Who must be included in *clinical research?* ***Everyone.***

What is a clinical trial?

Research includes me™
Diversity+Equity+Inclusion in Clinical Trials

- A clinical trial is also called a clinical research study.
- A clinical trial is designed to evaluate or study investigational medications.
- Clinical trials are conducted by doctors, nurses, and other health care providers.

PHASES OF CLINICAL TRIALS

PHASE 1	PHASE 2	PHASE 3	PHASE 4
First study in humans with 20-100 healthy volunteer participants	Small studies of 100-500 participants	Large studies of 500 or more participants to determine whether a drug will be approved by authorities for public use	Large studies after the medicine has received approval
Each phase is conducted to investigate:			
• Safety of the study medication. • How the study medication is absorbed by the body and what dosage should be used. • How the study medication is removed from the body. • Potential side effects.	• Ongoing safety. • Whether the study medication works for a particular disease. • The appropriate dose of the study medication.	• Safety and side effects in bigger populations. • Whether the study medication works for a particular disease. • How the treatment compares to already existing standard therapies.	• Side effects during day-to-day use in the population. • Risks and benefits over a period of time.

Why should we participate?

Certain medicines work differently based on sex assigned at birth, gender identity, age, race, and ethnicity. Some diseases and conditions are more common in certain groups of people.
For example:

- In the United States, 87% of tuberculosis cases occur in racial and ethnic minorities, particularly in Black, Asian, and Latine Americans.[1]
- Black Americans have higher rates of diabetes, hypertension, and heart disease than other groups. Black adults are 60 percent more likely than White adults to be diagnosed with diabetes.[2]
- Latine women are 40% more likely to be diagnosed with cervical cancer and 20% more likely to die from cervical cancer, as compared to White women.[3]
- Asian-Americans have disproportionately high rates of certain types of cancer, tuberculosis, and hepatitis B.[4,5]
- The LGBTQ+ population disproportionately faces health disparities compared to the majority.[6,7]

And yet...

- Patients participating in clinical trials for new medicines and treatments are mainly White — in some cases, 80% to 90%. Participation by people of color, including Black, Latine, and other racial or ethnic minorities, is much lower.[8]
  The United States Food & Drug Administration 2019 Drug Trials Snapshot assessed the clinical trial participation rates associated with 11 new drug approvals. A total of 3,593 patients participated in the trials that led to the approvals of 11 new drugs.
  Overall, 38% of all participants were women, 73% were White, 18% were Asian, 4% were Black, 5% were Latine, 59% were 65 years and older, and 24% were from sites in the United States.[9]
- Black Americans are more likely than White Americans to suffer from respiratory conditions such as asthma. Yet as of 2015, only 1.9% of studies of respiratory diseases included Black American participants.[9]

This is why everyone needs to be included in clinical research!

Your safety is the priority!

- Researchers and the pharmaceutical companies that sponsor the trials must follow strict rules and ethical guidelines.
- Trials are reviewed and monitored by an independent body called an Institutional Review Board to ensure the trials are conducted ethically.
- The FDA also monitors trials and must approve the medicines before the public can use them.
- Researcher must follow a study plan called a protocol that outlines what will happen in the study.
- Participants must give permission by signing a document called the Informed Consent Form.
- If you decide to take part in a clinical trial, you can change your mind and withdraw from the trial at any time.

It is important to consider the risks and opportunities of participating in a clinical trial.

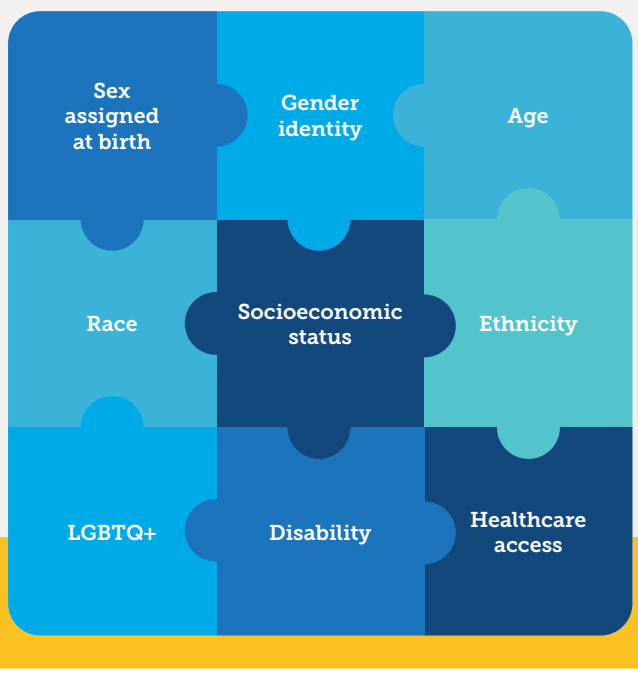
There may be opportunities when you take part in a clinical trial:

- Supporting the development of effective medicines for all
- Increasing diverse representation in clinical research
- Expanding knowledge for all about a disease or condition
- Pushing science closer to achieving health equity for all

There are potential risks that come with being part of a clinical trial:

- The investigational medication may cause discomfort or mild to moderate side effects. In some cases side effects may be serious.
- The investigational medicine may not work, or it may not work any better than existing treatments.
- You may have to provide samples for several lab tests and procedures.
- Being a clinical trial participant may require a hospital stay and/or travel.
- Your current condition may not improve while in the clinical trial.
- You could be selected to be in a placebo (control) group.
- Clinical trial participation can be time consuming.

People of all backgrounds are needed and welcome in clinical trials.



Our goal is to find new and better ways to treat conditions and diseases.

Clinical trials can help answer important questions about study medications:

- Is the study medication safe?
- How well does the study medication work?
- How does the medication act in the body?
- Does the medication work better than other available medicines?
- How does the medication affect certain diseases or conditions?
- What are the side effects and reactions to the medication?
- Are there any differences in the way the medicine acts due to sex assigned at birth, gender identity, age, race, ethnicity, or any other factors?

Deciding to participate in a clinical trial is an important decision.

As you think about your decision to participate in a clinical trial, the clinical trial team must explain:

- The purpose of the clinical trial.
- What to expect as a clinical trial participant.
- The possible risks and possible benefits of participating in the trial.
- The visits and tests required in the clinical trial.

Ask the clinical trial team any other questions you have.

If you agree to participate, you'll be asked to sign an Informed Consent Form. Remember, participation in a clinical trial is voluntary.

Important questions to ask:

- Why is the study being done?
- Has this drug been tested before?
- What will be expected of me?
- What kinds of procedures/tests are involved?
- Will I be reimbursed for my expenses?
- How will I know that the treatment is working?

What happens after the clinical trial?

Depending on the clinical trial's results, a healthcare authority such as the FDA may approve the investigational medication for public use. Investigational medications are approved when they are proven to be generally safe and effective or when the benefits of using the medicine outweigh the risks for the intended population.

Learn more: **www.ResearchIncludesMe.com**

1. Health Disparities in TB. Centers for Disease Control and Prevention. Updated November 10, 2022. Accessed October 12, 2023. https://www.cdc.gov/tb/topic/populations/healthdisparities/default.htm **2.** Diabetes and African Americans. U.S. Department of Health and Human Services Office of Minority Health. Updated March 1, 2021. Accessed October 12, 2023. https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=18 **3.** Cancer and Hispanic Americans. U.S. Department of Health and Human Services of Minority Health. Updated August 26, 2021. Accessed October 12, 2023. https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=61 **4.** TB and Asian Persons. Center for Disease Control and Prevention. Updated October 18, 2021. Accessed October 12, 2023. https://www.cdc.gov/tb/topic/populations/tbinasians/default.htm **5.** Philbin MM, Erby LA, Lee S, Juon HS. Hepatitis B and Liver Cancer Among Three Asian American Sub-groups: A Focus Group Inquiry. *J Immigr Minor Health.* 2012;14(5):858-868. doi:10.1007/s10903-011-9523-0 **6.** Krehely J. How to close the LGBT health disparities gap. Center for American Progress. Accessed October 12, 2023. https://www.americanprogress.org/article/how-to-close-the-lgbt-health-disparities-gap/ **7.** Making clinical research inclusive: Strategies to include the LGBTQIA+ community in research trials. WCG Clinical Services. June 10, 2021. Accessed October 12, 2023. https://www.wcgclinical.com/insights/making-clinical-research-inclusive-strategies-to-include-the-lgbtqia-com-munity-in-research-trials **8.** QuickFacts: United States Table. U.S. Census Bureau. Accessed October 12, 2023. https://www.census.gov/quickfacts/fact/table/US/PST045219 **9.** 2019 Drug Trials Snapshots Summary Report. U.S. Food & Drug Administration. Published January 2020. Accessed October 12, 2023. https://www.fda.gov/media/135337/download