Understanding Clinical Trials

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What Are Clinical Trials?

Clinical trials are designed to find new ways to prevent, detect, or treat a disease.[1]

What Types of Treatments Are Studied in Clinical Trials?[1]

New drugs

New combinations of drugs

New or different ways to use current treatments

New surgical procedures or medical devices

Where Do Clinical Trials Commonly Take Place?

Doctors' offices[2]

Medical and/or research centers[2]

Clinics[2]

Homes with virtual tools (in decentralized trials and telehealth)[3]

Who Is Involved in Clinical Trials?[2,4]

Principal Investigator, also called a PI, is responsible for organizing and leading the trial as well as recording and studying the data

Research Coordinator/ Research Nurse is like an assistant manager who helps the PI coordinate the day-to-day activities

Patients/ Caregivers

Staff Doctor or Nurse takes care of the patients during a clinical trial, treating the patients according to the study protocol

Data Manager collects and manages all the data gathered within the trial

Glossary

REFERENCES: 1. National Institutes of Health. Why do researchers do different kinds of clinical trials? https://www.nih.gov/sites/default/files/health-info/clinical-trials/infographic-why-researchers-different-kinds-clinical-studies.pdf. Accessed April 3, 2024. **2.** Bayer. What are clinical trials? https://clinicaltrials.bayer.com/what-are-clinical-trials/. Accessed April 3, 2024. **3.** Van Norman GA. Decentralized clinical trials: the future of medical product development? JACC Basic Transl Sci. 2021;6(4):384-387. https://www.jacc.org/doi/10.1016/j.jacbts.2021.01.011#d2213961e100. **4.** National Cancer Institute. Research team members. https://www.cancer.gov/research/participate/clinical-trials/how-trials-work. Accessed April 2, 2024.

What Are the Phases of Clinical Trials?

Clinical trials are done only after **preclinical studies** show that the new treatment is likely to be safe.[1] Clinical trials are divided into different phases. If a new treatment works in one phase, it will move on to the next phase.

EACH CLINICAL TRIAL PHASE IS DESIGNED TO ANSWER A SPECIFIC QUESTION[1,2]	HOW MANY PEOPLE ARE INVOLVED?
PHASE 1 (Safety) — **IS THE NEW TREATMENT SAFE?** Learn how the treatment affects the body and find the right dose	 Usually fewer than **100** healthy people or patients with the disease or condition[3]
PHASE 2 (Efficacy) — **DOES THE NEW TREATMENT WORK?** Learn whether the new treatment has an effect on a certain disease or condition	 **25** to **100** patients with the disease or condition[3]
PHASE 3 (Efficacy & Safety) — **DOES THE NEW TREATMENT WORK BETTER THAN PLACEBO OR THE STANDARD OF CARE?** Lasts longer than phase 1 or 2, with **side effects** monitored closely	 **100** to **1000s** of patients with the disease or condition[3]
PHASE 4 (Usually after the treatment is approved for use) — **IS THERE ANYTHING ELSE WE NEED TO KNOW ABOUT THE NEW TREATMENT?** Long-term safety **data** are gathered, such as unknown or rare side effects. Other effects are measured, such as quality of life	 **1000s** of patients with the disease or condition[3]

Knowing the phase of the clinical trial is important because it can give you some idea about how much is known about the treatment being studied.[1]

Glossary

REFERENCES: 1. US Food and Drug Administration. Clinical research. https://www.fda.gov/patients/drug-development-process/step-3-clinical-research. Accessed April 3, 2024. **2.** Bayer. What are clinical trials? https://clinicaltrials.bayer.com/what-are-clinical-trials/. Accessed April 3, 2024. **3.** National Institutes of Health. Why do researchers do different kinds of clinical trials? https://www.nih.gov/sites/default/files/health-info/clinical-trials/infographic-why-researchers-different-kinds-clinical-studies.pdf. Accessed April 3, 2024.

Should I Consider Joining a Clinical Trial?

Deciding to join a clinical trial is an important decision. You and your loved ones should talk to a healthcare professional and decide together whether joining a clinical trial is something you should consider.

How Might I Benefit From Joining a Clinical Trial?[1]

Discover a new treatment option
You may receive a new treatment option not available outside of a clinical trial.

Receive medical care
Additional doctor visits and more frequent checkups may be part of the trial.

Contribute to medical research
You have the chance to help others receive better treatment in the future.

What Are Some Things I Need to Be Aware of Before Joining a Clinical Trial?[1]

Treatment effects
The new treatment may cause **side effects**, and it may not work.

Treatment
You may not receive the new treatment but rather receive the **standard of care** or **placebo**.

Time and commitment
You may need to travel long distances to frequent medical appointments/visits. Some trials pay for travel costs and time commitment. Not all do, and the amount of pay varies.

You can leave a clinical trial at any time for any reason.
Clinical trials may also be discontinued or stopped.[1]

Glossary

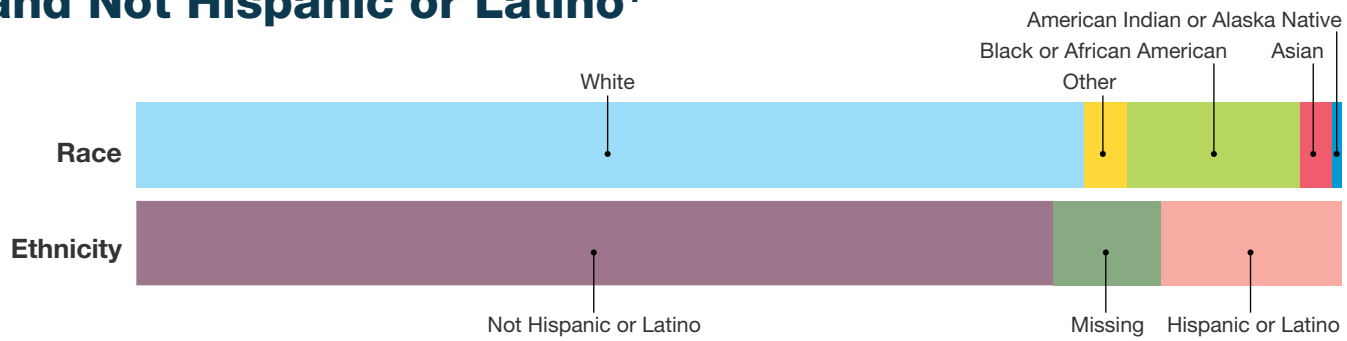
REFERENCE: 1. National Institutes of Health. The basics. https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics. Accessed April 3, 2024.

What Is the Importance of Diversity in Clinical Trials?

Globally, the majority of clinical trial participants are of White **race**, do not report Hispanic/Latino **ethnicity**, and are less than 65 years of age, and there is limited representation of the **LGBTQIA+** community.[1,2]

Participation of patients with diverse backgrounds in clinical trials is important to help researchers better understand patterns of difference in health and illness.

US Clinical Trial Participants Are Primarily White and Not Hispanic or Latino[1]*



*Data from demographic study of newly FDA-approved drugs (2015-2019).

Why Should Clinical Trials Have Diverse Participants?[3]

Patients respond to treatments in different ways
Treatments may work differently depending on race, ethnicity, age, and sex. If clinical trials do not include diverse participants, we cannot know whether treatments work for everyone who needs them.

Improve representation of patients from different communities
Diversity in clinical trials is the only way to know whether a treatment will work and be safe in all the patients who might receive it. Clinical trials sometimes do not include a group of participants that is as diverse as the full population of patients who might use the treatment.

Improve access to treatments
Improving diversity in clinical trials is one way to help ensure equal access to new treatments.

Improve fair treatment in health care
Diverse clinical trials can help healthcare professionals learn which treatments are appropriate for patients from different communities and improve care in underrepresented communities.

It is important that you and your loved ones talk to a healthcare professional and decide together whether joining a clinical trial is something you should consider.

Glossary

REFERENCES: 1. Lolic M, Araojo R, Okeke M, Temple R. U.S. racial and ethnic participation in global clinical trials by therapeutic areas. *J Clin Pharm Ther*. 2021;46(6):1576-1581. **2.** Round R, Gokool N, Manica G, Paschall L, Foulcer S. Improving access for and experience of transgender and non-binary patients in clinical research: insights from a transgender patient focus group and targeted literature reviews. *Contemp Clin Trials.* 2023; 131:107243. https://www.sciencedirect.com/science/article/pii/S1551714423001660. **3.** Center for Information and Study on Clinical Research Participation. Finding treatments together: a guide to the importance of diversity in clinical trials. https://www.ciscrp.org/a-guide-to-the-importance-of-diversity-in-clinical-trials/. Accessed April 3, 2024.

What Should I Expect During a Clinical Trial?

There are many steps in a clinical trial.[1]

Prescreening

You will talk to the clinical trial team to learn more about the clinical trial.

Informed Consent

You are provided with information that can help you decide whether to take part in the clinical trial.[2] If you decide to take part in the clinical trial, you will sign a consent form that explains your rights and responsibilities.[1]

Screening

Your medical history is reviewed and a physical examination is done to determine whether you qualify for the clinical trial.

Enrollment

If you qualify after screening, you join the clinical trial and learn what to do and how often.

Clinical Trial Participation

You are assigned to a treatment group.[2] You will have clinical trial visits that may include physical examinations, questionnaires, or other procedures while you take part in the clinical trial.[1]

End of Treatment

Follow up with the study team so they know how you are doing after the end of treatment.

Can I Leave a Clinical Trial?

You can leave a clinical trial at any time for any reason.[2]

Glossary

REFERENCES: 1. Bayer. What to expect during a trial? https://clinicaltrials.bayer.com/what-to-expect/. Accessed April 3, 2024. **2.** National Institutes of Health. The basics. https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics. Accessed April 3, 2024.

What Happens to the Data Gathered During a Clinical Trial?

Data are reviewed by the study team. Your personal information, such as your name and address, is not part of the data that are collected.[1]

Data are shared with others in scientific journals, presented at scientific meetings, and/or talked about by patient advocacy groups.[1]

The data help the study team decide whether to go to the next phase of the clinical trial.[1]

Please see *What Are the Phases of Clinical Trials?* for more information

Regulatory authorities may approve the new treatment based on the data gathered during the clinical trial.[1]

You can leave a clinical trial at any time for any reason. Clinical trials may also be discontinued or stopped.[2]

Glossary

REFERENCES: 1. Bayer. What to expect during a trial? https://clinicaltrials.bayer.com/what-to-expect/. Accessed April 3, 2024.
2. National Institutes of Health. The basics. https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics. Accessed April 3, 2024.

Where Can I Find Additional Information About Clinical Trials?

Here is a list of websites you can visit to learn more about clinical trials.

Education

National Institutes of Health (NIH)
https://www.nhlbi.nih.gov/research/clinical-trials/safety-benefits-risks

Clinical Trial Information

Database of clinical trials
https://www.clinicaltrials.gov/ct2/help/for-patient

Listing of clinical trial registries
https://www.hhs.gov/ohrp/international/clinical-trial-registries/index.html

Additional Database for Cancer Trials

Cancer.net
https://www.cancer.net/research-and-advocacy/clinical-trials/finding-clinical-trial

Deciding to join a clinical trial is an important decision. You and your loved ones should talk to a healthcare professional and decide together whether joining a clinical trial is something you should consider.

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A **control** or **control group** gets standard-of-care treatment or placebo. Researchers compare the results from the group receiving the new treatment with those from the control group to see whether the new treatment works better.[1]

Data is factual information.[2]

Decentralized trials, also called direct-to-participant trials, are less dependent on traditional research facilities for data collection. Instead, decentralized trials use virtual tools, such as telehealth, to collect data.[3]

Demographics refers to distinct characteristics of a population.[4]

Diverse or **diversity** means including people with different physical, social, and personal traits or characteristics, such as race, ethnicity, age, gender, and sexual identity.[2,5]

Efficacy refers to how well a therapy provides the expected therapeutic effect under ideal and controlled circumstances.[6]

Enroll or **enrollment** means to register or enter.[2] When you enroll in a clinical trial, it means you join the clinical trial.

Ethnicity is based on a group of people in which they share cultural and traditional background.[2]

Informed consent is a process that explains the reason for the clinical trial. It also explains any risks and benefits of taking part in the clinical trial.[4]

LGBTQIA+ is an abbreviation for lesbian, gay, bisexual, transgender, queer or questioning, intersex, asexual, and more, which describe a person's sexual orientation or gender identity.[7]

A **placebo** is designed to resemble the new treatment but does not have any real effect.[1] Some people may know this as a "sugar pill."

Preclinical studies take place before any testing in humans is done. Preclinical studies use animals to find out whether a drug, procedure, or treatment is likely to be useful.[5]

Race is based on physical characteristics regarded as common among people of shared ancestry.[2]

Safety refers to a measurement/evaluation in clinical trials to determine a safe dosage range/treatment and identify side effects.[6]

A **side effect** is an unintended effect of a drug or treatment.[5]

Standard of care or **SoC** is a treatment that has already been tested and approved by the local health authority.[1]

A **study protocol** is like a recipe, explaining in detail what the study is for, how it will be carried out, and why each part of the study is necessary.[4]

Telehealth is delivery of healthcare from a distance using electronic information and technology, such as computers, cameras, videoconferencing, satellites, wireless communications, and the internet. It is also called telemedicine.[5]

This information is not intended to replace the advice of a healthcare professional and should not be considered as a recommendation. Patients should always seek medical advice before making any decisions on their treatment.

REFERENCES: 1. Bayer. What are clinical trials? https://clinicaltrials.bayer.com/what-are-clinical-trials. Accessed April 3, 2024. **2.** Merriam-Webster. https://www.merriam-webster.com/. Accessed April 3, 2024. **3.** Van Norman GA. Decentralized clinical trials: the future of medical product development? *JACC Basic Transl Sci*. 2021;6(4):384-387. https://www.jacc.org/doi/10.1016/j.jacbts.2021.01.011#d2213961e100. **4.** ClinicalTrials.gov. https://www.clinicaltrials.gov/study-basics/glossary. Accessed April 3, 2024. **5.** National Cancer Institute. https://www.cancer.gov/publications/dictionaries/cancer-terms. Accessed April 3, 2024. **6.** National Center for Advancing Translational Sciences. Toolkit for Patient-Focused Therapy Development. https://toolkit.ncats.nih.gov/glossary. Accessed April 3, 2024. **7.** Lesbian & Gay Community Services Center, Inc. What is LGBTQIA+? https://gaycenter.org/about/lgbtq/. Accessed April 3, 2024.

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