Understanding

Clinical Trials & the Importance of Diversity

What you will find in this book

This book will explain clinical trials and the importance of diversity in medical research involving people.

What is a clinical trial?

Every medicine or vaccine you've ever had has gone through a clinical trial.

Clinical trials, also called clinical studies, are research studies that help doctors and scientists learn more about a disease or medical condition and investigate an investigational study drug which may prevent, diagnose, or treat that disease or medical condition.

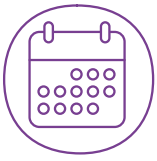
When an investigational study drug is discovered, it is usually not known whether it will be helpful, harmful, or no better than approved treatments that are already available.

Clinical trials test investigational study drugs to see if they are safe and effective for a specific disease, medical condition, or population.

Clinical trials rely on volunteers who choose to participate to help advance science.

Different diseases and medicines can affect people differently

How a person is affected by a disease or medicine depends on many factors, including age, sex/gender, race/ethnicity, lifestyle (how a person lives), and environment (where a person lives), among others.



Age

Sex/Gender

Race/Ethnicity

Lifestyle

Environment

Some populations have a higher occurrence of certain diseases. For example:

- Black Americans and Indigenous Peoples have the highest asthma rates compared to other races and ethnicities.[1]
- Black Americans are more at risk for kidney failure than any other race.[2]
- Asian Americans have the highest rates of liver cancer of any ethnic group in the United States.[3]
- Black Americans and Hispanic/Latino Americans have higher rates of diabetes than White Americans.[4]

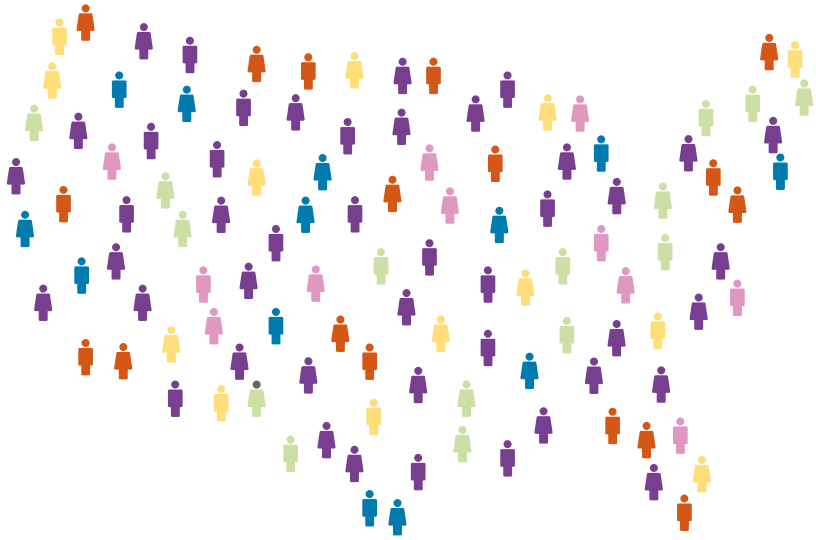
Clinical trials should represent the diversity of the real-world population to make sure the investigational study drug is safe and effective for those who would need it most.

The importance of diversity

When clinical trials include diverse participants, the study results may have a much wider applicability. Representative trials allow for better prediction.

Having a diverse group of people included in a clinical trial can reveal important information that affects how an investigational study drug is used for certain groups. For example:

- Some people need a different dose or need to take the investigational study drug at different times.
- The investigational study drug may not work for some groups.



It's important that clinical trial participants represent the real-world patient population that has (or are at risk of) the disease/medical condition being studied. This way, the trial data represents real-world outcomes.

Developing new medicines

Investigational study drugs go from the lab to the real world through a highly regulated process. Clinical trials are a very important part of that process.

1 *Lab research*

When a potential investigational study drug is being developed, lab tests provide information about what the investigational study drug does, the best way to deliver the investigational study drug (for example as a pill or shot), and if the investigational study drug is safe enough to test in humans.

2 *Clinical trials*

Clinical trials are done to answer questions about whether the investigational study drug is safe and effective. Typically an investigational study drug is tested for a specific disease, medical condition, age group, or population of people, such as those for whom another medicine didn't work.

3 *The real world*

If an investigational study drug has been found safe and effective, it becomes approved by your country's Health Authorities, such as the Food and Drug Administration. This means that doctors can now prescribe the medicine in regular medical practices to patients who may benefit from it.

It can take decades for an investigational study drug to go from the lab to becoming an approved medicine.

Phases of clinical trials

Clinical trials are usually done in 3 to 4 phases. Each phase involves a larger group of people and is designed to answer different questions about the investigational study drug. Each phase must also show that the investigational study drug is safe before it can move on to the next phase. Clinical trials can last for months or for many years, depending on what is being studied.

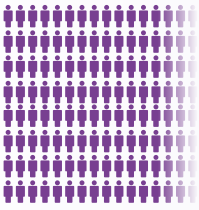
What is being studied

Phase 1

- Safety of the investigational study drug
- The highest amount (dose) of the investigational study drug that can be given to treat the disease safely

Phase 2

- Safety of the investigational study drug in a larger group of people
- Whether the investigational study drug is effective



Phase 3

- Safety of the investigational study drug over a long period of time
- Whether the investigational study drug works as planned in large groups of people
- If the investigational study drug is better than currently available treatments

Phase 4

- How the investigational study drug works in the real world once it's approved
- Side effects that may happen over a long period of time when used by the general public

The Informed Consent Process

Every clinical trial includes a process called Informed Consent. This is when you learn about the trial, ask any questions you have, and ultimately agree to participate if you qualify and wish to enroll. The study team will explain:

- Why the study is being done.
- How long the study lasts and the schedule of visits.
- Health checks and tests to be done.
- Possible benefits and risks.
- Who will be involved in your care.
- Available support, such as reimbursement for travel and meals.

Take your time to think about it. Joining the trial is your choice. You can choose not to join and to continue with your usual medical care.

If you agree to join and qualify to enroll, you will sign the Informed Consent Form. This is not a contract, and you do not give up any legal rights by signing it.

What happens during a clinical trial?

Most clinical trials follow a similar process that includes a Screening Period, a Study Treatment Period, and a Follow-up Period.

1 *Screening*

The study team will check to see if you are eligible for the trial. You will answer questions about you, your current and past health, and any medicines you take. You will also have a checkup and some tests.

2 *Study Treatment*

You will be placed by chance in a group to receive either the investigational study drug, an already available treatment, or a placebo. You will have visits with tests to check on your health. Visits may be in person or by computer/phone.

Some common tests include:

Physical exam

Blood test

Urine test

3 *Follow-up*

After your final dose of the investigational study drug, you may have a few more visits to check on your health.

Your well-being is the number one priority

Participants' health and safety are the most important things in clinical trials. Many processes are put into place to make sure:

- Your rights and well-being are protected.
- Any possible risks are minimal.
- The trial is ethical (fair).
- Your personal information is appropriately protected.

Your health and safety are closely monitored by a team of doctors and nurses throughout the entire trial. They want to know if anything bothers you or if there are any changes in your health.

Benefits and challenges of being in a clinical trial

Every clinical trial has possible benefits and possible challenges.

Possible benefits	Possible challenges
The investigational study drug may help you.	The investigational study drug may not help you.
You'll be helping to find new and better treatments.	Study visits require time and commitment.
Your health will be closely monitored by a team of doctors and nurses.	There is the possibility of side effects from the investigational study drug or study procedures.

Sometimes people have heard misconceptions or incorrect information about clinical trials. By being open and honest with your concerns, your study team can help make sure you have accurate and up-to-date information.

Summary of key points

- Clinical trials help doctors and scientists learn more about a disease and new ways to possibly prevent, diagnose, or treat it.
- It's important for clinical trials to represent the diversity of the real world to make sure the investigational study drug is safe and effective for everyone who would need it.
- Clinical trials are started only after enough lab data have shown that the investigational study drug shows possible safety and efficacy.
- Clinical trials go through several phases to make sure that the investigational study drug is safe and effective.
- Your health and safety are the most important things to everyone involved in running a clinical trial.
- Participation in a clinical trial is 100% your choice.

Words to know

Approval:
Once an investigational study drug is shown in clinical trials to be safe and effective, it may be approved by the applicable Health Authorities, such as the Food and Drug Administration. If approved, the drug is made available to people who may benefit from it.

Informed Consent:
The study team will go over all the details of the study. If you understand and agree to the information, and qualify for enrollment, you will sign the Informed Consent Form before any study procedures can begin.

Investigational study drug:
This is what is being tested in the clinical trial. It may be a medicine that is already approved for one condition or age group but is investigational (ie, not approved) for another condition or age group.

Phases:
Clinical trials are divided into phases, or stages, that are designed to answer different questions about the investigational study drug. Each phase must show that the investigational study drug is safe before it can move on to the next phase.

Placebo:
This looks like the investigational study drug but contains no active ingredients. Placebos give researchers something to compare with the investigational study drug to better understand its effects. Placebos are only used if no effective treatment is available and are rarely used in cancer trials.

Screening:
This is the first part of a trial, in which the study team determines whether you are eligible to join.

References:
1. American Lung Association. Current asthma demographics. Accessed August 19, 2024.
2. American Kidney Fund. Race/ethnicity – Kidney disease risk factors. Accessed August 19, 2024.
3. UCLA Health. Liver disease in Asians. Accessed August 19, 2024.
4. Rodríguez JE, Campbell KM. *Clin Diabetes*. 2017;35(1):66-70. doi: 10.2337/cd15-0048

Notes

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