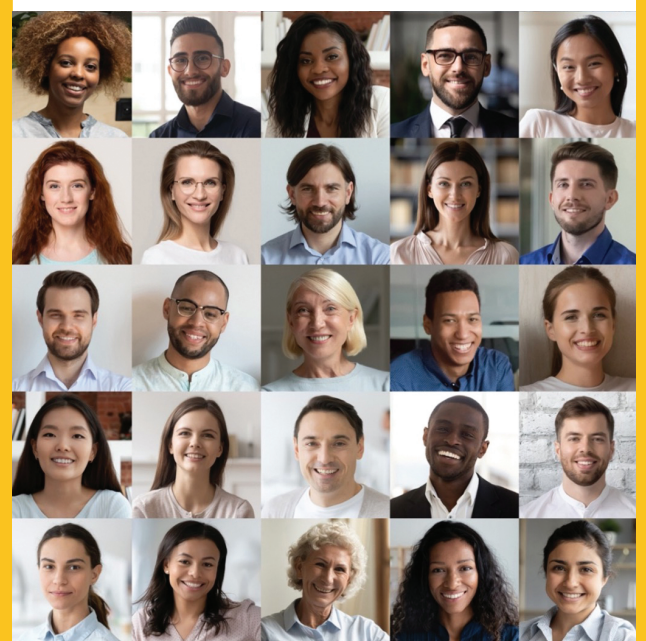
***Our goal is to find new and better ways to treat conditions and diseases.***

## 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 of the medication?
- Are there any differences in the way the medicine acts due to gender, 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
- Any other questions you may have

If you agree to participate, you'll be asked to sign an Informed Consent Form and 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 Food and Drug Administration (FDA), may approve the investigational medication for public use.

Investigational medications are approved when: they are generally proven to be safe and effective or the benefits of using the medicine outweighs the risks for the intended population.

**Learn more: www.researchincludesme.com**

**1.** Health Disparities in TB. Centers for Disease Control and Prevention. Updated October 23, 2020. Accessed December 21, 2021. 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 December 21, 2021. 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 December 21, 2021. 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 December 21, 2021. 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.** U.S. Census Bureau QuickFacts: United States Table. U.S. Census Bureau. Accessed December 21, 2021. https://www.census.gov/quickfacts/fact/table/US/PST045219 **7.** 2019 Drug Trials Snapshots Summary Report. U.S. Food & Drug Administration. Published January 2020. Accessed December 21, 2021. https://www.fda.gov/media/135337/download



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

## What is a clinical trial?

- 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 healthcare providers

Research includes me™

Diversity+Equity+Inclusion in Clinical Trials

## PHASES OF CLINICAL TRIALS

| PHASE 1 | PHASE 2 | PHASE 3 | PHASE 4 |
|---|---|---|---|
| First study in humans of 20-100 participants in healthy volunteers. | Small studies of 100-500 participants. | Large studies of 500 or more participants to determine if 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<br>• How the study medication is absorbed by the body and what dosage should be used<br>• How the study medication is removed from the body<br>• Potential side effects | • Ongoing safety<br>• Whether the study medication works for a particular disease<br>• The appropriate dose of the study medication | • Safety and side effects in bigger populations<br>• Whether the study medication works for a particular disease<br>• How the treatment compares to already existing standard therapies | • Side effects during day-to-day use in the population<br>• Risks and benefits over a period of time |

*It is important to consider the risks and opportunities for 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
- Increasing awareness of clinical research
- Building trust in new medicines by increasing diverse representation

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

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

## Why should we participate?

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

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

### *And yet...*

- Patients participating in clinical trials for new medicines and treatments are mainly White — in some cases, 80 to 90 percent. Participation by people of color, including Black/African-Americans, Hispanics/Latinos, and other racial or ethnic minorities, is much lower[6]
- 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 or African American, 5% were Hispanic, 59% were 65 years and older, and 24% were from sites in the United States[7]
- African-Americans are more likely to suffer from respiratory conditions, like asthma, than White Americans. Yet as of 2015, only 1.9 percent of studies of respiratory diseases included African-American participants[7]

*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

## Clinical trial participation