Participating in Clinical Trials

What Is a Clinical Trial?

Are you thinking about taking part in a clinical trial? Is a friend or family member already in a trial? Has that made you want to learn more about it? In this chapter, you will learn about the different types of trials and the risks and benefits of taking part in a trial.

What Is a Clinical Trial? - About Clinical Trials

A clinical trial is a research study that involves human subjects. The purpose of a clinical trial is to find out if an experimental drug, therapy, medical device, lifestyle change, or test will help treat, find, or prevent a disease. A clinical trial may also compare experimental treatments or tests to those already available in order to determine which one is safer or more effective.

The five main types of clinical trials are treatment, screening, diagnostic, prevention, and quality of life trials.

In treatment trials, researchers may

- gather information about experimental treatments, their risks, and how well they work
- compare existing therapies to decide which one, or a combination of them, is the best treatment for a disease
- evaluate treatment methods such as surgical techniques, psychiatric therapy, or radiotherapy.

Scientists usually do years of experiments in the laboratory and in animals before they even consider testing an experimental treatment in people. Most of this early research occurs at universities and medical centers across the country. The National Institutes of Health funds much of this basic research.

In screening trials, researchers study ways of finding a disease before symptoms occur. These methods, often called screening tests, can include

- imaging tests that produce pictures of what is inside the body
- laboratory tests that check samples of blood, urine, or other body tissues
- genetic tests that look for genes linked to some types of disease.
In diagnostic trials, researchers evaluate new tests that could identify a disease in its early stages. Usually, trial participants must show signs of the disease or condition before they can join this type of trial.

In prevention trials, researchers study ways to reduce the risk of getting a disease or a specific medical problem. These trials find out if

- lifestyle changes, such as exercising more, getting more sleep, keeping mentally active, or eating nutritious foods, can prevent a problem
- taking certain medicines, or vitamins, or getting vaccines will prevent a disease in people who have never had the disease or prevent a disease from returning.

In quality of life trials, researchers look for ways to make life better for people living with a life threatening disease or chronic health problem. For example, they may study the role of caregivers, support groups, and various types of social interventions.

A clinical trial usually includes three phases. In some cases, four phases may be required.

A Phase I trial tests an experimental treatment on a small group of often healthy people (20 to 80), to judge its safety and side effects, and to find the correct drug dosage.

A Phase II trial is similar to a Phase I trial but uses more people (100 to 300) to find out if the experimental treatment is effective and safe. This phase can last several years.

A Phase III trial is usually a large study with several hundred or more participants (1,000 to 3,000). This phase compares the experimental drug or procedure to a placebo or standard treatment, to make sure it is safe and works well. Some side effects that didn’t show up in Phase II may show up in a Phase III trial because many more people are tested. If the U.S. Food and Drug Administration agrees that the trial results are positive, they will approve the experimental drug or device.

A Phase IV trial for drugs or devices takes place after the U.S. Food and Drug Administration approves their use. A device or drug's effectiveness and safety are monitored in large, diverse populations. Sometimes the side effects of a drug may not become clear until more people have taken it over a longer period of time.

Quiz

1. A clinical trial
   A. does research on animals in a laboratory.
   B. only tests experimental drugs.
C. uses volunteers to study an experimental drug, therapy, medical device, lifestyle change, or test.

C is the correct answer. A clinical trial is a research study that involves human volunteers. The purpose of a clinical trial is to find out if an experimental drug, therapy, medical device, lifestyle change, or test will help treat, find, or prevent a disease.

2. The clinical trial that evaluates the effectiveness of an experimental drug or therapy is called a

A. treatment trial.
B. prevention trial.
C. diagnostic trial.

A is the correct answer. A treatment trial evaluates the effectiveness and safety of experimental drugs and other therapies in combating disease. Prevention trials study ways to reduce the risk of getting a disease or having the disease return. Diagnostic trials study new tests that may identify a disease in its early stages.

3. A prevention trial may study

A. experimental drugs.
B. whether exercising and eating nutritious foods will prevent diseases.
C. surgical procedures.

B is the correct answer. A prevention trial studies ways to reduce the risk of getting a disease or having the disease return. It may study how diet, exercise, taking vitamins, or keeping mentally active can prevent certain diseases.

4. A Phase III study

A. has several hundred to thousands of participants.
B. compares the experimental therapy to a placebo, standard treatment, or no treatment.
C. ensures the experimental treatment is safe and works well.
D. all of the above

D is the correct answer. A Phase III trial is usually a large study with 1,000 to 3,000 subjects, although many Phase III trials are smaller. This phase compares the experimental drug or procedure to a placebo or standard treatment, to make sure it is safe and works well.
You may ask yourself, "Why should I join a clinical trial? Should I try something that hasn't been approved?" Asking questions is good because there are always some risks in joining a trial, but there may be benefits too.

Here are some possible benefits in joining a clinical trial.

- Your participation may help others get a better treatment for their disease in the future and allow researchers to learn more about how diseases can be prevented, identified, or managed.
- Researchers, doctors, and other health care professionals may check your physical condition frequently, giving you regular, careful medical attention, because they need data to make comparisons in a trial.
- It may be a way to get an experimental treatment for a life threatening illness before it is approved and widely available.

Here are some possible risks in joining a clinical trial.

- You may experience unpleasant, serious, or even life-threatening side effects.
- You may not get the experimental treatment, but a standard treatment or a placebo instead.
- The experimental treatment may not be better or even as good as the standard treatment for your condition.
- Even if a new procedure works for other people, it may not work for you.

Keep in mind that a few people have increased their risk of getting another condition during experimental drug trials.

For example, while testing the arthritis drug Vioxx as a treatment for colorectal polyps, researchers discovered that the drug increased the risk of heart attack and other cardiovascular problems. The drug has been taken off the market.

Another possible concern, though not a health risk, is that your health insurance or the trial may not cover all of your costs or expenses.

Quiz

1. What may be a benefit of taking part in a clinical trial?

   A. You get your name in the news.
   B. You may help others get a successful new treatment.
   C. You get paid a lot of money for being in a trial.

   B is the correct answer. If the experimental treatment works, you may help others get a better treatment. Researchers do not reveal the names of trial participants. You don't get paid for being in a trial, but you may receive a small payment to cover your expenses.

2. What are the risks of taking part in a clinical trial?

   A. You may experience serious side effects.
B. You may be in the placebo or standard practice group.
C. Even if a new procedure proves beneficial for some, it may not work for you.
D. All of the above

D is the correct answer. There are real risks that you need to consider before deciding to participate in a trial. Sometimes the experimental treatment may not work for you or have serious side effects. Even if the new procedure has benefits, it may not work for you. And you may not even be in the group that gets the experimental treatment.

**What Is a Clinical Trial? - Terms to Know**

Here are some terms used in clinical trials.

- protocol
- inclusion and exclusion criteria
- placebo
- standard treatment
- side effects
- treatment group and control group
- randomized clinical trial
- double-blind study

A protocol is the detailed study plan that will be followed to answer specific research questions and protect the trial participants. It describes

- what type of people are needed in the trial
- the schedule of tests, procedures, drugs, and dosages
- how long the study will last
- how to measure the beneficial and harmful effects.

Inclusion or exclusion criteria are the set of social and medical characteristics researchers use to decide who can take part in a clinical trial. These may include

- a person's age and gender
- the type and stage of their disease
- previous treatment history
- any other medical conditions.

A placebo, sometimes called a sugar pill, is a substance that looks like the experimental drug but has no active ingredients. Researchers compare the effects of experimental treatments with placebos.

Standard treatment is a therapy that is

- effective for a specific disease or condition
- currently in wide use
- usually approved by the U.S. Food and Drug Administration
• used to compare with the newer treatment, to see which is better.

Side effects are unwanted or unexpected negative effects, such as a headache or skin irritation, caused by taking a drug or treatment. Adverse reactions are more serious side effects that can even be life threatening.

The treatment group gets the experimental treatment and the control group gets the standard treatment, a placebo, or no treatment at all. The results from the two groups are compared to determine the effectiveness of the experimental treatment.

A randomized clinical trial (RCT) is a study in which participants are randomly (that is, by chance) assigned to either the control group or the treatment group. Neither the researchers nor the participants can choose the group in which they are placed.

In a "double-blind" study, the researchers and participants won't know who has been placed into the treatment group until the study is over.

For more clinical trial terms go to ClinicalTrials.gov Glossary at http://clinicaltrials.gov/ct/info/glossary.

**Quiz**

1. A placebo is
   A. a substance that has no active ingredients in it.
   B. a substance with active ingredients.
   C. sometimes called a salt pill.

   A is the correct answer. A placebo is a substance that has no active ingredients in it and is sometimes called a sugar pill. It looks like the experimental treatment and is given to some of the volunteers in the study. Researchers compare the results of taking a placebo with the experimental drug results.

2. The control group gets
   A. the experimental treatment.
   B. the standard treatment for a disease or a placebo.
   C. the cure.

   B is the correct answer. The control group gets the standard treatment for a disease, a placebo, or no treatment at all.

3. The treatment group gets
   A. the standard treatment.
   B. a placebo.
   C. the experimental treatment.
C is the correct answer. The treatment group gets the experimental treatment and the results are compared with the control group. Usually the researchers don't know who is getting the placebo or who is getting the experimental therapy.

4. In a randomized trial, participants are assigned

A. to the treatment group or the placebo group.
B. only to the treatment group.
C. only to the placebo group.

A is the correct answer. In a randomized trial, participants are randomly (that is, by chance) assigned to either the control group or the treatment group. You cannot ask to be put into the experimental treatment or the standard treatment group.

Finding a Clinical Trial

Before looking for a clinical trial to join, you need to talk to your health care provider about your health. He or she can discuss with you the possible risks and benefits of being in a trial. If you are a caregiver for someone who can't decide for themselves about a trial, and you don't have a power of attorney, you should also talk to a lawyer.

Remember, clinical trials don't accept everyone. Researchers are looking for specific types of participants to meet the needs of the study, so you may not be eligible. Some trials, however, are looking for healthy older volunteers. If you are interested, keep trying. Most participants in clinical trials feel they get more medical attention, and they are helping themselves and others to live longer and healthier lives.

Here are ways to find a clinical trial.

- Your health care provider may know about trials that you can join.
- The National Institutes of Health has a Web site called ClinicalTrials.gov that you can search, found at http://clinicaltrials.gov.

To find studies for older people, use one or more of these terms in your search: aged, elderly, senior, age > 55, or 65 years and above.

Here are ways to find a clinical trial.

- Support groups often have lists of trials.
- Newspapers in large cities often have advertisements for trials at nearby hospitals, clinics or universities.

Here is how you can enroll in a clinical trial.
• Contact the clinical trial or study coordinator. You can find this information in the trial description. Your health care provider may also want to talk to this person about your health conditions.

• Set up a screening appointment. During this appointment, researchers will ask you questions and may test you to see if you meet the needs of the study.

Quiz

1. Clinical trials will accept

   A. everyone.
   B. healthy older people if appropriate.
   C. only sick people.

   B is the correct answer. Clinical trials don’t accept everyone. Researchers are looking for specific types of participants to meet the needs of the study, so you may not be eligible. However, some trials are looking for healthy older volunteers to participate.

2. Which is the best way to find a clinical trial?

   A. Ask a friend.
   B. Look in the telephone book.
   C. Ask your doctor.

   C is the correct answer. Your friend may know about a clinical trial, but your own doctor can tell you whether you should consider volunteering. The doctor knows about your health concerns and the possible benefits of joining a trial.

3. Before enrolling in a clinical trial, you should

   A. speak to a lawyer.
   B. talk to your doctor.
   C. go on vacation.

   B is the correct answer. First, talk to your doctor to see if you should apply. Then contact the clinical trial coordinator and ask questions.

Informed Consent
After you find a clinical trial and pass the screening process, there is another step before joining a trial. The research team must give you some important information about the trial before you decide to participate. This is called the informed consent process. During this time you will have the chance to ask questions until you have all the information you need.

Before you can enroll in a clinical trial, the research team must tell you what to expect during a trial and what might happen unexpectedly. The informed consent document outlines all this information.

If you agree to take part in a trial after you learn about the potential risks, benefits, and your rights and responsibilities, you sign the informed consent document. However, this document is not a contract. You can leave the trial at any time for any reason.

Informed consent is a continuing process that helps you decide whether to enroll in a trial. During the first meeting and in follow-up meetings the research team will tell you about:

- tests or treatments that you may get if you are assigned to the treatment group
- possible risks and benefits of these tests or treatments
- standard tests and treatments available now
- what you need to do, such as take medications at a certain time.

Scientific studies can be complicated, and the research team needs to know if you understand all the information they give you. They may test how well you understand by having you fill out a questionnaire, asking you questions, or having you explain certain parts of the trial in your own words.

Sometimes, a potential participant may not be able to give informed consent because of memory problems or mental confusion. Someone else, usually a family member with a durable power of attorney, can give consent for that participant. That caregiver must be confident there is small risk to the participant, and the participant would have agreed to consent if he or she were able to do so.

So what questions should you ask the research team to help you decide whether or not to enroll in the trial? You have the right to ask them anything about their clinical trial. If you do not like the answers they give you, ask more questions. If you are still not satisfied, do not agree to take part in the trial.

You should ask the research team the following questions.

- Why are you doing the study?
- What treatment, procedure, or test will I have? Will it hurt?
- What will I have to do?
- What are my chances of getting the experimental treatment?
- How will the study affect my daily life?

Ask the research team the following questions.
• What are my possible benefits?
• What are my risks, such as side effects?
• How will I be protected?
• Can I take my regular medicines while in the trial?
• Will I be able to see my own doctor?

Ask the research team the following questions.

• Where will the study take place?
• Will transportation be provided if I need it?
• How long will the study take?
• Will being in the study cost me anything?
• Will my insurance cover the costs?

One question the research team can't answer is whether you will be assigned to the experimental treatment group. Your placement in the treatment or control group is done randomly, usually by a computer.

After getting the facts about the trial, and if you agree to participate, the research team will give you the informed consent document. It describes the trial and explains your rights and responsibilities as a participant. If there is anything you don't understand in the consent document, ask for a better explanation before signing it.

During the trial, the research team may discover new information that could affect your health or change your mind about staying in the study. They will give you this information and may ask you to sign a new informed consent document. Of course, you are free to leave the study if this information makes you uneasy about continuing.

Quiz

1. Informed consent is
   A. a contract.
   B. a continuing process.
   C. a single discussion.

   B is the correct answer. Informed consent is a continuing process that helps you decide whether to enroll in a trial.

2. The informed consent document
   A. tells you what is going to happen during the trial and what your rights are.
   B. is only used in randomized trials.
   C. is only used in double-blind trials.

   A is the correct answer. The informed consent document provides a written summary of the trial and tells you your rights as a participant. The informed consent document is a part of all types of clinical trials.
3. Once you agree to participate in the trial,
   A. you are required to sign the informed consent document.
   B. you can take part without signing anything.
   C. you cannot change your mind.

   A is the correct answer. Once you agree to participate in the trial, you are required to sign the informed consent document which indicates that you have understood the potential risks, benefits, and your rights and responsibilities. However, this document is not a contract. You can leave the trial at any time for any reason.

4. If the researchers find out the experimental drug is not working,
   A. they are required to keep it a secret.
   B. they do not have to tell the participants if they don't want to.
   C. they have to tell the participants.

   C is the correct answer. If the researchers find out the experimental drug is not working, they have to tell the participants. They may even stop the study.

Should I Join a Clinical Trial?

The results of clinical trials can lead to new treatments for many diseases such as Alzheimer's disease, heart disease, various types of cancers, stroke, and diabetes. Older adults are more likely to be affected by these diseases, yet many clinical trials for these and other diseases often do not include older adults.

There are many reasons a trial may not include older adults. Researchers may worry that the treatment won't work as well for them, or there may be severe side effects that could have an effect on their quality of life.

Also, many older people may have several health problems at the same time such as diabetes, high blood pressure, or heart disease, which might affect trial results.

Other reasons may include a lack of support by friends and family, costs of care, and difficulty getting to health care centers where many trials take place.

Yet, clinical trials need more older participants so that researchers can better learn how potential new drugs, therapies, medical devices, or tests may work in older people.
Although older adults take more medicine than any other group, they are often not a part of experimental drug trials. As people age, their bodies absorb drugs differently. Older adults may need different dosages or have different side effects than younger people. If there are not enough older people enrolled in a drug trial, researchers may not get the information they need to develop appropriate treatments for older people.

For more on older adults and medicines go to Taking Medicines at http://nihseniorhealth.gov/takingmedicines/toc.html.

If you are interested in taking part in a clinical trial, be sure to ask yourself these questions before making your decision.

- Have I gotten all the facts?
- Have I talked to my health care provider about my health condition?
- Do I know how my participation in the clinical trial will affect my daily life and activities?
- Am I able to get to the research site for appointments?
- Will it cost me anything?

Before making a decision to join a clinical trial, ask yourself these questions.

- Am I willing to take the chance that I won't get the experimental treatment? Remember, you can't choose the group where you'll be placed. So there is a chance you will be in the placebo or standard treatment group.
- Can I fulfill my responsibilities, such as following the research team's instructions, taking medications on time, and completing logs or questionnaires?

Take time to think about what the research team told you and review the informed consent document at home. Read it as many times as you need. Discuss it with family, friends, your doctor, or other health care professionals.

If you have concerns about your safety being protected by someone other than the research team, there are outside organizations that protect trial participants. They will stop a trial if they find that the experimental treatment is harming the participants or not having any effect. These organizations include Institutional Review Boards and Data and Safety Monitoring Committees.

Before starting a trial, researchers must get permission from their organization's Institutional Review Board or IRB. IRB members are independent of the study and do not have an interest in how it turns out. The IRB reviews the trial's protocol, or study plan, to look for possible risks to human subjects.

Data and Safety Monitoring Committees are independent of the study and look at data collected during studies comparing different drugs. They pay special attention to treatment trials for life threatening diseases. If a committee finds the experimental treatment is harming participants or is not working, it will stop the study.
Clinical trials can be stopped any time in any phase of testing if

- early results show the experimental treatment works much better than the others. In these cases, researchers offer the experimental treatment to the control group.
- the study finds no difference between the control group and treatment group, so further testing is useless.
- the Institutional Review Board or the Data and Safety Monitoring Committee find a problem with the way the researchers are running the trial.
- there are too many dangerous side effects.

If you finally decide to enter the trial, sign the document to give your official consent. Remember, this is not a contract. You can leave the trial any time for any reason.

You don't have to be sick to be part of a trial. Trials need healthy people of all ages, as well as, people with various diseases or conditions. Many participants in clinical trials feel they get more medical attention, and they are helping themselves and others to live longer and healthier lives.

To search for a clinical trial for you, go to [http://clinicaltrials.gov](http://clinicaltrials.gov).

**Quiz**

1. Why should researchers include older people in experimental drug trials?

   A. To find out if a drug works for older adults.
   B. To discover what side effects it may have in older people.
   C. To learn the dosage for older adults.
   D. All of the above

   D is the correct answer. Researchers should test experimental drugs in older populations to see if they are safe, effective, and improve their quality of life.

2. Before signing the informed consent document, I need to

   A. discuss the trial with my health care provider
   B. find out how being in a trial is going to affect my daily life
   C. find out if I will have to pay for any procedures or medications.
   D. All of the above

   D is the correct answer. You must be sure you understand what your risks may be when you are in a trial. You should talk to your doctor about your health concerns. You should find out from the research team if you will have any costs because of the trial, and how it is going to affect your daily activities.

3. Why can a clinical trial be stopped?
A. The researchers run out of money.
B. The placebo makes people sick.
C. The experimental treatment is obviously better than standard treatment.

C is the correct answer. When the experimental treatment results are clearly positive, the trial will be stopped. Then the control group is usually offered the treatment.

4. Who protects the safety of trial participants?

A. The Institutional Review Board
B. Law firms
C. The Supreme Court

A is the correct answer. The Institutional Review Board reviews the trial's procedures for safety. Sometimes the Data Monitoring Committee will stop a study if participants are at risk.

Frequently Asked Questions

1. What is a clinical trial?

A clinical trial is a research study that involves human subjects. The purpose of a clinical trial is to find out if an experimental drug, therapy, medical device, lifestyle change, or test will help treat, find, or prevent a disease. A clinical trial may also compare experimental treatments or tests to those already available in order to determine which one is safer or more effective.

2. What are the different types of clinical trials?

There are five different types of clinical trials.

- Treatment trials
- Screening trials
- Diagnostic trials
- Prevention trials
- Quality of life trials

3. What is a treatment trial?

The most common trial is the treatment trial. In treatment trials, researchers gather information about how well an experimental drug, medical device, or medical procedure works. Sometimes they compare different treatments to see which one works best.

4. What is a screening trial?

In a screening trial, researchers learn about new ways of finding a disease before symptoms show up. These methods, often called screening tests, can include
• imaging tests that produce pictures of what is inside the body
• laboratory tests that check samples of blood, urine, or other body tissues
• genetic tests that look for genes linked to some types of disease.

5. What is a prevention trial?

Prevention trials study ways to reduce the risk of getting a disease. These trials attempt to find out if

• lifestyle changes, such as exercising more, getting more sleep, keeping mentally active, or eating nutritious foods, can prevent a problem
• taking certain medicines, vitamins, or getting vaccines will prevent a disease in people who have never had the disease or prevent a disease from returning.

6. What is a diagnostic trial?

Diagnostic trials evaluate new tests that could identify a disease in its early stages. Usually, trial participants must show signs of the disease or condition before they can join this type of trial.

7. What is a quality of life trial?

Quality of life trials find ways to make life better for people living with a life threatening disease or chronic health problem. For example, they may study the role of caregivers, support groups, and various types of social interventions.

8. What are the potential benefits of taking part in a clinical trial?

Here are ways you may benefit from taking part in a clinical trial.

• Your participation may help others get a better treatment for their disease in the future and allow researchers to learn more about how diseases can be prevented, identified, or managed.
• Researchers, doctors, and other health care professionals may check your physical condition frequently, giving you regular, careful medical attention, because they need data to make comparisons in a trial.
• It may be a way to get an experimental treatment for a life threatening illness before it is approved and widely available.

9. What are the risks of taking part in a clinical trial?

Here are some possible risks of taking part in a clinical trial.

• You may experience serious, unpleasant, or even life-threatening side effects.
• You may get the standard treatment or placebo instead of the experimental treatment.
• The experimental treatment may not be better or even as good as the standard treatment for your condition.
• Even if a new procedure works for other people, it may not work for you.

10. Why should older adults participate in clinical trials?

Since older adults take more medicine than any other group, it is important to find out how they might respond to new medications, especially those that target diseases and conditions of aging.

Older adults should take part in clinical trials because the trial results can lead to new treatments for many diseases and conditions that affect older adults such as Alzheimer's disease, heart disease, various types of cancers, stroke, and diabetes.

Researchers also need to know how potential new drugs, therapies, medical devices or tests may work in older people. As people age, their bodies absorb drugs differently. They may need to take different dosages of drugs than younger people, and they may have different side effects.

For more on older adults and medicines go to Taking Medicines at http://nihseniorhealth.gov/takingmedicines/toc.html

11. Are there enough older adults participating in clinical trials?

No. Clinical trials need more older participants so that researchers can better learn how potential new drugs, therapies, medical devices, or tests work in older people.

When older adults participate in greater numbers, researchers will have better information about ways to diagnose, prevent, treat, and cure diseases and conditions of aging.

12. What keeps older adults from participating in clinical trials?

Researchers may not include older people in trials because of worries that the treatment won't work as well for them, or there may be severe side effects that could have an effect on their quality of life.

Older adults may not join trials because of a lack of support by friends and family, the costs of care, or difficulty getting to health care centers where many trials take place.

Also, many times older people may have several health problems at the same time such as diabetes, high blood pressure or heart disease which might affect trial results.

13. What are the phases of a clinical trial?

A clinical trial usually includes three phases. In some cases, four phases may be required.
A Phase I trial tests an experimental treatment on a small group of often healthy people (20 to 80), to judge its safety and side effects, and to find the correct drug dosage.

A Phase II trial is similar to a Phase I trial but uses more people (100 to 300) to find out if the experimental treatment is effective and safe. This phase can last several years.

A Phase III trial is a large study using several hundred or more participants (1,000 to 3,000). This phase compares the experimental drug or procedure to a placebo or standard treatment, to make sure it is safe and works well. Some side effects that didn't show up in Phase II may show up in a Phase III trial because many more people are tested.

If the U.S. Food and Drug Administration agrees that the trial results are positive, they will approve the experimental drug or device.

A Phase IV trial for drugs or devices takes place after the U.S. Food and Drug Administration approves their use. A device or drug's effectiveness and safety are monitored in large, diverse populations. Sometimes the side effects of a drug may not become clear until more people have taken it over a longer period of time.

14. Who sponsors clinical trials?

Federal agencies like the National Institutes of Health, drug companies, universities, disease support groups, foundations, and other groups fund clinical trial research.

15. Where do clinical trials take place?

Clinical trials take place in doctors’ offices, community medical centers, university clinics or medical centers, hospitals and clinics, and veterans or military hospitals. They take place in the USA and other countries. One trial may be held in many locations or just one place.

16. How do I find a clinical trial?

Your healthcare provider may know about trials that you can join. Newspapers in large cities and disease support groups often have lists of trials. The National Institutes of Health has a database called ClinicalTrials.gov that you or your doctor can search at http://clinicaltrials.gov.

17. How do I get into a clinical trial?

Talk to your healthcare provider and discuss the risks and benefits. Contact the clinical trial coordinator. You can find this contact information in the trial description found in ClinicalTrials.gov at http://www.clinicaltrials.gov.

Set up a screening appointment. During this appointment, the research team will ask questions and may test you to see if you meet the criteria of the study.
18. Can healthy people volunteer for a clinical trial?

Yes. Healthy people of all ages are needed, especially for prevention or screening trials.

19. What is a protocol?

A protocol is the detailed study plan that will be followed to answer specific research questions and protect the trial participants. It describes

- what type of people are needed in the trial
- the schedule of tests, procedures, drugs, and dosages
- how long the study will last.

20. What are inclusion and exclusion criteria?

Inclusion and exclusion criteria are the set of qualifications listed in the protocol that allow or prevent someone from taking part in a clinical trial. These may include age, gender, the type and stage of a disease, previous treatments, and other medical conditions.

21. What is a standard treatment?

A standard treatment is a therapy that is effective for a specific disease or condition, currently in wide use, and usually has been approved by the U.S. Food and Drug Administration.

22. What is a placebo?

A placebo, sometimes called a sugar pill, is a substance that looks like the experimental drug but has no active ingredients.

Researchers compare experimental drugs with placebos to measure the effectiveness of a treatment.

23. What is a control group?

The control group is the group of trial participants that do not get the experimental drug or procedure. They get a standard treatment for the disease or condition, a placebo, or no treatment at all.

24. In a treatment trial, can I ask to be in the experimental drug group?
No. Participants in a large drug trial are randomly assigned to an experimental treatment group or a control group. Participants are not supposed to know what they are getting because that might affect the results. In a "double-blind" trial, neither the participants nor the researchers know who is getting the experimental therapy.

25. What are side effects and adverse reactions?

Side effects or adverse reactions are unwanted or unexpected negative effects, such as a headache or skin irritation, caused by taking a drug or treatment procedures. Adverse reactions are more serious side effects that can even be life-threatening.

26. What is informed consent?

Informed consent is an ongoing process that helps you decide whether to enroll in a trial after you have been told all about the study. The informed consent document is an agreement to take part in a trial.

During the first meeting, and in follow-up meetings, the research team will tell you about

• tests or treatments that you may get if you are assigned to the treatment group
• possible risks and benefits of these tests or treatments
• standard tests and treatments available now
• what you need to do, such as take medications at a certain time.

Once you agree to participate in the trial, you must sign the informed consent document. However, it is not a contract. You can leave the trial at any time for any reason.

27. What organizations exist to protect participants in clinical trials?

If you have concerns about your safety being protected by someone other than the research team, there are outside organizations that protect trial participants. They will stop a trial if they find that the experimental treatment is harming the participants or not having any effect. These organizations include Institutional Review Boards and Data and Safety Monitoring Committees.

Before starting a trial, researchers must get permission from their organization's Institutional Review Board or IRB. IRB members are independent of the study and do not have an interest in how it turns out. The IRB reviews the trial's protocol, or study plan, to look for possible benefits and risks to human subjects.
Data and Safety Monitoring Committees are independent of the study and look at data collected during studies comparing different drugs. They pay special attention to treatment trials for life threatening diseases. If a committee finds the experimental treatment is harming participants or is not working, it will stop the study.

28. Can I leave a clinical trial after it has begun?

Yes. You may leave a clinical trial at any time, for any reason. Signing an informed consent document is not like signing a contract.

29. How much does it cost to be in a clinical trial and will my insurance cover it?

Your health insurance coverage may not include all the patient care costs related to a clinical trial. You may have to pay for care which is not a part of the routine tests or procedures that your insurance normally covers.

Medicare does cover some trial costs. You may get some payment from the researchers to cover expenses like transportation. Each trial is different, so be sure to ask the trial administrator about costs.

30. Why would a clinical trial be stopped early?

Clinical trials can be stopped any time in any phase of testing for several reasons.

- Early results may show that the experimental treatment works much better than the others. In these cases, researchers would offer the experimental treatment to the control group.
- The study may find no difference between the control group and treatment group, so further testing is useless.

Clinical trials can be stopped any time in any phase of testing for several reasons.

- The IRB or the Data and Safety Monitoring Committee may find a problem with the way the researchers are running the trial.
- There may be too many dangerous side effects.

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