the United States' National Institutes of Health and the European Medicines Agency have made diversity a priority in trials.

Researchers are still working to improve access

Researchers are working to improve access for those who have been underrepresented in trials.

There has also been more focus on hiring nurses, doctors, research coordinators, and other research team members from diverse communities.

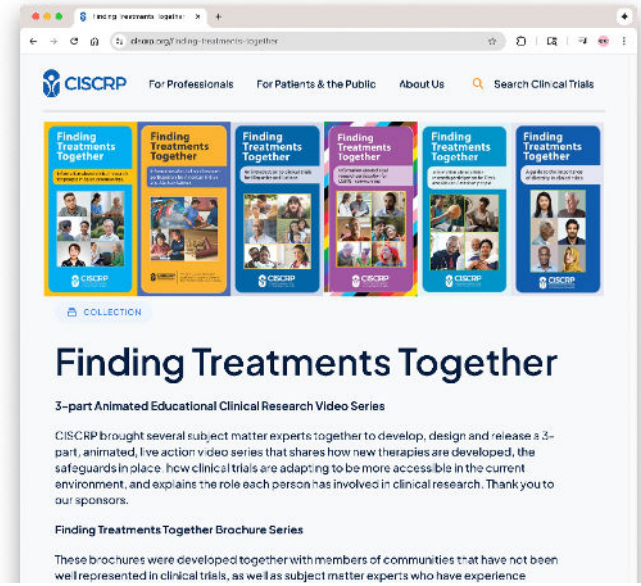
"It's vital to know that clinical trials are an option. It's important to weigh your options. Can you get the support you need from family or a caregiver? Ask questions of the study staff. There are risks involved, so ask about them."

Melvin Mann, chronic myelogenous leukemia (CML) advocate

Thank you to the Medical Heroes who shared thoughts and insights about their journeys and about clinical trial participation.

How can you find more information?

There is a lot of information about clinical trials, including ways to participate and how participants are protected.



For more information from CISCRP's *Finding Treatments Together* series and for translations of this brochure, go to: findingtreatments.org

CISCRP COMMUNITY COLLABORATION

This brochure was co-developed together with a diverse group of people and experts who have experience working with diverse communities.

It was also reviewed and tested with patients, the public, and health professionals. They all helped to make sure it is clear, non-biased, and culturally appropriate.

CISCRP

CISCRP is an independent non-profit organization dedicated to engaging the public and patients as partners in the clinical research process.

CISCRP does not recruit patients for clinical trials and does not conduct clinical research. CISCRP is also known as the Center for Information and Study on Clinical Research Participation.

Visit www.CISCRP.org or call toll free 1-877-633-4376

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