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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.



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 combination of drugs



New or different ways to use current treatments



New surgical procedures or medical devices

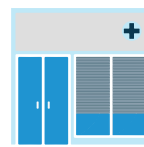
Where Do Clinical Trials Commonly Take Place?



Doctor offices²



Medical and/or research centers²



Clinics²



Home with virtual tools (in **decentralized trials** and **telehealth**)³

Who Are 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



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



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



Patients/ Caregivers



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



Glossary

REFERENCES: 1. National Institute 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 December, 2023. 2. Bayer. What are clinical trials? <https://clinicaltrials.bayer.com/what-are-clinical-trials/>. Accessed May 1, 2023. 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/about-cancer/treatment/clinical-trials/what-are-trials/team>. Accessed May 1, 2023.



What Are the Phases of Cancer Clinical Trials?

Clinical trials are done only after **preclinical studies** show that the new treatment is likely to be safe and will work well in people.¹ Clinical trials are divided into different phases. If a new treatment works in one phase, it will move 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 less than **100** healthy people or patients with cancer³

PHASE 2

Efficacy

DOES THE NEW TREATMENT WORK?

Learn whether the new treatment has an effect on a certain cancer



25 to 100 patients with cancer¹

PHASE 3

Efficacy & Safety

DOES THE NEW TREATMENT WORK BETTER THAN PLACEBO OR THE STANDARD OF CARE?

Lasts longer than phase 1 or 2 trials, with **side effects** monitored closely



100 to 1000s of patients with cancer³

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 cancer³

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.** American Cancer Society. Types and phases of clinical trials. <https://www.cancer.org/treatment/treatments-and-side-effects/clinical-trials/what-you-need-to-know/phases-of-clinical-trials.html>. Accessed May 1, 2023. **2.** Bayer. What are clinical trials? <https://clinicaltrials.bayer.com/what-are-clinical-trials/>. Accessed May 1, 2023. **3.** National Institute 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 December, 2023.



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 if joining a clinical trial is something you should consider.

How Might I Benefit From Joining a Clinical Trial?^{1,2}



Discover new treatment option

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



Medical care

Additional doctor visits and more frequent check-ups may be part of the trial.



Contribute to medical research

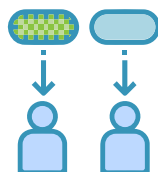
You have the chance to help others receive better treatment in the future.

What Are Some Things I Need to Be Aware of Before Joining a Clinical Trial?^{1,2}



Treatment effects

The new treatment may cause **side effects**, or it may not work as well as the standard of care.



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 amount of pay varies.

You can leave a clinical trial at any time for any reason. Clinical trials may also be discontinued or stopped.³



Glossary

REFERENCES: 1. National Institute on Aging. Clinical trials: Benefits, risks, and safety. <https://www.nia.nih.gov/health/clinical-trials-benefits-risks-and-safety>. Accessed May 1, 2023. 2. American Cancer Society. Deciding whether to be part of a clinical trial. <https://www.cancer.org/treatment/treatments-and-side-effects/clinical-trials/what-you-need-to-know/who-does-clinical-trials.html>. Accessed May 1, 2023. 3. American Cancer Society. Being in a clinical trial. <https://www.cancer.org/treatment/treatments-and-side-effects/clinical-trials/what-you-need-to-know/what-does-a-clinical-trial-involve.html>. Accessed May 1, 2023.

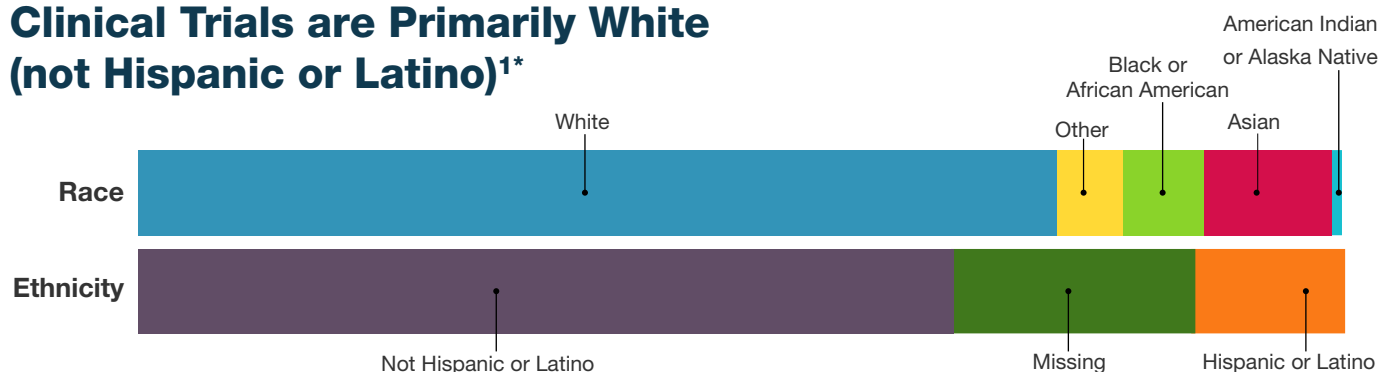


What Is the Importance of Diversity in Clinical Trials?

Globally, the majority of clinical trial participants are of White **race**, not identified as Hispanic/Latino **ethnicity**, and are less than 65 years of age with 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.

Global Trial Participation in Oncology and Hematology Clinical Trials are Primarily White (not Hispanic or Latino)^{1*}



*The 2015-2019 Drug Trials Snapshots Summary Report by the FDA analyzed the demographics of the participants enrolled in clinical trials during the five years.



Why Should Clinical Trials Include Diverse Participants?³

Patients respond to treatment in different ways

Treatments may work differently depending on race, ethnicity, age, sex, and gender. If clinical trials do not include diverse participants, we cannot know if treatments work for everyone who needs them.

Improve representation of patients of 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 cancer trials is one way to improve 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 if joining a clinical trial is something you should consider.



Glossary

REFERENCES: 1. U.S. Food and Drug Administration. 2015-2019 Drug trials snapshots report: Five-year summary and analysis of clinical trial participation and demographics. Available at: <https://www.fda.gov/media/143592/download>. 2. Cathcart-Rake EJ, et al. Acquisition of sexual orientation and gender identity data among NCI Community Oncology Research Program practice groups. *Cancer*. 2019;125(8):1313-1318. Available at: <https://acsjournals.onlinelibrary.wiley.com/doi/pdf/10.1002/cncr.31925>. 3. Finding treatments together: A guide to the importance of diversity in clinical trials: Available at: <https://www.cisrcp.org/a-guide-to-the-importance-of-diversity-in-clinical-trials/>



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

Information that can help you decide whether or not 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 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 go through what to do and how often.



Clinical Trial Participation

You are put in a treatment group.² You will have clinical trial visits, 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.³



Glossary

REFERENCES: 1. Bayer. What to expect during a trial? <https://clinicaltrials.bayer.com/what-to-expect/>. Accessed May 1, 2023. 2. National Cancer Institute. Taking part in cancer treatment research studies. <https://www.cancer.gov/publications/patient-education/crs.pdf>. Accessed May 1, 2023. 3. American Cancer Society. Being in a clinical trial. <https://www.cancer.org/treatment/treatments-and-side-effects/clinical-trials/what-you-need-to-know/what-does-a-clinical-trial-involve.html>. Accessed May 1, 2023.



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

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

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

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 May 1, 2023. 2. American Cancer Society. Being in a clinical trial. <https://www.cancer.org/treatment/treatments-and-side-effects/clinical-trials/what-you-need-to-know/what-does-a-clinical-trial-involve.html>. Accessed May 1, 2023.



Where Can I Find Additional Information About Clinical Trials?

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



Education

American Cancer Society (ACS)

www.cancer.org/treatment/treatments-and-side-effects/clinical-trials.html



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://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 if joining a clinical trial is something you should consider.

Glossary

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 telemedicine, to collect data.³

Demographics refers to distinct characteristics of a population.²

Diverse or **diversity** means including people with different physical, social, and personal traits or characteristics, such as race, ethnicity, age, gender, or sexual identity.^{2,4}

Efficacy is the ability of an intervention, such as a drug, to produce the desired beneficial effect.⁴

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.⁴

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 if a drug, procedure, or treatment is likely to be useful.⁴

Race is based on physical characteristics regarded as common among people of shared ancestry.⁴

Safety measurement/evaluation in clinical trials is finding the dose/treatment that can be safely given without causing severe side effects.⁵

A **side effect** is an unintended effect that occurs from a drug or treatment.⁴

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.⁶

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.⁴

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 May 1, 2023. 2. Merriam Webster. <https://www.merriam-webster.com/>. Accessed May 1, 2023. 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. NCI Dictionary of Cancer Terms. National Cancer Institute. <https://www.cancer.gov/publications/dictionaries/cancer-terms>. Accessed May 1, 2023. 5. American Cancer Society. Types and Phases of Clinical Trials. <https://www.cancer.org/treatment/treatments-and-side-effects/clinical-trials/what-you-need-to-know/phases-of-clinical-trials.html>. Accessed May 1, 2023. 6. National Cancer Institute. Taking part in cancer treatment research studies. <https://www.cancer.gov/publications/patient-education/crs.pdf>. Accessed May 1, 2023. 7. Lesbian & Gay Community Services Center, Inc. <https://gaycenter.org/about/lgbtq/>. Accessed May 1, 2023.