Clinical Trials Information

What are clinical trials and why do people participate? 1

Clinical research is medical research that involves people like you. When you volunteer to take part in clinical research, you help doctors and researchers learn more about disease and improve health care for people in the future. Clinical research includes all research that involves people. Types of clinical research include: Epidemiology, which improves the understanding of a disease by studying patterns, causes, and effects of health and disease in specific groups. Behavioral, which improves the understanding of human behavior and how it relates to health and disease. Health services, which looks at how people access health care providers and health care services, how much care costs, and what happens to patients as a result of this care. Clinical trials, which evaluate the effects of an intervention on health outcomes.

What are clinical trials and why would I want to take part? 2

Clinical trials are part of clinical research and at the heart of all medical advances. Clinical trials look at new ways to prevent, detect, or treat disease. Clinical trials can study: New drugs or new combinations of drugs, New ways of doing surgery, New medical devices, New ways to use existing treatments, New ways to change behaviors to improve health, New ways to improve the quality of life for people with acute or chronic illnesses. The goal of clinical trials is to determine if these treatment, prevention, and behavior approaches are safe and effective. People take part in clinical trials for many reasons. Healthy volunteers say they take part to help others and to contribute to moving science forward. People with an illness or disease also take part to help others, but also to possibly receive the newest treatment and to have added (or extra) care and attention from the clinical trial staff. Clinical trials offer hope for many people and a chance to help researchers find better treatments for others in the future

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People may experience the same disease differently. It?s essential that clinical trials include people with a variety of lived experiences and living conditions, as well as characteristics like race and ethnicity, age, sex, and sexual orientation, so that all communities benefit from scientific advances.

The idea for a clinical trial often starts in the lab. After researchers test new treatments or procedures in the lab and in animals, the most promising treatments are moved into clinical trials. As new treatments move through a series of steps called phases, more information is gained about the treatment, its risks, and its effectiveness.

Clinical trials follow a plan known as a protocol. The protocol is carefully designed to balance the potential benefits and risks to participants, and answer specific research questions. A protocol describes the following: The goal of the study, Who is eligible to take part in the trial, Protections against risks to participants, Details about tests, procedures, and treatments, How long the trial is expected to last, What information will be gathered. A clinical trial is led by a principal investigator (PI). Members of the research team regularly monitor the participants? health to determine the study?s safety and effectiveness.

Most, but not all, clinical trials in the United States are approved and monitored by an Institutional Review Board (IRB) to ensure that the risks are reduced and are outweighed by potential benefits.

IRBs are committees that are responsible for reviewing research in order to protect the rights and safety of people who take part in research, both before the research starts and as it proceeds. You should ask the sponsor or research coordinator whether the research you are thinking about joining was reviewed by an IRB.

What is a clinical trial sponsor? 7

Clinical trial sponsors may be people, institutions, companies, government agencies, or other organizations that are responsible for initiating, managing or financing the clinical trial, but do not conduct the research.

What is informed consent? 8

Informed consent is the process of providing you with key information about a research study before you decide whether to accept the offer to take part. The process of informed consent continues throughout the study. To help you decide whether to take part, members of the research team explain the details of the study. If you do not understand English, a translator or interpreter may be provided. The research team provides an informed consent document that includes details about the study, such as its purpose, how long it?s expected to last, tests or procedures that will be done as part of the research, and who to contact for further information. The informed consent document also explains risks and potential benefits. You can then decide whether to sign the document. Taking part in a clinical trial is voluntary and you can leave the study at any time.

What are the types of clinical trials? 9

There are different types of clinical trials. Prevention trials look for better ways to prevent a disease in people who have never had the disease or to prevent the disease from returning. Approaches

may include medicines, vaccines, or lifestyle changes. Screening trials test new ways for detecting diseases or health conditions. Diagnostic trials study or compare tests or procedures for diagnosing a particular disease or condition. Treatment trials test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy. Behavioral trials evaluate or compare ways to promote behavioral changes designed to improve health. Quality of life trials (or supportive care trials) explore and measure ways to improve the comfort and quality of life of people with conditions or illnesses.

What are the phases of clinical trials? 10

Clinical trials are conducted in a series of steps called ?phases.? Each phase has a different purpose and helps researchers answer different questions. Phase I trials: Researchers test a drug or treatment in a small group of people (20?80) for the first time. The purpose is to study the drug or treatment to learn about safety and identify side effects. Phase II trials: The new drug or treatment is given to a larger group of people (100?300) to determine its effectiveness and to further study its safety. Phase III trials: The new drug or treatment is given to large groups of people (1,000?3,000) to confirm its effectiveness, monitor side effects, compare it with standard or similar treatments, and collect information that will allow the new drug or treatment to be used safely. Phase IV trials: After a drug is approved by the FDA and made available to the public, researchers track its safety in the general population, seeking more information about a drug or treatment?s benefits, and optimal use.

What do the terms placebo, randomization, and blinded mean in clinical trials? 11

In clinical trials that compare a new product or therapy with another that already exists, researchers try to determine if the new one is as good, or better than, the existing one. In some studies, you may be assigned to receive a placebo (an inactive product that resembles the test product, but without its

treatment value). Comparing a new product with a placebo can be the fastest and most reliable way to show the new product?s effectiveness. However, placebos are not used if you would be put at risk ? particularly in the study of treatments for serious illnesses ? by not having effective therapy. You will be told if placebos are used in the study before entering a trial. Randomization is the process by which treatments are assigned to participants by chance rather than by choice. This is done to avoid any bias in assigning volunteers to get one treatment or another. The effects of each treatment are compared at specific points during a trial. If one treatment is found superior, the trial is stopped so that the most volunteers receive the more beneficial treatment. "Blinded" (or "masked") studies are designed to prevent members of the research team and study participants from influencing the results. Blinding allows the collection of scientifically accurate data. In single-blind ("single-masked") studies, you are not told what is being given, but the research team knows. In a double-blind study, neither you nor the research team are told what you are given; only the pharmacist knows. Members of the research team are not told which participants are receiving which treatment, in order to reduce bias. If medically necessary, however, it is always possible to find out which treatment you are receiving.

Who takes part in clinical trials? 12

Many different types of people take part in clinical trials. Some are healthy, while others may have illnesses. Research procedures with healthy volunteers are designed to develop new knowledge, not to provide direct benefit to those taking part. Healthy volunteers have always played an important role in research. Healthy volunteers are needed for several reasons. When developing a new technique, such as a blood test or imaging device, healthy volunteers help define the limits of "normal." These volunteers are the baseline against which patient groups are compared and are often matched to patients on factors such as age, gender, or family relationship. They receive the same tests, procedures, or drugs the patient group receives. Researchers learn about the disease

process by comparing the patient group to the healthy volunteers. Factors like how much of your time is needed, discomfort you may feel, or risk involved depends on the trial. While some require minimal amounts of time and effort, other studies may require a major commitment of your time and effort, and may involve some discomfort. The research procedure(s) may also carry some risk. The informed consent process for healthy volunteers includes a detailed discussion of the study's procedures and tests and their risks. A patient volunteer has a known health problem and takes part in research to better understand, diagnose, or treat that disease or condition. Research with a patient volunteer helps develop new knowledge. Depending on the stage of knowledge about the disease or condition, these procedures may or may not benefit the study participants. Patients may volunteer for studies similar to those in which healthy volunteers take part. These studies involve drugs, devices, or treatments designed to prevent,or treat disease. Although these studies may provide direct benefit to patient volunteers, the main aim is to prove, by scientific means, the effects and limitations of the experimental treatment. Therefore, some patient groups may serve as a baseline for comparison by not taking the test drug, or by receiving test doses of the drug large enough only to show that it is present, but not at a level that can treat the condition. Researchers follow clinical trials guidelines when deciding who can participate, in a study. These guidelines are called Inclusion/Exclusion Criteria. Factors that allow you to take part in a clinical trial are called "inclusion criteria." Those that exclude or prevent participation are "exclusion criteria." These criteria are based on factors such as age, gender, the type and stage of a disease, treatment history, and other medical conditions. Before joining a clinical trial, you must provide information that allows the research team to determine whether or not you can take part in the study safely. Some research studies seek participants with illnesses or conditions to be studied in the clinical trial, while others need healthy volunteers. Inclusion and exclusion criteria are not used to reject people personally. Instead, the criteria are used to identify appropriate participants and keep them safe, and to help ensure that researchers can find new information they need.

What do I need to know if I am thinking about taking part in a clinical trial? 13

Risks and potential benefits: Clinical trials may involve risk, as can routine medical care and the activities of daily living. When weighing the risks of research, you can think about these important factors: The possible harms that could result from taking part in the study, The level of harm, The chance of any harm occurring. Most clinical trials pose the risk of minor discomfort, which lasts only a short time. However, some study participants experience complications that require medical attention. In rare cases, participants have been seriously injured or have died of complications resulting from their participation in trials of experimental treatments. The specific risks associated with a research protocol are described in detail in the informed consent document, which participants are asked to consider and sign before participating in research. Also, a member of the research team will explain the study and answer any questions about the study. Before deciding to participate, carefully consider risks and possible benefits. Potential benefits: Well-designed and well-executed clinical trials provide the best approach for you to: Help others by contributing to knowledge about new treatments or procedures, Gain access to new research treatments before they are widely available, Receive regular and careful medical attention from a research team that includes doctors and other health professionals. Risks: Risks to taking part in clinical trials include the following: There may be unpleasant, serious, or even life-threatening effects of experimental treatment, The study may require more time and attention than standard treatment would, including visits to the study site, more blood tests, more procedures, hospital stays, or complex dosage schedules.

What questions should I ask if offered a clinical trial? 14

If you are thinking about taking part in a clinical trial, you should feel free to ask any questions or bring up any issues concerning the trial at any time. The following suggestions may give you some

ideas as you think about your own questions. The study: What is the purpose of the study? Why do researchers think the approach may be effective? Who will fund the study? Who has reviewed and approved the study? How are study results and safety of participants being monitored? How long will the study last? What will my responsibilities be if I take part? Who will tell me about the results of the study and how will I be informed? Risks and possible benefits: What are my possible short-term benefits? What are my possible long-term benefits? What are my short-term risks, and side effects? What are my long-term risks? What other options are available? How do the risks and possible benefits of this trial compare with those options? Participation and care: What kinds of therapies, procedures and/or tests will I have during the trial? Will they hurt, and if so, for how long? How do the tests in the study compare with those I would have outside of the trial? Will I be able to take my regular medications while taking part in the clinical trial? Where will I have my medical care? Who will be in charge of my care? Personal issues: How could being in this study affect my daily life? Can I talk to other people in the study? Cost issues: Will I have to pay for any part of the trial such as tests or the study drug? If so, what will the charges likely be? What is my health insurance likely to cover? Who can help answer any questions from my insurance company or health plan? Will there be any travel or child care costs that I need to consider while I am in the trial? Tips for asking your doctor about trials: Consider taking a family member or friend along for support and for help in asking questions or recording answers. Plan what to ask ? but don't hesitate to ask any new questions. Write down questions in advance to remember them all. Write down the answers so that they?re available when needed. Ask about bringing a tape recorder to make a taped record of what's said (even if you write down answers).

How is my safety protected? 15

Ethical guidelines: The goal of clinical research is to develop knowledge that improves human health or increases understanding of human biology. People who take part in clinical research make it

possible for this to occur. The path to finding out if a new drug is safe or effective is to test it on patients in clinical trials. The purpose of ethical guidelines is both to protect patients and healthy volunteers, and to preserve the integrity of the science. Informed consent: Informed consent is the process of learning the key facts about a clinical trial before deciding whether to participate. The process of providing information to participants continues throughout the study. To help you decide whether to take part, members of the research team explain the study. The research team provides an informed consent document, which includes such details about the study as its purpose, duration, required procedures, and who to contact for various purposes. The informed consent document also explains risks and potential benefits. If you decide to enroll in the trial, you will need to sign the informed consent document. You are free to withdraw from the study at any time. IRB review: Most, but not all, clinical trials in the United States are approved and monitored by an Institutional Review Board (IRB) to ensure that the risks are minimal when compared with potential benefits. An IRB is an independent committee that consists of physicians, statisticians, and members of the community who ensure that clinical trials are ethical and that the rights of participants are protected. You should ask the sponsor or research coordinator whether the research you are considering participating in was reviewed by an IRB.

What happens after a clinical trial is completed? 16

After a clinical trial is completed, the researchers carefully examine information collected during the study before making decisions about the meaning of the findings and about the need for further testing. After a phase I or II trial, the researchers decide whether to move on to the next phase or to stop testing the treatment or procedure because it was unsafe or not effective. When a phase III trial is completed, the researchers examine the information and decide whether the results have medical importance. Results from clinical trials are often published in peer-reviewed scientific journals. Peer review is a process by which experts review the report before it is published to ensure that the

analysis and conclusions are sound. If the results are particularly important, they may be featured in the news, and discussed at scientific meetings and by patient advocacy groups before or after they are published in a scientific journal. Once a new approach has been proven safe and effective in a clinical trial, it may become a new standard of medical practice. Ask the research team members if the study results have been or will be published. Published study results are also available by searching for the study's official name or Protocol ID number in the National Library of Medicine's PubMed® database.

How does clinical research make a difference to me and my family? 17

Only through clinical research can we gain insights and answers about the safety and effectiveness of treatments and procedures. Groundbreaking scientific advances in the present and the past were possible only because of participation of volunteers, both healthy and those with an illness, in clinical research. Clinical research requires complex and rigorous testing in collaboration with communities that are affected by the disease. As research opens new doors to finding ways to diagnose, prevent, treat, or cure disease and disability, clinical trial participation is essential to help us find the answers.

Find a clinical trial Around the Nation and Worldwide 18

NIH conducts clinical research trials for many diseases and conditions, including cancer, Alzheimer?s disease, allergy and infectious diseases, and neurological disorders. To search for other diseases and conditions, you can visit ClinicalTrials.gov. ClinicalTrials.gov is a searchable registry and results database of federally and privately supported clinical trials conducted in the United States and around the world. ClinicalTrials.gov gives you information about a trial's purpose, who may participate, locations, and phone numbers for more details. This information should be

used in conjunction with advice from health care professionals. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read the disclaimer on ClinicalTrials.gov for details. Before participating in a study, talk to your health care provider and learn about the risks and potential benefits.

Join a National Registry of Research Volunteers 19

ResearchMatch.org is an NIH-funded initiative to connect 1) people who are trying to find research studies, and 2) researchers seeking people to participate in their studies. It is a free, secure registry to make it easier for the public to volunteer and to become involved in clinical research studies that contribute to improved health in the future.

Clinical Research 20

Clinical research is medical research that involves people to test new treatments and therapies.

Clinical Trial 21

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Healthy Volunteer 22

A Healthy volunteer is a person with no known significant health problems who participates in clinical research to test a new drug, device, or intervention.

Inclusion/Exclusion Criteria 23

Inclusion/Exclusion Criteria are factors that allow someone to participate in a clinical trial are inclusion criteria. Those that exclude or not allow participation are exclusion criteria.

Informed Consent 24

Informed consent explains risks and potential benefits about a clinical trial before someone decides whether to participate.

Patient Volunteer 25

A patient volunteer has a known health problem and participates in research to better understand, diagnose, treat, or cure that disease or condition.

Phases of Clinical Trials 26

Clinical trials are conducted in ?phases.? The trials at each phase have a different purpose and help researchers answer different questions. Phase I trials ? An experimental drug or treatment in a small group of people (20?80) for the first time. The purpose is to evaluate its safety and identify side effects. Phase II trials ? The experimental drug or treatment is administered to a larger group of people (100?300) to determine its effectiveness and to further evaluate its safety. Phase III trials ? The experimental drug or treatment is administered to large groups of people (1,000?3,000) to confirm its effectiveness, monitor side effects, compare it with standard or equivalent treatments. Phase IV trials ? After a drug is licensed and approved by the FDA researchers track its safety, seeking more information about its risks, benefits, and optimal use.

Placebo 27

A placebo is a pill or liquid that looks like the new treatment but does not have any treatment value from active ingredients.

Protocol 28

A Protocol is a carefully designed plan to safeguard the participants? health and answer specific research questions.

Principal Investigator 29

A Principal Investigator is a doctor who leads the clinical research team and, along with the other members of the research team, regularly monitors study participants? health to determine the study?s safety and effectiveness.

Randomization 30

Randomization is the process by which two or more alternative treatments are assigned to volunteers by chance rather than by choice.

Single- or Double-Blind Studies 31

Single- or double-blind studies (also called single- or double-masked studies) are studies in which the participants do not know which medicine is being used, so they can describe what happens without bias. In single-blind ("single-masked") studies, you are not told what is being given, but the research team knows. In a double-blind study, neither you nor the research team are told what you are given; only the pharmacist knows. Members of the research team are not told which participants

are receiving which treatment, in order to reduce bias. If medically necessary, however, it is always possible to find out which treatment you are receiving.

Types of Clinical Trials 32

Diagnostic trials determine better tests or procedures for diagnosing a particular disease or condition. Natural history studies provide valuable information about how disease and health progress. Prevention trials look for better ways to prevent a disease in people who have never had the disease or to prevent the disease from returning. Quality of life trials (or supportive care trials) explore and measure ways to improve the comfort and quality of life of people with a chronic illness. Screening trials test the best way to detect certain diseases or health conditions. Treatment trials test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

What is clinical research and why is it done? 33

Clinical research is medical research that studies people to understand health and disease. Clinical research helps improve the way doctors treat and prevent illness. Through clinical research, researchers learn: How the body works How illness develops in people, such as how diseases get better or worse over time How the body handles a possible treatment Which behaviors help people stay healthy and prevent illness, and which behaviors raise the chance of illness The goal is to use science to improve people?s health care and health over time. The participants who join and take part in clinical research studies may or may not get any benefit for themselves.

What are the types of clinical research? 34

There are 2 main types of clinical research: Clinical trials, also called interventional studies Observational studies Both may try to learn more about an intervention, which may be a drug,

behavior, or medical device. The main difference is clinical trial participants are assigned to get an intervention, but observational study participants are not assigned to get an intervention.

Clinical trials 35

Clinical trials are research studies in which researchers assign participants to get one or more interventions to test what happens in people. Because of this, clinical trials are also called interventional studies. Often, the intervention is investigational, which means it is not approved for doctors to prescribe to people. In some clinical trials, researchers assign participants to interventions randomly. This means that researchers assign the participants by chance. Usually, participants (or their doctors) don't choose what intervention they will get when they join a clinical trial.

Observational studies 36

Observational studies are research studies in which researchers simply collect information (called data) from participants or look at data that was already collected. The data may be about participants? health, habits, or environments. In observational studies, researchers do not assign participants to get an intervention. If there is an intervention, participants were already using it as part of their regular health care or daily life. Often, researchers use observational studies to look at (observe) the different ways people behave and how it affects their health. Some observational studies use patient registries. A patient registry is an organized collection of data that patients agree to give. Researchers can use a patient registry to quickly access data provided by hundreds, or thousands, of similar patients.

What is the main difference between the types of clinical research studies? 37

What is the main difference between the types of clinical research studies? The main difference is if

researchers assign participants to get an intervention, such as a drug, behavior, or medical device. Clinical trial: In clinical trials, researchers do assign participants to one or more interventions. Sometimes, researchers randomly assign participants to interventions. Observational study: In observational studies, researchers do not assign participants to an intervention. If there is an intervention, participants were already using as part of their regular health care or daily life.

Who can join clinical research? 38

Researchers look for people who fit a certain description, called eligibility criteria. These criteria give details on who can and cannot join a study and could include: People of a certain age or gender People who do or do not have a certain illness, disease, or health condition People with or without a certain health history, such as a prior treatment People who are exposed to or are in contact with something that affects their health Researchers use eligibility criteria to keep participants safe and enroll the right participants to collect the data they need to answer the research question. There are many kinds of research studies, all with different types of eligibility criteria.

Why do people join clinical research? 39

Participants may or may not get any benefit themselves from joining a clinical research study. In clinical trials, researchers often don?t know if the intervention will be helpful, harmful, or the same as regular health care. Some people volunteer to join clinical research to: Help researchers learn about health, illness, or treatments Be a part of discovering health information that may help others in the future Possibly get a drug or medical device that is not yet approved to be used in people with a certain health condition

What about safety and chance of harm (risk) during clinical research? 40

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All studies involve some level of risk or harm to participants. Because of this, there are people and systems in place to look out for participants? safety. The possible risks of taking part in clinical research include: The chance that participants will have a side effect or other health problem during a study (also called an adverse event) Participants may not get the intervention being tested in a clinical trial ? instead, they may get the standard treatment or no treatment at all The intervention being tested may not work or may not work better than the standard treatment The study may require more time and visits than their regular health care. All clinical research involves some risk. Different kinds of studies have different amounts of risk to participants. For example, the amount of risk may be the same or different as participants? regular health care.

How do researchers manage risk during clinical research? 41

In most clinical research studies, researchers use a group of experts, called an ethics review committee or Institutional Review Board (IRB), to make sure the amount of risk to participants is acceptable and as low as possible. They compare the study risks to the study benefits that participants or others in the future may receive to improve their health. For example, the IRB may decide that a clinical trial with a higher risk can proceed because the trial is testing a new drug that could help people who have no other treatment options. Some studies that take place in the U.S. or are funded by the U.S. government must follow rules set by other U.S. agencies to help manage risk. These agencies include the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA). Other countries may have their own rules, agencies, or offices to help manage risk. Many clinical trials for new drugs or medical devices move in a series of steps (called phases) to keep risk to participants as low as possible and answer different research questions. Each phase is designed to test the drug or device in as few participants as possible to answer the research question. Some clinical trials are considered more than one phase.

What happens during clinical research: Before clinical research begins 42

Clinical research relies on people who join. People who are thinking about joining a study get information about the study to help them decide. Research staff are available to answer their questions. This process is called informed consent. It?s the main way people get study information before deciding whether or not to join a study. Informed consent is a process that includes a document that has important information about taking part in the study, including: A description of what will happen during the study Who can join the study How much of participants? time the study will take Any payments and costs, such as payment participants get from taking part and any costs participants may need to pay The known benefits and risks of taking part in the study Other ways people can get information about a study may include: Asking the research study staff questions Reading brochures or websites Watching videos about the study If someone has discussed the study with the research staff, has had their questions answered, and agrees to join the study, they sign the informed consent form. Even if they sign the informed consent, they can leave the study at any time and for any reason. If they decide to leave, they can talk to the research staff to do so safely.

What happens during clinical research: During clinical research 43

Clinical research happens in many ways, depending on the type of study. Studies can take place at hospitals, clinics, research centers, universities, over the phone, or on the internet. They may take a few days, weeks, or even years. Researchers may assign participants into different groups. This happens in studies that compare an intervention to something else. For example, researchers may: Compare 2 drugs to see which works better or has fewer unwanted side effects Compare a drug to a placebo (a substance or treatment that looks like the drug, and is given in the same way, but has no active drug) Compare getting a treatment to no treatment Often in clinical trials, researchers

assign participants into the groups at random (by chance). These participants may not know what group (or intervention) they have been assigned, and the staff may not know either. This is called "masking" or "blinding". This ensures that participants and research staff do not know what intervention each participant receives to help make sure the results are looked at fairly In other types of clinical trials, all the participants get the intervention being studied.

How does joining a study affect participants? usual health care? 44

In most studies, participants can keep seeing their regular doctors. If needed, the research staff will work with participants? doctors to make sure that being in the study will not cause problems. In some studies, participants may have to change or limit their usual health care, such as stopping other medicines they take.

What if participants have health problems during clinical research? 45

Research staff will explain what to do if participants have health problems during the study. Usually, research staff ask participants to report health problems to them right away. Research staff include doctors and nurses who will work with participants and the participants? regular doctors to address the problem. A group of experts may also oversee what is happening in the study. If they have a safety concern, they contact the researchers right away. If very serious health problems happen to participants during the study, the researchers may stop the study. Participants can choose to leave the study, called "withdrawal", at any time and for any reason. If they decide to leave, they can talk to the research staff to do so safely.

How do researchers collect data? 46

During the study, researchers collect data from participants to help answer their research question.

They do this in different ways, such as: Surveys or questionnaires Getting images, such as X-rays or MRIs Taking measurements, such as height, weight, or blood pressure Taking samples of participants? blood or tissue to look at in a lab Researchers may need to collect data from participants many times or only a few times.

How do researchers use the data they collect? 47

Researchers analyze (study) the data they collect from participants based on the research plan to answer their research questions. Different countries have different rules about how researchers can use each type of data. The informed consent form describes what researchers plan to do with participants? data.

After clinical research, how do researchers share what they learned? 48

After the researchers analyze the data and the study is complete, researchers can share the study results. Study results summarize group data collected from all participants. These results can be published in research journals, on the internet, and on ClinicalTrials.gov. In some cases, researchers may list data from individual participants, but not in a way that allows readers to identify the participant. If the researchers tested a new drug or treatment that they want to make available to all patients, they submit the data and results from clinical trials to the FDA. Experts at the FDA will look at the data from the clinical trials and decide whether to approve the treatment for use in people with a certain condition. Usually, researchers need many studies before changing the way doctors prevent and treat illnesses.

Who carries out clinical research? 49

The sponsor oversees a study and may be: An organization, such as a medical center or drug

maker An individual, such as a doctor The sponsor may have another organization carry out the study on their behalf. The person leading a research study is called the principal investigator (PI). The PI is usually a medical doctor or another type of scientist. The PI typically works for the sponsor and leads a team of research staff that could include doctors, nurses, researchers, and technicians. The team of research staff may work at sites around the U.S. and other countries to carry out the research.

Who pays for clinical research? 50

The funder is the organization that pays the costs of carrying out a study. The funder can be: The U.S. government, or governments of other countries Drug makers or other private companies (industry) Medical centers Universities Charities or non-profit organizations

Do participants have to pay any costs or do they get paid for taking part in clinical research? 51

The informed consent form describes the study?s payment and costs. Some studies pay participants who take part, but the amount varies based on the study. Many clinical studies pay for the cost of the intervention and any research-related tests and visits. Some studies may pay costs for research-related travel and lodging, such as costs for parking or meals. Participants, or their insurance companies, still have to pay the cost of their regular health care.

What is expanded access? 52

Expanded access is a possible way for a patient with a serious illness who is unable to take part in a clinical trial to get an intervention (such as a drug or medical device) that isn?t yet approved for treatment. Expanded access is not clinical research and is not available for all interventions being tested. For patients who cannot join a clinical trial and have no other treatment options, expanded

access may be an option. The U.S. FDA regulates expanded access. Read more about expanded access on the FDA?s website.

Diversity and Inclusion in Clinical Trials 53

Our health is a combination of physical and mental well-being, which is affected by our behavior, biology, environment, societal policies, and importantly, our lived experiences. The lived experiences of people in the United States vary based on their race and ethnicity, socioeconomic status (SES), geographic location, sexual orientation, gender identity, and other sociodemographic characteristics. Lived experiences also need to be understood in the context of the individual and structural social determinants of health. How and where we live, learn, work and play, and our access to high-quality health care, healthy foods, and quality education can enhance our health outcomes. Similarly, negative experiences and exposures, such as pollution, violence, and structural racism and discrimination, can negatively affect our health. Our health status reflects the interwoven effects of such factors.

Why Are Clinical Trials Important? 54

A clinical trial is a type of clinical research that evaluates the effects of intervention(s), including drugs, devices, surgeries, diets, behavioral approaches, and lifestyle interventions, on health-related biomedical or behavioral outcomes. To account for the diverse lived experiences and exposures of various populations, clinical research should be appropriately inclusive of racial and ethnic minority groups, as well as other populations experiencing health disparities, including sexual and gender minority or socioeconomically disadvantaged populations. Clinical trials can determine if a new intervention is safe, works better, and/or has fewer side effects than an existing treatment or intervention, examine ways to detect a disease early, when it is potentially more treatable, or ways

to prevent a health problem altogether, evaluate ways to improve the quality of life of people who have an illness or chronic medical condition, and include testing of behavioral, social, environmental, and structural interventions.

The Importance of Diversity & Inclusion in Clinical Trials 55

People may experience the same disease differently. It?s essential that clinical trials include people with a variety of lived experiences and living conditions, as well as characteristics like race and ethnicity, age, sex, and sexual orientation, so that all communities can benefit from scientific advances. Factors that can influence the risk and likelihood of developing a disease, experiencing a long-term health outcome, and responding to treatment include age, biological sex, pregnancy status, life experiences (negatives, such as psychosocial stress and lack of basic resources, or positives, such as educational and employment opportunities), unhealthy behaviors (e.g., substance use, sedentary lifestyle, overeating, risky sexual activity), health-promoting behaviors (e.g., adequate sleep, obtaining recommended preventive services, physical activity, healthy eating), environmental conditions (e.g., pollution, access to health care or healthy foods, neighborhood segregation), genetic variation, and geographic ancestry, and underlying medical problems or presence of comorbidities (i.e., additional diseases or conditions).

Historical Issues and Considerations in Clinical Trials 56

Historically, clinical trials did not always recruit participants who represented the individuals most affected by a particular disease, condition, or behavior, often relying almost exclusively on White male study participants. This shortcoming has created gaps in our understanding of diseases and conditions, preventive factors, and treatment effectiveness across populations, impeding the quality of health care decision making, ability to counsel people on ways to reduce their risk, optimal

treatment responses, and even the development of more effective medications or interventions.

Considerations for Inclusive Clinical Trials 57

Clinicians and researchers should carefully consider the inclusion or exclusion criteria for their clinical trials, for example, a clinical trial excluding participants with high blood pressure or other comorbidities may end up excluding many people over 65 years old, who are more likely to have these conditions, thereby underrepresenting certain groups in the study and making the results less applicable to groups who may benefit the most from the findings.

Real-World Examples of the Need for Inclusion in Clinical Trials: COVID-19 Disparities 58

During the early stages of the pandemic, Coronavirus disease 2019 (COVID-19) disproportionately affected racial and ethnic minority populations, including African American, Hispanic/Latino, American Indian/Alaska Native, and Native Hawaiian and Pacific Islander population groups, with increased cases, hospitalizations and deaths. It was critical that COVID-19 vaccine trials included sufficient representation across population groups to better understand vaccine effectiveness in populations who vary on environmental exposures and other lived experiences. By using inclusive recruitment practices in COVID-19 clinical trials, researchers have been able to show that vaccine safety and efficacy are similar across all racial and ethnic populations. Engaging diverse populations in planning and implementing such trials can also help increase public confidence that the vaccine is safe and effective.

Real-World Examples of the Need for Inclusion in Clinical Trials: Asthma Disparities 59

Asthma disparities are intricately linked with the environment. Living in a city may increase exposure to air pollution and risk for developing asthma. Exposure to tobacco smoke, chronic social stress, or

unhealthy diets may also influence asthma risk or severity. Thus, it is vital for clinicians and researchers to consider where patients live, what they eat, and how they feel?as well as characteristics like race, ethnicity, socioeconomic status, and age?to get a more thorough understanding of their patients? experience with asthma symptoms and identify the best preventative strategies or treatment options.

Inclusive Participation in Clinical Trials Benefits Scientific Discovery 60

NIH is committed to inclusivity in clinical trial research. It is essential to have a wide range of people from different communities participate in clinical trials to reduce biases, promote social justice and health equity, and produce more innovative science. Below is a list of topics and examples to illustrate the important role of inclusive participation in clinical trial research.

Countering Mistrust in Clinical Research 61

Historical atrocities and incidents have engendered mistrust in clinical research and medical institutions. Investigators conducting the U.S. Public Health Service Syphilis Study at Tuskegee between 1932 and 1972 did not explain the study?s risks and obtain formal agreements (called informed consent) from the African American men who were its participants. The researchers wanted to study the effects of untreated syphilis and withheld penicillin treatment when it became available in 1945, which would have helped the 399 study participants with the disease. Only when news leaked of the study in 1972 did their unethical and discriminatory behavior come to light. Their actions caused preventable illness and death in study participants and their families. In 2003, members of the Havasupai Tribe in Northern Arizona learned that DNA samples given in the early 1990?s for a diabetes research study were later being used for additional research on ethnic migration, schizophrenia, and other unrelated genetic studies. The informed consent form from the

original study did not ask participants for their permission to use these samples for these other analyses. The researchers failed to obtain their consent for use of their data and specimens for other research purposes. The failings of the Syphilis Study at Tuskegee contributed to the creation of the Belmont Report in 1976, which addresses ethical issues in research with human participants. It outlines basic ethical principles and essential guidelines to protect human research participants and ensure safety in clinical trial research. Today, Institutional Review Boards are responsible for reviewing all studies involving humans for compliance with these guidelines and reports of any study protocol violations. In recent years, people from racial and ethnic minority communities and other populations experiencing health disparities have become more willing to participate in clinical research . Developing trust with communities who have been marginalized is best achieved through meaningful partnerships between researchers and community members in planning and carrying out studies with their input.

Inclusion of Women and People from Racial and Ethnic Minority Groups in Clinical Trials 62

The NIH Revitalization of Act of 1993 was signed into law, authorizing NIH to continue its mission and importantly establishing guidelines for the inclusion of women and persons from racial and ethnic minority populations in clinical research. The goal of this law, and other guidelines, is for clinical trial participants to adequately reflect the diversity of the real-world population, so that researchers can determine whether the variables being studied affect women or members of any racial and ethnic population group. This helps ensure that research findings are generalizable to the entire population. NIH efforts toward research inclusion remain at the forefront of clinical research policy. Recent activities include the publicly available NIH Research, Conditions and Disease Categorization Inclusion Statistics Report, which provides data on human research participation in NIH clinical research studies by race, ethnicity, and sex/gender. Additionally, in 2017, NIH updated its policy on the inclusion of women and people from racial and ethnic minority populations with a

requirement that "recipients conducting applicable NIH-defined Phase III clinical trials ensure results of valid analyses by sex/gender, race, and/or ethnicity are submitted to Clinicaltrials.gov." See NIH Inclusion Outreach Toolkit: How to Engage, Recruit, and Retain Women in Clinical Research for more information.

Inclusion of Sexual and Gender Minority Populations 63

Until recently, health care systems and epidemiological surveys often didn?t ask sexual orientation and gender identity questions to consider inclusion of sexual and gender minority (SGM) persons. This has made it difficult to know if individuals within SGM populations are represented in clinical research studies in significant numbers to make results representative for them. This lack of knowledge can influence patient-clinician communication and can result in fewer health screening or treatment opportunities.

Inclusion by Socioeconomic Status (SES) 64

An individual?s SES is a major predictor of health outcomes, because it can impact access to health care, nutritious foods, prescription medications, and other resources for healthy living. Yet, SES measures (i.e., education and income level) are not collected routinely and reported in clinical trials. In an analysis of all randomized clinical trials published in 2015 and 2019 in the Journal of the American Medical Association, The Lancet, and the New England Journal of Medicine, study investigators reported that less than 15% of studies reported on the SES of trial participants. Lack of data collection and reporting on SES measures make it difficult to generalize research findings to all SES groups or to tailor interventions (e.g., new medications or other treatment interventions) to people with lower SES who may not be able to access or maximize the benefits of clinical trial outcomes. In addition, limited access to socioeconomic resources may pose a barrier to participation

in clinical trials. To ensure the inclusion and representation of participants across different SES levels in clinical trials, researchers should use appropriate data collection and reporting protocols. For example, NIMHD supported a social determinants of health collection in the PhenX Toolkit that includes established instruments for conducting research with human participants, such as clinical trials. Researchers should also design their studies and provide resources to make it easier for people with lower SES to participate in clinical trials, such as offering convenient locations and hours of operation, childcare services, and transportation vouchers.

Data Collection and Reporting: Unmasking Hidden Truths 65

When scientists combine information from individual research participants, this is called data aggregation. Data aggregation is an important part of the research process that protects the anonymity of research volunteers and strengthens the statistical analysis of the study. However, aggregation of demographic data, including race and ethnicity, can also mask important differences in health risks or outcomes for specific subpopulations. For example, many prior studies on the health of Asian Americans have not always examined differences by nationality. A recent study found that among Filipino, Vietnamese, Chinese, Japanese, and Korean American adults living in California, categorizing all participants as ?Asian American? masked at least one health disparity for each subpopulation. Clinicians and researchers must take care to define as best as possible the clinical trial sample in their studies and consider whether their findings can be generalized across population groups, including consideration for differences in lived experiences.

Minority health research vs health disaprities research 66

Minority health research focuses on understanding and improving the health of people from specific racial or ethnic minority groups. The central core of health disparities research involves identifying

how race, ethnicity, and socioeconomic status interact with health determinants, such as social determinants, individual behaviors, the physical and cultural environment, and biological systems, to lead to differential clinical and population health outcomes.

Minority Health Definition 67

Distinctive health characteristics and attributes of racial and/or ethnic minority populations who are socially disadvantaged due in part to being subject to racist or discriminatory acts and are underserved in health care.

Health Disparity Definition 68

A health disparity is a health difference that adversely affects disadvantaged populations in comparison to a reference population, based on one or more health outcomes. All populations with health disparities are socially disadvantaged due in part to being subject to racist or discriminatory acts and are underserved in health care.

Minority Health Research 69

The scientific investigation of singular and combinations of attributes, characteristics, behaviors, biology, and societal and environmental factors that influence the health of minority racial and/or ethnic population(s), including within-group or ethnic sub-populations, with the goals of improving health and preventing disease.

Health Disparity Research 70

A multi-disciplinary field of study devoted to: Gaining greater scientific knowledge about the

influence of health determinants. Understanding the role of mechanisms. Determining how this knowledge is translated into interventions to reduce or eliminate adverse health outcomes.

Minority Health Populations 71

Racial and ethnic minority populations are: American Indian or Alaska Native Asian Black or African American Hispanic or Latino American Native Hawaiian and Pacific Islander

Populations with Health Disparities 72

Populations that experience health disparities include: Racial and ethnic minority groups People with lower socioeconomic status (SES) Underserved rural communities Sexual and gender minority (SGM) groups People with disabilities

Health Disparity Outcomes 73

The health outcomes are categorized as: Higher incidence and/or prevalence of disease, including earlier onset or more aggressive progression of disease. Premature or excessive mortality from specific health conditions. Greater global burden of disease, such as Disability Adjusted Life Years (DALY), as measured by population health metrics. Poorer health behaviors and clinical outcomes related to the aforementioned. Worse outcomes on validated self-reported measures that reflect daily functioning or symptoms from specific conditions.

What Is a Clinical Study? 74

A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials (also called

interventional studies) and observational studies. ClinicalTrials.gov includes both interventional and observational studies.

Clinical Trials 75

In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the investigators. These interventions may be medical products, such as drugs or devices; procedures; or changes to participants' behavior, such as diet. Clinical trials may compare a new medical approach to a standard one that is already available, to a placebo that contains no active ingredients, or to no intervention. Some clinical trials compare interventions that are already available to each other. When a new product or approach is being studied, it is not usually known whether it will be helpful, harmful, or no different than available alternatives (including no intervention). The investigators try to determine the safety and efficacy of the intervention by measuring certain outcomes in the participants. For example, investigators may give a drug or treatment to participants who have high blood pressure to see whether their blood pressure decreases. Clinical trials used in drug development are sometimes described by phase. These phases are defined by the Food and Drug Administration (FDA). Some people who are not eligible to participate in a clinical trial may be able to get experimental drugs or devices outside of a clinical trial through expanded access.

Observational Studies 76

In an observational study, investigators assess health outcomes in groups of participants according to a research plan or protocol. Participants may receive interventions (which can include medical products such as drugs or devices) or procedures as part of their routine medical care, but participants are not assigned to specific interventions by the investigator (as in a clinical trial). For

example, investigators may observe a group of older adults to learn more about the effects of different lifestyles on cardiac health.

Who Conducts Clinical Studies? 77

Every clinical study is led by a principal investigator, who is often a medical doctor. Clinical studies also have a research team that may include doctors, nurses, social workers, and other health care professionals. Clinical studies can be sponsored, or funded, by pharmaceutical companies, academic medical centers, voluntary groups, and other organizations, in addition to Federal agencies such as the National Institutes of Health, the U.S. Department of Defense, and the U.S. Department of Veterans Affairs. Doctors, other health care providers, and other individuals can also sponsor clinical research.

Where Are Clinical Studies Conducted? 78

Clinical studies can take place in many locations, including hospitals, universities, doctors' offices, and community clinics. The location depends on who is conducting the study.

How Long Do Clinical Studies Last? 79

The length of a clinical study varies, depending on what is being studied. Participants are told how long the study will last before they enroll.

Reasons for Conducting Clinical Studies 80

In general, clinical studies are designed to add to medical knowledge related to the treatment, diagnosis, and prevention of diseases or conditions. Some common reasons for conducting clinical

studies include: Evaluating one or more interventions (for example, drugs, medical devices, approaches to surgery or radiation therapy) for treating a disease, syndrome, or condition Finding ways to prevent the initial development or recurrence of a disease or condition. These can include medicines, vaccines, or lifestyle changes, among other approaches. Evaluating one or more interventions aimed at identifying or diagnosing a particular disease or condition Examining methods for identifying a condition or the risk factors for that condition Exploring and measuring ways to improve the comfort and quality of life through supportive care for people with a chronic illness

Participating in Clinical Studies 81

A clinical study is conducted according to a research plan known as the protocol. The protocol is designed to answer specific research questions and safeguard the health of participants. It contains the following information: The reason for conducting the study Who may participate in the study (the eligibility criteria) The number of participants needed The schedule of tests, procedures, or drugs and their dosages The length of the study What information will be gathered about the participants

Who Can Participate in a Clinical Study? 82

Clinical studies have standards outlining who can participate. These standards are called eligibility criteria and are listed in the protocol. Some research studies seek participants who have the illnesses or conditions that will be studied, other studies are looking for healthy participants, and some studies are limited to a predetermined group of people who are asked by researchers to enroll. Eligibility. The factors that allow someone to participate in a clinical study are called inclusion criteria, and the factors that disqualify someone from participating are called exclusion criteria. They are based on characteristics such as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions.

How Are Participants Protected? 83

Informed consent is a process used by researchers to provide potential and enrolled participants with information about a clinical study. This information helps people decide whether they want to enroll or continue to participate in the study. The informed consent process is intended to protect participants and should provide enough information for a person to understand the risks of, potential benefits of, and alternatives to the study. In addition to the informed consent document, the process may involve recruitment materials, verbal instructions, question-and-answer sessions, and activities to measure participant understanding. In general, a person must sign an informed consent document before joining a study to show that he or she was given information on the risks, potential benefits, and alternatives and that he or she understands it. Signing the document and providing consent is not a contract. Participants may withdraw from a study at any time, even if the study is not over. Institutional review boards. Each federally supported or conducted clinical study and each study of a drug, biological product, or medical device regulated by FDA must be reviewed, approved, and monitored by an institutional review board (IRB). An IRB is made up of doctors, researchers, and members of the community. Its role is to make sure that the study is ethical and that the rights and welfare of participants are protected. This includes making sure that research risks are minimized and are reasonable in relation to any potential benefits, among other responsibilities. The IRB also reviews the informed consent document. In addition to being monitored by an IRB, some clinical studies are also monitored by data monitoring committees (also called data safety and monitoring boards). Various Federal agencies, including the Office of Human Subjects Research Protection and FDA, have the authority to determine whether sponsors of certain clinical studies are adequately protecting research participants.

Relationship to Usual Health Care 84

Typically, participants continue to see their usual health care providers while enrolled in a clinical study. While most clinical studies provide participants with medical products or interventions related to the illness or condition being studied, they do not provide extended or complete health care. By having his or her usual health care provider work with the research team, a participant can make sure that the study protocol will not conflict with other medications or treatments that he or she receives.

Considerations for Participation 85

Participating in a clinical study contributes to medical knowledge. The results of these studies can make a difference in the care of future patients by providing information about the benefits and risks of therapeutic, preventative, or diagnostic products or interventions. Clinical trials provide the basis for the development and marketing of new drugs, biological products, and medical devices. Sometimes, the safety and the effectiveness of the experimental approach or use may not be fully known at the time of the trial. Some trials may provide participants with the prospect of receiving direct medical benefits, while others do not. Most trials involve some risk of harm or injury to the participant, although it may not be greater than the risks related to routine medical care or disease progression. (For trials approved by IRBs, the IRB has decided that the risks of participation have been minimized and are reasonable in relation to anticipated benefits.) Many trials require participants to undergo additional procedures, tests, and assessments based on the study protocol. These requirements will be described in the informed consent document. A potential participant should also discuss these issues with members of the research team and with his or her usual health care provider.

Questions to Ask 86

Clinical Trials Information

Anyone interested in participating in a clinical study should know as much as possible about the study and feel comfortable asking the research team questions about the study, the related procedures, and any expenses. The following questions may be helpful during such a discussion. Answers to some of these questions are provided in the informed consent document. Many of the questions are specific to clinical trials, but some also apply to observational studies. What is being studied? Why do researchers believe the intervention being tested might be effective? Why might it not be effective? Has it been tested before? What are the possible interventions that I might receive during the trial? How will it be determined which interventions I receive (for example, by chance)? Who will know which intervention I receive during the trial? Will I know? Will members of the research team know? How do the possible risks, side effects, and benefits of this trial compare with those of my current treatment? What will I have to do? What tests and procedures are involved? How often will I have to visit the hospital or clinic? Will hospitalization be required? How long will the study last? Who will pay for my participation? Will I be reimbursed for other expenses? What type of long-term follow-up care is part of this trial? If I benefit from the intervention, will I be allowed to continue receiving it after the trial ends? Will results of the study be provided to me? Who will oversee my medical care while I am participating in the trial? What are my options if I am injured during the study?

Accepts healthy volunteers 87

A type of eligibility criteria that indicates whether people who do not have the condition/disease being studied can participate in that clinical study.

Active comparator arm 88

An arm type in which a group of participants receives an intervention/treatment considered to be

effective (or active) by health care providers.

Adverse event 89

An unfavorable change in the health of a participant, including abnormal laboratory findings, that happens during a clinical study or within a certain amount of time after the study has ended. This change may or may not be caused by the intervention/treatment being studied.

Age or age group 90

A type of eligibility criteria that indicates the age a person must be to participate in a clinical study. This may be indicated by a specific age or the following age groups: The age groups are: Child (birth-17) Adult (18-64) Older Adult (65+)

All-cause mortality 91

A measure of all deaths, due to any cause, that occur during a clinical study.

Allocation 92

A method used to assign participants to an arm of a clinical study. The types of allocation are randomized allocation and nonrandomized.

Arm 93

A group or subgroup of participants in a clinical trial that receives a specific intervention/treatment, or no intervention, according to the trial's protocol.

Arm type 94

A general description of the clinical trial arm. It identifies the role of the intervention that participants receive. Types of arms include experimental arm, active comparator arm, placebo comparator arm, sham comparator arm, and no intervention arm.

Baseline characteristics 95

Data collected at the beginning of a clinical study for all participants and for each arm or comparison group. These data include demographics, such as age, sex/gender, race and ethnicity, and study-specific measures (for example, systolic blood pressure, prior antidepressant treatment).

Canceled submission 96

Indicates that the study sponsor or investigator recalled a submission of study results before quality control (QC) review took place. If the submission was canceled on or after May 8, 2018, the date is shown. After submission of study results, a study record cannot be modified until QC review is completed, unless the submission is canceled.

Certain agreements 97

Information required by the Food and Drug Administration Amendments Act of 2007. In general, this is a description of any agreement between the sponsor of a clinical study and the principal investigator (PI) that does not allow the PI to discuss the results of the study or publish the study results in a scientific or academic journal after the study is completed.

Certification 98

A sponsor or investigator may submit a certification to delay submission of results information if they are applying for FDA approval of a new drug or device, or new use of an already approved drug or device. A sponsor or investigator who submits a certification can delay results submission up to 2 years after the certification/extension first submitted date, unless certain events occur sooner. See Delay Results Type in the Results Data Element definitions for more information about this certification.

Certification/extension first posted 99

The date on which information about a certification to delay submission of results or an extension request was first available on ClinicalTrials.gov. ClinicalTrials.gov does not indicate whether the submission was a certification or extension request. There is typically a delay between the date the study sponsor or investigator submitted the certification or extension request and the first posted date.

Certification/extension first submitted 100

The date on which the study sponsor or investigator first submitted a certification or an extension request to delay submission of results. A sponsor or investigator who submits a certification can delay results submission up to 2 years after this date, unless certain events occur sooner. There is typically a delay between the date the certification or extension request was submitted and the date the information is first available on ClinicalTrials.gov (certification/extension first posted).

Certification/extension first submitted that met QC criteria 101

The date on which the study sponsor or investigator first submitted a certification or an extension request that is consistent with National Library of Medicine (NLM) quality control (QC) review

criteria. The sponsor or investigator may need to revise and submit a certification or extension request one or more times before NLM's QC review criteria are met. It is the responsibility of the sponsor or investigator to ensure that the study record is consistent with the NLM QC review criteria. Meeting QC criteria for an extension request does not mean that the National Institutes of Health (NIH) has determined that the request demonstrates good cause. The process for review and granting of extension requests by the NIH is being developed.

City and distance 102

In the search feature, the City field is used to find clinical studies with locations in a specific city. The Distance field is used to find studies with locations within the specified distance from a city in number of miles. For example, if you choose Illinois as the state, identifying "Chicago" as the city and "100 miles" as the distance will find all studies listing a location within 100 miles of Chicago.

Clinical study 103

A research study involving human volunteers (also called participants) that is intended to add to medical knowledge. There are two types of clinical studies: interventional studies (also called clinical trials) and observational studies.

Clinical trial 104

A research study involving human volunteers (also called participants) that is intended to add to medical knowledge. There are two types of clinical studies: interventional studies (also called clinical trials) and observational studies.

ClinicalTrials.gov identifier (NCT number) 105

The unique identification code given to each clinical study upon registration at ClinicalTrials.gov. The format is "NCT" followed by an 8-digit number (for example, NCT00000419).

Collaborator 106

An organization other than the sponsor that provides support for a clinical study. This support may include activities related to funding, design, implementation, data analysis, or reporting.

Condition/disease 107

The disease, disorder, syndrome, illness, or injury that is being studied. On ClinicalTrials.gov, conditions may also include other health-related issues, such as lifespan, quality of life, and health risks.

Contact 108

The name and contact information for the person who can answer enrollment questions for a clinical study. Each location where the study is being conducted may also have a specific contact, who may be better able to answer those questions.

Country 109

In the search feature, the Country field is used to find clinical studies with locations in a specific country. For example, if you choose the United States, you can then narrow your search by selecting a state and identifying a city and distance.

Cross-over assignment 110

A type of intervention model describing a clinical trial in which groups of participants receive two or more interventions in a specific order. For example, two-by-two cross-over assignment involves two groups of participants. One group receives drug A during the initial phase of the trial, followed by drug B during a later phase. The other group receives drug B during the initial phase, followed by drug A. So during the trial, participants "cross over" to the other drug. All participants receive drug A and drug B at some point during the trial but in a different order, depending on the group to which they are assigned.

Data Monitoring Committee (DMC) 111

A group of independent scientists who monitor the safety and scientific integrity of a clinical trial. The DMC can recommend to the sponsor that the trial be stopped if it is not effective, is harming participants, or is unlikely to serve its scientific purpose. Members are chosen based on the scientific skills and knowledge needed to monitor the particular trial. Also called a data safety and monitoring board, or DSMB.

Early Phase 1 (formerly listed as Phase 0) 112

A phase of research used to describe exploratory trials conducted before traditional phase 1 trials to investigate how or whether a drug affects the body. They involve very limited human exposure to the drug and have no therapeutic or diagnostic goals (for example, screening studies, microdose studies).

Eligibility criteria 113

The key requirements that people who want to participate in a clinical study must meet or the characteristics they must have. Eligibility criteria consist of both inclusion criteria (which are required

for a person to participate in the study) and exclusion criteria (which prevent a person from participating). Types of eligibility criteria include whether a study accepts healthy volunteers, has age or age group requirements, or is limited by sex.

Enrollment 114

The number of participants in a clinical study. The "estimated" enrollment is the target number of participants that the researchers need for the study.

Exclusion criteria 115

A type of eligibility criteria. These are reasons that a person is not allowed to participate in a clinical study.

Expanded access 116

A way for patients with serious diseases or conditions who cannot participate in a clinical trial to gain access to a medical product that has not been approved by the U.S. Food and Drug Administration (FDA). Also called compassionate use. There are different expanded access types.

Expanded access status 117

Available: Expanded access is currently available for this investigational treatment, and patients who are not participants in the clinical study may be able to gain access to the drug, biologic, or medical device being studied. No longer available: Expanded access was available for this intervention previously but is not currently available and will not be available in the future. Temporarily not available: Expanded access is not currently available for this intervention but is expected to be

available in the future. Approved for marketing: The intervention has been approved by the U.S. Food and Drug Administration for use by the public.

Expanded access type 118

Describes the category of expanded access under U.S. Food and Drug Administration (FDA) regulations. There are three types of expanded access: Individual Patients: Allows a single patient, with a serious disease or condition who cannot participate in a clinical trial, access to a drug or biological product that has not been approved by the FDA. This category also includes access in an emergency situation. Intermediate-size Population: Allows more than one patient (but generally fewer patients than through a Treatment IND/Protocol) access to a drug or biological product that has not been approved by the FDA. This type of expanded access is used when multiple patients with the same disease or condition seek access to a specific drug or biological product that has not been approved by the FDA. Treatment IND/Protocol: Allows a large, widespread population access to a drug or biological product that has not been approved by the FDA. This type of expanded access can only be provided if the product is already being developed for marketing for the same use as the expanded access use.

Experimental arm 119

An arm type in which a group of participants receives the intervention/treatment that is the focus of the clinical trial.

Extension request 120

In certain circumstances, a sponsor or investigator may request an extension to delay the standard results submission deadline (generally one year after the primary completion date). The request for

an extension must demonstrate good cause (for example, the need to preserve the scientific integrity of an ongoing masked trial). All requests must be reviewed and granted by the National Institutes of Health. This process for review and granting of extension requests is being developed. See Delay Results Type in the Results Data Element definitions for more information.

Factorial assignment 121

A type of intervention model describing a clinical trial in which groups of participants receive one of several combinations of interventions. For example, two-by-two factorial assignment involves four groups of participants. Each group receives one of the following pairs of interventions: (1) drug A and drug B, (2) drug A and a placebo, (3) a placebo and drug B, or (4) a placebo and a placebo. So during the trial, all possible combinations of the two drugs (A and B) and the placebos are given to different groups of participants.

FDAAA 801 Violations 122

A FDAAA 801 Violation is shown on a study record when the U.S. Food and Drug Administration (FDA) has issued a Notice of Noncompliance to the responsible party of an applicable clinical trial. A Notice of Noncompliance indicates that the FDA has determined the responsible party was not in compliance with the registration or results reporting requirements for the clinical trial under the Food and Drug Administration Amendments Act of 2007, Section 801 (FDAAA 801). The National Library of Medicine (NLM) is required by FDAAA 801 to add information to a study record about any FDAAA 801 Violation. This information is provided by the FDA. There are three categories of information that may be included: Violation: Shown when the FDA issues a Notice of Noncompliance and posts the Notice of Noncompliance on its designated webpage. There are three types of violations: Failure to submit required clinical trial information Submission of false or misleading clinical trial information

Failure to submit primary and secondary outcomes Correction: Shown when the FDA confirms that the responsible party has updated the study record to correct the violation and posts the correction notice on its designated webpage. Because of the time for FDA review and processing, there may be a delay between the date when the study record was updated and the addition of correction information to the FDAAA 801 Violation information. Penalty: Shown when the FDA imposes a penalty for the violation and posts the penalty notice on its designated webpage.

First posted 123

The date on which the study record was first available on ClinicalTrials.gov after National Library of Medicine (NLM) quality control (QC) review has concluded. There is typically a delay of a few days between the date the study sponsor or investigator submitted the study record and the first posted date.

First submitted 124

The date on which the study sponsor or investigator first submitted a study record to ClinicalTrials.gov. There is typically a delay of a few days between the first submitted date and the record's availability on ClinicalTrials.gov (the first posted date).

First submitted that met QC criteria 125

The date on which the study sponsor or investigator first submits a study record that is consistent with National Library of Medicine (NLM) quality control (QC) review criteria. The sponsor or investigator may need to revise and submit a study record one or more times before NLM's QC review criteria are met. It is the responsibility of the sponsor or investigator to ensure that the study record is consistent with the NLM QC review criteria.

Food and Drug Administration Amendments Act of 2007, Section 801 (FDAAA 801) 126

U.S. Public Law 110-85, which was enacted on September 27, 2007. Section 801 of FDAAA amends Section 402 of the U.S. Public Health Service Act to expand ClinicalTrials.gov and create a clinical study results database.

Funder type 127

Describes the organization that provides funding or support for a clinical study. This support may include activities related to funding, design, implementation, data analysis, or reporting. Organizations listed as sponsors and collaborators for a study are considered the funders of the study. ClinicalTrials.gov refers to four types of funders: U.S. National Institutes of Health Other U.S. Federal agencies (for example, Food and Drug Administration, Centers for Disease Control and Prevention, or U.S. Department of Veterans Affairs) Industry (for example: pharmaceutical and device companies) All others (including individuals, universities, and community-based organizations)

Gender-based eligibility 128

A type of eligibility criteria that indicates whether eligibility to participate in a clinical study is based on a person's self-representation of gender identity. Gender identity refers to a person's own sense of gender, which may or may not be the same as their biological sex.

Group/cohort 129

A group or subgroup of participants in an observational study that is assessed for biomedical or health outcomes.

Human subjects protection review board 130

A group of people who review, approve, and monitor the clinical study's protocol. Their role is to protect the rights and welfare of people participating in a study (referred to as human research subjects), such as reviewing the informed consent form. The group typically includes people with varying backgrounds, including a community member, to make sure that research activities conducted by an organization are completely and adequately reviewed. Also called an institutional review board, or IRB, or an ethics committee.

Inclusion criteria 131

A type of eligibility criteria. These are the reasons that a person is allowed to participate in a clinical study.

Informed consent 132

A process used by researchers to communicate to potential and enrolled participants the risks and potential benefits of participating in a clinical study.

Informed consent form (ICF) 133

The document used in the informed consent or process.

Intervention model 134

The general design of the strategy for assigning interventions to participants in a clinical study. Types of intervention models include: single group assignment, parallel assignment, cross-over assignment, and factorial assignment.

Intervention/treatment 135

A process or action that is the focus of a clinical study. Interventions include drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Interventions can also include noninvasive approaches, such as education or modifying diet and exercise.

Interventional study (clinical trial) 136

A type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study's protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.

Investigator 137

A researcher involved in a clinical study. Related terms include site principal investigator, site sub-investigator, study chair, study director, and study principal investigator.

Last update posted 138

The most recent date on which changes to a study record were made available on ClinicalTrials.gov. There may be a delay between when the changes were submitted to ClinicalTrials.gov by the study's sponsor or investigator (the last update submitted date) and the last update posted date.

Last update submitted 139

The most recent date on which the study sponsor or investigator submitted changes to a study

record to ClinicalTrials.gov. There is typically a delay of a few days between the last update submitted date and when the date changes are posted on ClinicalTrials.gov (the last update posted date).

Last update submitted that met QC criteria 140

The most recent date on which the study sponsor or investigator submitted changes to a study record that are consistent with National Library of Medicine (NLM) quality control (QC) review criteria. It is the responsibility of the sponsor or investigator to ensure that the study record is consistent with the NLM QC review criteria.

Last verified 141

The most recent date on which the study sponsor or investigator confirmed the information about a clinical study on ClinicalTrials.gov as accurate and current. If a study with a recruitment status of recruiting; not yet recruiting; or active, not recruiting has not been confirmed within the past 2 years, the study's recruitment status is shown as unknown.

Listed location countries 142

Countries in which research facilities for a study are located. A country is listed only once, even if there is more than one facility in the country. The list includes all countries as of the last update submitted date; any country for which all facilities were removed from the study record are listed under removed location countries.

Location terms 143

In the search feature, the Location terms field is used to narrow a search by location-related terms other than Country, State, and City or distance. For example, you may enter a specific facility name (such as National Institutes of Health Clinical Center) or a part of a facility name (such as Veteran for studies listing Veterans Hospital or Veteran Affairs in the facility name). Note: Not all study records include this level of detail about locations.

Masking 144

A clinical trial design strategy in which one or more parties involved in the trial, such as the investigator or participants, do not know which participants have been assigned which interventions. Types of masking include: open label, single blind masking, and double-blind masking.

NCT number 145

A unique identification code given to each clinical study record registered on ClinicalTrials.gov. The format is "NCT" followed by an 8-digit number (for example, NCT00000419). Also called the ClinicalTrials.gov identifier.

No intervention arm 146

An arm type in which a group of participants does not receive any intervention/treatment during the clinical trial.

Observational study 147

A type of clinical study in which participants are identified as belonging to study groups and are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or

other types of interventions, but the investigator does not assign participants to a specific interventions/treatment. A patient registry is a type of observational study.

Observational study model 148

The general design of the strategy for identifying and following up with participants during an observational study. Types of observational study models include cohort, case-control, case-only, case-cross-over, ecologic or community studies, family-based, and other.

Other adverse event 149

An adverse event that is not a serious adverse event, meaning that it does not result in death, is not life-threatening, does not require inpatient hospitalization or extend a current hospital stay, does not result in an ongoing or significant incapacity or interfere substantially with normal life functions, and does not cause a congenital anomaly or birth defect; it also does not put the participant in danger and does not require medical or surgical intervention to prevent one of the results listed above.

Other study IDs 150

Identifiers or ID numbers other than the NCT number that are assigned to a clinical study by the study's sponsor, funders, or others. These numbers may include unique identifiers from other trial registries and National Institutes of Health grant numbers.

Other terms 151

In the search feature, the Other terms field is used to narrow a search. For example, you may enter the name of a drug or the NCT number of a clinical study to limit the search to study records that

contain these words.

Outcome measure 152

For clinical trials, a planned measurement described in the protocol that is used to determine the effect of an intervention/treatment on participants. For observational studies, a measurement or observation that is used to describe patterns of diseases or traits, or associations with exposures, risk factors, or treatment. Types of outcome measures include primary outcome measure and secondary outcome measure.

Parallel assignment 153

A type of intervention model describing a clinical trial in which two or more groups of participants receive different interventions. For example, a two-arm parallel assignment involves two groups of participants. One group receives drug A, and the other group receives drug B. So during the trial, participants in one group receive drug A "in parallel" to participants in the other group, who receive drug B.

Participant flow 154

A summary of the progress of participants through each stage of a clinical study, by study arm or group/cohort. This includes the number of participants who started, completed, and dropped out of the study.

Patient registry 155

A type of observational study that collects information about patients' medical conditions and/or

treatments to better understand how a condition or treatment affects patients in the real world.

Phase 156

The stage of a clinical trial studying a drug or biological product, based on definitions developed by the U.S. Food and Drug Administration (FDA). The phase is based on the study's objective, the number of participants, and other characteristics. There are five phases: Early Phase 1 (formerly listed as Phase 0), Phase 1, Phase 2, Phase 3, and Phase 4. Not Applicable is used to describe trials without FDA-defined phases, including trials of devices or behavioral interventions.

Phase 1 157

A phase of research to describe clinical trials that focus on the safety of a drug. They are usually conducted with healthy volunteers, and the goal is to determine the drug's most frequent and serious adverse events and, often, how the drug is broken down and excreted by the body. These trials usually involve a small number of participants.

Phase 2 158

A phase of research to describe clinical trials that gather preliminary data on whether a drug works in people who have a certain condition/disease (that is, the drug's effectiveness). For example, participants receiving the drug may be compared to similar participants receiving a different treatment, usually an inactive substance (called a placebo) or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.

Phase 3 159

A phase of research to describe clinical trials that gather more information about a drug's safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs. These studies typically involve more participants.

Phase 4 160

A phase of research to describe clinical trials occurring after FDA has approved a drug for marketing. They include postmarket requirement and commitment studies that are required of or agreed to by the study sponsor. These trials gather additional information about a drug's safety, efficacy, or optimal use.

Phase Not Applicable 161

Describes trials without FDA-defined phases, including trials of devices or behavioral interventions.

Placebo 162

An inactive substance or treatment that looks the same as, and is given in the same way as, an active drug or intervention/treatment being studied.

Placebo comparator arm 163

An arm type in which a group of participants receives a placebo during a clinical trial.

Primary completion date 164

The date on which the last participant in a clinical study was examined or received an intervention to collect final data for the primary outcome measure. Whether the clinical study ended according to

the protocol or was terminated does not affect this date. For clinical studies with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all the primary outcome measures. The "estimated" primary completion date is the date that the researchers think will be the primary completion date for the study.

Primary outcome measure 165

In a clinical study's protocol, the planned outcome measure that is the most important for evaluating the effect of an intervention/treatment. Most clinical studies have one primary outcome measure, but some have more than one.

Primary purpose 166

The main reason for the clinical trial. The types of primary purpose are: treatment, prevention, diagnostic, supportive care, screening, health services research, basic science, and other.

Principal investigator (PI) 167

The person who is responsible for the scientific and technical direction of the entire clinical study.

Protocol 168

The written description of a clinical study. It includes the study's objectives, design, and methods. It may also include relevant scientific background and statistical information.

Quality control (QC) review 169

National Library of Medicine (NLM) staff perform a limited review of submitted study records for

apparent errors, deficiencies, or inconsistencies. NLM staff identify potential major and advisory issues and provide comments directly to the study sponsor or investigator. Major issues identified in QC review must be addressed or corrected (see First submitted that met QC criteria and Results first submitted that met QC criteria). Advisory issues are suggestions to help improve the clarity of the record. NLM staff do not verify the scientific validity or relevance of the submitted information. The study sponsor or investigator is responsible for ensuring that the studies follow all applicable laws and regulations.

Randomized allocation 170

A type of allocation strategy in which participants are assigned to the arms of a clinical trial by chance.

Recruitment status 171

Not yet recruiting: The study has not started recruiting participants. Recruiting: The study is currently recruiting participants. Enrolling by invitation: The study is selecting its participants from a population, or group of people, decided on by the researchers in advance. These studies are not open to everyone who meets the eligibility criteria but only to people in that particular population, who are specifically invited to participate. Active, not recruiting: The study is ongoing, and participants are receiving an intervention or being examined, but potential participants are not currently being recruited or enrolled. Suspended: The study has stopped early but may start again. Terminated: The study has stopped early and will not start again. Participants are no longer being examined or treated. Completed: The study has ended normally, and participants are no longer being examined or treated (that is, the last participant's last visit has occurred). Withdrawn: The study stopped early, before enrolling its first participant. Unknown: A study on ClinicalTrials.gov

whose last known status was recruiting; not yet recruiting; or active, not recruiting but that has passed its completion date, and the status has not been last verified within the past 2 years.

Registration 172

The process of submitting and updating summary information about a clinical study and its protocol, from its beginning to end, to a structured, public Web-based study registry that is accessible to the public, such as ClinicalTrials.gov.

Removed location countries 173

Countries that appeared under listed location countries but were removed from the study record by the sponsor or investigator.

Reporting group 174

A grouping of participants in a clinical study that is used for summarizing the data collected during the study. This grouping may be the same as or different from a study arm or group.

Responsible party 175

The person responsible for submitting information about a clinical study to ClinicalTrials.gov and updating that information. Usually the study sponsor or investigator.

Results database 176

A structured online system, such as the ClinicalTrials.gov results database, that provides the public with access to registration and summary results information for completed or terminated clinical

studies. A study with results available on ClinicalTrials.gov is described as having the results "posted." The ClinicalTrials.gov results database became available in September 2008. Older studies are unlikely to have results available in the database.

Results delayed 177

Indicates that the sponsor or investigator submitted a certification or extension request.

Results first posted 178

The date on which summary results information was first available on ClinicalTrials.gov after National Library of Medicine (NLM) quality control (QC) review has concluded. There is typically a delay between the date the study sponsor or investigator first submits summary results information (the results first submitted date) and the results first posted date. Some results information may be available at an earlier date if Results First Posted with QC Comments.

Results first posted with QC comments 179

The date on which summary results information was first available on ClinicalTrials.gov with quality control review comments from the National Library of Medicine (NLM) identifying major issues that must be addressed by the sponsor or investigator. As of January 1, 2020, initial results submissions for applicable clinical trials (ACTs) that do not meet quality control review criteria will be publicly posted on ClinicalTrials.gov with brief standardized major comments. Accordingly, the Results First Posted with QC Comments date may be earlier than the Results First Posted date for an ACT with summary results information that is not consistent with NLM quality control review criteria.

Results first submitted 180

The date on which the study sponsor or investigator first submits a study record with summary results information. There is typically a delay between the results first submitted date and when summary results information becomes available on ClinicalTrials.gov (the results first posted date).

Results first submitted that met QC criteria 181

The date on which the study sponsor or investigator first submits a study record with summary results information that is consistent with National Library of Medicine (NLM) quality control (QC) review criteria. The sponsor or investigator may need to revise and submit results information one or more times before NLM's QC review criteria are met. It is the responsibility of the sponsor or investigator to ensure that the study record is consistent with the NLM QC review criteria.

Results returned after quality control review 182

The date on which the National Library of Medicine provided quality control (QC) review comments to the study sponsor or investigator. The sponsor or investigator must address major issues identified in the review comments. If there is a date listed for results returned after quality control review, but there is not a subsequent date listed for results submitted to ClinicalTrials.gov, this means that the submission is pending changes by the sponsor or investigator.

Results submitted to ClinicalTrials.gov 183

Indicates that the study sponsor or investigator has submitted summary results information for a clinical study to ClinicalTrials.gov but the quality control (QC) review process has not concluded. The results submitted date indicates when the study sponsor or investigator first submitted summary results information or submitted changes to summary results information. Submissions with changes are typically in response to QC review comments from the National Library of Medicine (NLM). If

there is a date listed for results submitted to ClinicalTrials.gov, but there is not a subsequent date listed for results returned after quality control review, this means that the submission is pending review by NLM.

Secondary outcome measure 184

In a clinical study's protocol, a planned outcome measure that is not as important as the primary outcome measure for evaluating the effect of an intervention but is still of interest. Most clinical studies have more than one secondary outcome measure.

Serious adverse event 185

An adverse event that results in death, is life-threatening, requires inpatient hospitalization or extends a current hospital stay, results in an ongoing or significant incapacity or interferes substantially with normal life functions, or causes a congenital anomaly or birth defect. Medical events that do not result in death, are not life-threatening, or do not require hospitalization may be considered serious adverse events if they put the participant in danger or require medical or surgical intervention to prevent one of the results listed above.

Sex 186

A type of eligibility criteria that indicates the sex of people who may participate in a clinical study (all, female, male). Sex is a person's classification as female or male based on biological distinctions. Sex is distinct from gender-based eligibility.

Sham comparator arm 187

An arm type in which a group of participants receives a procedure or device that appears to be the same as the actual procedure or device being studied but does not contain active processes or components.

Single group assignment 188

A type of intervention model describing a clinical trial in which all participants receive the same intervention/treatment.

Sort studies by 189

In Advanced Search, the Sort studies by option is used to change the order of studies listed on the Search Results page. You can sort by Relevance or Newest First: Relevance: Studies that best match your search terms appear higher in the search results list. This is the default display for all searches. Newest First: Studies with the most recent First posted dates appear higher in the search results list.

Sponsor 190

The organization or person who initiates the study and who has authority and control over the study.

State 191

In the search feature, the State field is used to find clinical studies with locations in a specific state within the United States. If you choose United States in the Country field, you can search for studies with locations in a specific state.

Statistical analysis plan (SAP) 192

The written description of the statistical considerations and methods for analyzing the data collected in the clinical study.

Status 193

Indicates the current recruitment status or the expanded access status.

Study completion date 194

The date on which the last participant in a clinical study was examined or received an intervention/treatment to collect final data for the primary outcome measures, secondary outcome measures, and adverse events (that is, the last participant's last visit). The "estimated" study completion date is the date that the researchers think will be the study completion date.

Study design 195

The investigative methods and strategies used in the clinical study.

Study documents 196

Refers to the type of documents that the study sponsor or principal investigator may add to their study record. These include a study protocol, statistical analysis plan, and informed consent form.

Study IDs 197

Identifiers that are assigned to a clinical study by the study's sponsor, funders, or others. They

include unique identifiers from other trial study registries and National Institutes of Health grant numbers. Note: ClinicalTrials.gov assigns a unique identification code to each clinical study registered on ClinicalTrials.gov. Also called the NCT number, the format is "NCT" followed by an 8-digit number (for example, NCT00000419).

Study record 198

An entry on ClinicalTrials.gov that contains a summary of a clinical study's protocol information, including the recruitment status; eligibility criteria; contact information; and, in some cases, summary results. Each study record is assigned a ClinicalTrials.gov identifier, or NCT number.

Study registry 199

A structured online system, such as ClinicalTrials.gov, that provides the public with access to summary information about ongoing and completed clinical studies.

Study results 200

A study record that includes the summary results posted in the ClinicalTrials.gov results database. Summary results information includes participant flow, baseline characteristics, outcome measures, and adverse events (including serious adverse events).

Study start date 201

The actual date on which the first participant was enrolled in a clinical study. The "estimated" study start date is the date that the researchers think will be the study start date.

Study type 202

Describes the nature of a clinical study. Study types include interventional studies (also called clinical trials), observational studies (including patient registries), and expanded access.

Submitted date 203

The date on which the study sponsor or investigator submitted a study record that is consistent with National Library of Medicine (NLM) quality control (QC) review criteria.

Title 204

The official title of a protocol used to identify a clinical study or a short title written in language intended for the lay public.

Title acronym 205

The acronym or initials used to identify a clinical study (not all studies have one). For example, the title acronym for the Women's Health Initiative is "WHI."

U.S. Agency for Healthcare Research and Quality (AHRQ) 206

An agency within the U.S. Department of Health and Human Services. AHRQ's mission is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used.

U.S. Food and Drug Administration (FDA) 207

An agency within the U.S. Department of Health and Human Services. The FDA is responsible for protecting the public health by making sure that human and veterinary drugs, vaccines and other biological products, medical devices, the Nation's food supply, cosmetics, dietary supplements, and products that give off radiation are safe, effective, and secure.

Unknown 208

A type of recruitment status. It identifies a study on ClinicalTrials.gov whose last known status was recruiting; not yet recruiting; or active, not recruiting but that has passed its completion date, and the status has not been verified within the past 2 years. Studies with an unknown status are considered closed studies.

What is clinical research and why is it done? 209

Clinical research is medical research that studies people to understand health and disease. Clinical research helps improve the way doctors treat and prevent illness. Through clinical research, researchers learn: - How the body works

- How illness develops in people, such as how diseases get better or worse over time
- How the body handles a possible treatment
- Which behaviors help people stay healthy and prevent illness, and which behaviors raise the chance of illness The goal is to use science to improve people?s health care and health over time. The participants who join and take part in clinical research studies may or may not get any benefit for themselves.

What are the types of clinical research? 210

There are 2 main types of clinical research: - Clinical trials, also called interventional studies

- Observational studies Both may try to learn more about an intervention , which may be a drug, behavior, or medical device. The main difference is clinical trial participants are assigned to get an intervention, but observational study participants are not assigned to get an intervention.

Clinical trials 211

Clinical trials are research studies in which researchers assign participants to get one or more interventions to test what happens in people. Because of this, clinical trials are also called interventional studies . Often, the intervention is investigational, which means it is not approved for doctors to prescribe to people. In some clinical trials, researchers assign participants to interventions randomly. This means that researchers assign the participants by chance. Usually, participants (or their doctors) don't choose what intervention they will get when they join a clinical trial.

Observational studies 212

Observational studies are research studies in which researchers simply collect information (called data) from participants or look at data that was already collected. The data may be about participants? health, habits, or environments. In observational studies, researchers do not assign participants to get an intervention. If there is an intervention, participants were already using it as part of their regular health care or daily life. Often, researchers use observational studies to look at (observe) the different ways people behave and how it affects their health. Some observational studies use patient registries. A patient registry is an organized collection of data that patients agree to give. Researchers can use a patient registry to quickly access data provided by hundreds, or thousands, of similar patients.

Compare the 2 types of clinical research 213

The main difference is if researchers assign participants to get an intervention, such as a drug, behavior, or medical device. In clinical trials, researchers do assign participants to one or more interventions. Sometimes, researchers randomly assign participants to interventions. In observational studies, researchers do not assign participants to an intervention. If there is an intervention, participants were already using it as part of their regular health care or daily life.

Who can join clinical research? 214

Researchers look for people who fit a certain description, called eligibility criteria . These criteria give details on who can and cannot join a study and could include: - People of a certain age or gender

- People who do or do not have a certain illness, disease, or health condition
- People with or without a certain health history, such as a prior treatment
- People who are exposed to or are in contact with something that affects their health Researchers use eligibility criteria to keep participants safe and enroll the right participants to collect the data they need to answer the research question. There are many kinds of research studies, all with different types of eligibility criteria.

Why do people join clinical research? 215

Participants may or may not get any benefit themselves from joining a clinical research study. In clinical trials, researchers often don?t know if the intervention will be helpful, harmful, or the same as regular health care. Some people volunteer to join clinical research to: - Help researchers learn about health, illness, or treatments

- Be a part of discovering health information that may help others in the future
- Possibly get a drug or medical device that is not yet approved to be used in people with a certain

health condition

What about safety and chance of harm (risk) during clinical research? 216

All studies involve some level of risk or harm to participants. Because of this, there are people and systems in place to look out for participants? safety. The possible risks of taking part in clinical research include: - The chance that participants will have a side effect or other health problem during a study (also called anadverse event)

- Participants may not get the intervention being tested in a clinical trial ? instead, they may get the standard treatment or no treatment at all

- The intervention being tested may not work or may not work better than the standard treatment

- The study may require more time and visits than their regular health care. All clinical research involves some risk. Different kinds of studies have different amounts of risk to participants. For example, the amount of risk may be the same or different as participants? regular health care.

How do researchers manage risk during clinical research? 217

In most clinical research studies, researchers use a group of experts, called an ethics review committee or Institutional Review Board (IRB) , to make sure the amount of risk to participants is acceptable and as low as possible. They compare the study risks to the study benefits that participants or others in the future may receive to improve their health. For example, the IRB may decide that a clinical trial with a higher risk can proceed because the trial is testing a new drug that could help people who have no other treatment options. Some studies that take place in the U.S. or are funded by the U.S. government must follow rules set by other U.S. agencies to help manage risk. These agencies include the Office for Human Research Protections (OHRP) (https://www.hhs.gov/ohrp/) and the Food and Drug Administration (FDA)

(https://www.fda.gov/science-research/science-and-research-special-topics/clinical-trials-and-human-subject-protection) . Other countries may have their own rules, agencies, or offices to help manage risk. Many clinical trials for new drugs or medical devices move in a series of steps (called phases) to keep risk to participants as low as possible and answer different research questions. Each phase is designed to test the drug or device in as few participants as possible to answer the research question. Some clinical trials are considered more than one phase.

Before clinical research begins 218

Clinical research relies on people who join. People who are thinking about joining a study get information about the study to help them decide. Research staff are available to answer their questions. This process is called informed consent. It?s the main way people get study information before deciding whether or not to join a study. Informed consent is a process that includes a document that has important information about taking part in the study, including: - A description of what will happen during the study

- Who can join the study

- How much of participants? time the study will take

- Any payments and costs, such as payment participants get from taking part and any costs participants may need to pay

- The known benefits and risks of taking part in the study Other ways people can get information about a study may include: - Asking the research study staff questions

- Reading brochures or websites

- Watching videos about the study If someone has discussed the study with the research staff, has had their questions answered, and agrees to join the study, they sign the informed consent form. Even if they sign the informed consent, they can leave the study at any time and for any reason. If they decide to leave, they can talk to the research staff to do so safely.

During clinical research 219

Clinical research happens in many ways, depending on the type of study. Studies can take place at hospitals, clinics, research centers, universities, over the phone, or on the internet. They may take a few days, weeks, or even years. Researchers may assign participants into different groups. This happens in studies that compare an intervention to something else. For example, researchers may:

- Compare 2 drugs to see which works better or has fewer unwanted side effects
- Compare a drug to aplacebo(a substance or treatment that looks like the drug, and is given in the same way, but has no active drug)
- Compare getting a treatment to no treatment Often in clinical trials, researchers assign participants into the groups at random (by chance). These participants may not know what group (or intervention) they have been assigned, and the staff may not know either. This is called " masking " or "blinding". This ensures that participants and research staff do not know what intervention each participant receives to help make sure the results are looked at fairly In other types of clinical trials, all the participants get the intervention being studied.

How does joining a study affect participants? usual health care? 220

In most studies, participants can keep seeing their regular doctors. If needed, the research staff will work with participants? doctors to make sure that being in the study will not cause problems. In some studies, participants may have to change or limit their usual health care, such as stopping other medicines they take.

What if participants have health problems during clinical research? 221

Research staff will explain what to do if participants have health problems during the study. Usually, research staff ask participants to report health problems to them right away. Research staff include

doctors and nurses who will work with participants and the participants? regular doctors to address the problem. A group of experts may also oversee what is happening in the study. If they have a safety concern, they contact the researchers right away. If very serious health problems happen to participants during the study, the researchers may stop the study. Participants can choose to leave the study, called "withdrawal", at any time and for any reason. If they decide to leave, they can talk to the research staff to do so safely.

How do researchers collect data? 222

During the study, researchers collect data from participants to help answer their research question. They do this in different ways, such as: - Surveys or questionnaires

- Getting images, such as X-rays or MRIs
- Taking measurements, such as height, weight, or blood pressure
- Taking samples of participants? blood or tissue to look at in a lab Researchers may need to collect data from participants many times or only a few times.

How do researchers use the data they collect? 223

Researchers analyze (study) the data they collect from participants based on the research plan to answer their research questions. Different countries have different rules about how researchers can use each type of data. The informed consent form describes what researchers plan to do with participants? data.

After clinical research, how do researchers share what they learned? 224

After the researchers analyze the data and the study is complete, researchers can share the study results. Study results summarize group data collected from all participants. These results can be

published in research journals, on the internet, and on ClinicalTrials.gov. In some cases, researchers may list data from individual participants, but not in a way that allows readers to identify the participant. If the researchers tested a new drug or treatment that they want to make available to all patients, they submit the data and results from clinical trials to the FDA. Experts at the FDA will look at the data from the clinical trials and decide whether to approve the treatment for use in people with a certain condition. Usually, researchers need many studies before changing the way doctors prevent and treat illnesses.

Who carries out clinical research? 225

The sponsor oversees a study and may be: - An organization, such as a medical center or drug maker

- An individual, such as a doctor The sponsor may have another organization carry out the study on their behalf. The person leading a research study is called the principal investigator (PI) . The PI is usually a medical doctor or another type of scientist. The PI typically works for the sponsor and leads a team of research staff that could include doctors, nurses, researchers, and technicians. The team of research staff may work at sites around the U.S. and other countries to carry out the research.

Who pays for clinical research? 226

The funder is the organization that pays the costs of carrying out a study. The funder can be: - The U.S. government, or governments of other countries

- Drug makers or other private companies (industry)

- Medical centers

- Universities

- Charities or non-profit organizations

Do participants have to pay any costs or do they get paid for taking part in clinical research? 227

The informed consent form describes the study?s payment and costs. Some studies pay participants who take part, but the amount varies based on the study. Many clinical studies pay for the cost of the intervention and any research-related tests and visits. Some studies may pay costs for research-related travel and lodging, such as costs for parking or meals. Participants, or their insurance companies, still have to pay the cost of their regular health care.

What is expanded access? 228

Expanded access is a possible way for a patient with a serious illness who is unable to take part in a clinical trial to get an intervention (such as a drug or medical device) that isn?t yet approved for treatment. Expanded access is not clinical research and is not available for all interventions being tested. For patients who cannot join a clinical trial and have no other treatment options, expanded access may be an option. The U.S. FDA regulates expanded access. Read more about expanded access on the FDA?s website (https://www.fda.gov/news-events/public-health-focus/expanded-access) .

Why Should I Participate in a Clinical Trial? 229

Clinical trials are part of clinical research and at the heart of all medical advances. Clinical trials look at new ways to prevent, detect, or treat disease.

Treatments might be new drugs or new combinations of drugs, new surgical procedures or devices, or new ways to use existing treatments.

Clinical Trials Information

The goal of clinical trials is to determine if a new test or treatment works and is safe. Clinical trials can also look at other aspects of care, such as improving the quality of life for people with chronic illnesses.

People participate in clinical trials for a variety of reasons. Healthy volunteers say they participate to help others and to contribute to moving science forward. Participants with an illness or disease also participate to help others, but also to possibly receive the newest treatment and to have the additional care and attention from the clinical trial staff.

Clinical trials offer hope for many people and an opportunity to help researchers find better treatments for others in the future.

OHRP 230

Responsible for the rules that protect volunteers in HHS funded research

Funding Organizations 231

Ensure that human research is conducted ethically and complies with appropriate rules and standards of protections

Research Institutions 232

Agree to comply with the rules and educate research personnel about appropriate conduct toward research volunteers

IRBs 233

Review and oversee research to ensure that research volunteers are adequately protected according to ethical standards and relevant rules

Researchers 234

Carry out scientifically valid and ethical research. Often this includes providing information to help people make an informed decision about participating

Individuals 235

Learn about the risks and benefits associated with a research study through the informed consent process, and make an informed decision about whether to participate

Some Research is Outside of OHRP's Oversight 236

Even when research is not required to follow the Common Rule, there may be other regulations that provide protections.

For example, pharmaceutical companies that do research on new drugs that they plan to sell in the U.S. must comply with the U.S. Food and Drug Administration (FDA) rules to protect humans in research. The FDA?s rules are very similar to the Common Rule. The FDA protects public health by ensuring the safety and efficacy of drugs, biological products, and medical devices such as artificial heart valves. It is also responsible for advancing public health by helping the public get the accurate, science-based information they need to use medical products to maintain and improve their health.

Many institutions also voluntarily apply the protections laid out in the Common Rule, even if their research does not fall under OHRP oversight.

There are many research activities that do not come under the Common Rule. An example is research funded by private money such as research paid for by private companies, charitable foundations, or wealthy individuals. Some state or even federally funded research may not come under the Common Rule as well.

Office for Human Research Protections (OHRP) 237

OHRP is part of the U.S. Department of Health and Human Services (HHS). OHRP oversees and enforces the Common Rule and other HHS regulations for protecting participants in research that is funded with HHS money.

HHS agencies include, for example, the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). Researching involving humans that is funded by these agencies falls under OHRP?s oversight. Research funded by other Federal departments that follow the Common Rule is overseen by the respective departments.

OHRP works with institutions to ensure compliance with the regulations and responds to complaints about potential violations.

OHRP provides clarification and guidance about the regulations.

OHRP educates researchers and institutional staff on ethical expectations for conducting research with humans, Common Rule requirements, and the additional requirements in subparts B, C and D of the HHS regulations.

Clinical Trials Information

OHRP provides the general public information about research participation.

The Common Rule 238

The Federal rules that protect people who participate in research were initially published by the Department of Health and Human Services (HHS).

The first section of the HHS rules (Subpart A) is called the Common Rule because it was simultaneously adopted by 15 Federal departments and agencies in 1991. The Common Rule was revised in 2017 to reflect how research has changed since 1991.

One key protection in the Common Rule is the requirement for appropriate review and approval of research by institutional review boards, or IRBs . IRBs are committees that make sure researchers follow the HHS rules and ethical guidelines as they carry out their studies.

The Common Rule generally requires that researchers get informed consent from those who participate in research. This includes giving them information they would need to make an informed decision about participation in language they would understand.

Additional Protections 239

In addition to the Common Rule, there are 4 other subparts in the HHS rules. Three of these (Subparts B, C, & D) provide additional protections for certain groups of research participants that could be considered vulnerable.

Clinical Trials Information

What are clinical trials and why do people participate? 240

Clinical research is medical research that involves people like you. When you volunteer to take part in clinical research, you help doctors and researchers learn more about disease and improve health care for people in the future. Clinical research includes all research that involves people. Types of clinical research include:

A potential volunteer talks with her doctor about participating in a clinical trial.

Epidemiology, which improves the understanding of a disease by studying patterns, causes, and effects of health and disease in specific groups.
Behavioral, which improves the understanding of human behavior and how it relates to health and disease.
Health services, which looks at how people access health care providers and health care services, how much care costs, and what happens to patients as a result of this care.
Clinical trials, which evaluate the effects of an intervention on health outcomes.

What are clinical trials and why would I want to take part? 241

Clinical trials are part of clinical research and at the heart of all medical advances. Clinical trials look at new ways to prevent, detect, or treat disease. Clinical trials can study:

New drugs or new combinations of drugs
New ways of doing surgery
New medical devices
New ways to use existing treatments

Clinical Trials Information

New ways to change behaviors to improve health

New ways to improve the quality of life for people with acute or chronic illnesses.

The goal of clinical trials is to determine if these treatment, prevention, and behavior approaches are safe and effective. People take part in clinical trials for many reasons. Healthy volunteers say they take part to help others and to contribute to moving science forward. People with an illness or disease also take part to help others, but also to possibly receive the newest treatment and to have added (or extra) care and attention from the clinical trial staff. Clinical trials offer hope for many people and a chance to help researchers find better treatments for others in the future

Why is diversity and inclusion important in clinical trials? 242

People may experience the same disease differently. It?s essential that clinical trials include people with a variety of lived experiences and living conditions, as well as characteristics like race and ethnicity, age, sex, and sexual orientation, so that all communities benefit from scientific advances.

How does the research process work? 243

The idea for a clinical trial often starts in the lab. After researchers test new treatments or procedures in the lab and in animals, the most promising treatments are moved into clinical trials. As new treatments move through a series of steps called phases, more information is gained about the treatment, its risks, and its effectiveness.

What are clinical trial protocols? 244

Clinical trials follow a plan known as a protocol. The protocol is carefully designed to balance the potential benefits and risks to participants, and answer specific research questions. A protocol describes the following:

Clinical Trials Information

The goal of the study

Who is eligible to take part in the trial

Protections against risks to participants

Details about tests, procedures, and treatments

How long the trial is expected to last

What information will be gathered

A clinical trial is led by a principal investigator (PI). Members of the research team regularly monitor the participants? health to determine the study?s safety and effectiveness.

What is an Institutional Review Board? 245

Most, but not all, clinical trials in the United States are approved and monitored by an Institutional Review Board (IRB) to ensure that the risks are reduced and are outweighed by potential benefits. IRBs are committees that are responsible for reviewing research in order to protect the rights and safety of people who take part in research, both before the research starts and as it proceeds. You should ask the sponsor or research coordinator whether the research you are thinking about joining was reviewed by an IRB.

What is a clinical trial sponsor? 246

Clinical trial sponsors may be people, institutions, companies, government agencies, or other organizations that are responsible for initiating, managing or financing the clinical trial, but do not conduct the research.

What is informed consent? 247

Clinical Trials Information

Informed consent is the process of providing you with key information about a research study before you decide whether to accept the offer to take part. The process of informed consent continues throughout the study. To help you decide whether to take part, members of the research team explain the details of the study. If you do not understand English, a translator or interpreter may be provided. The research team provides an informed consent document that includes details about the study, such as its purpose, how long it?s expected to last, tests or procedures that will be done as part of the research, and who to contact for further information. The informed consent document also explains risks and potential benefits. You can then decide whether to sign the document. Taking part in a clinical trial is voluntary and you can leave the study at any time.

What are the types of clinical trials? 248

There are different types of clinical trials.

Prevention trials look for better ways to prevent a disease in people who have never had the disease or to prevent the disease from returning. Approaches may include medicines, vaccines, or lifestyle changes.

Screening trials test new ways for detecting diseases or health conditions.

Diagnostic trials study or compare tests or procedures for diagnosing a particular disease or condition.

Treatment trials test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

Behavioral trials evaluate or compare ways to promote behavioral changes designed to improve health.

Quality of life trials (or supportive care trials) explore and measure ways to improve the comfort and quality of life of people with conditions or illnesses.

What are the phases of clinical trials? 249

Clinical trials are conducted in a series of steps called ?phases.? Each phase has a different purpose and helps researchers answer different questions.

Phase I trials: Researchers test a drug or treatment in a small group of people (20?80) for the first time. The purpose is to study the drug or treatment to learn about safety and identify side effects.
Phase II trials: The new drug or treatment is given to a larger group of people (100?300) to determine its effectiveness and to further study its safety.
Phase III trials: The new drug or treatment is given to large groups of people (1,000?3,000) to confirm its effectiveness, monitor side effects, compare it with standard or similar treatments, and collect information that will allow the new drug or treatment to be used safely.
Phase IV trials: After a drug is approved by the FDA and made available to the public, researchers track its safety in the general population, seeking more information about a drug or treatment?s benefits, and optimal use.

What do the terms placebo, randomization, and blinded mean in clinical trials? 250

In clinical trials that compare a new product or therapy with another that already exists, researchers try to determine if the new one is as good, or better than, the existing one. In some studies, you may be assigned to receive a placebo (an inactive product that resembles the test product, but without its treatment value).

Comparing a new product with a placebo can be the fastest and most reliable way to show the new product?s effectiveness. However, placebos are not used if you would be put at risk ? particularly in the study of treatments for serious illnesses ? by not having effective therapy. You will be told if

placebos are used in the study before entering a trial.

Randomization is the process by which treatments are assigned to participants by chance rather than by choice. This is done to avoid any bias in assigning volunteers to get one treatment or another. The effects of each treatment are compared at specific points during a trial. If one treatment is found superior, the trial is stopped so that the most volunteers receive the more beneficial treatment. This video helps explain randomization for all clinical trials.

"Blinded" (or "masked") studies are designed to prevent members of the research team and study participants from influencing the results. Blinding allows the collection of scientifically accurate data. In single-blind ("single-masked") studies, you are not told what is being given, but the research team knows. In a double-blind study, neither you nor the research team are told what you are given; only the pharmacist knows. Members of the research team are not told which participants are receiving which treatment, in order to reduce bias. If medically necessary, however, it is always possible to find out which treatment you are receiving.

Who takes part in clinical trials? 251

Many different types of people take part in clinical trials. Some are healthy, while others may have illnesses. Research procedures with healthy volunteers are designed to develop new knowledge, not to provide direct benefit to those taking part. Healthy volunteers have always played an important role in research.

Healthy volunteers are needed for several reasons. When developing a new technique, such as a blood test or imaging device, healthy volunteers help define the limits of "normal." These volunteers are the baseline against which patient groups are compared and are often matched to patients on

factors such as age, gender, or family relationship. They receive the same tests, procedures, or drugs the patient group receives. Researchers learn about the disease process by comparing the patient group to the healthy volunteers.

Factors like how much of your time is needed, discomfort you may feel, or risk involved depends on the trial. While some require minimal amounts of time and effort, other studies may require a major commitment of your time and effort, and may involve some discomfort. The research procedure(s) may also carry some risk. The informed consent process for healthy volunteers includes a detailed discussion of the study's procedures and tests and their risks.

A patient volunteer has a known health problem and takes part in research to better understand, diagnose, or treat that disease or condition. Research with a patient volunteer helps develop new knowledge. Depending on the stage of knowledge about the disease or condition, these procedures may or may not benefit the study participants.

Patients may volunteer for studies similar to those in which healthy volunteers take part. These studies involve drugs, devices, or treatments designed to prevent,or treat disease. Although these studies may provide direct benefit to patient volunteers, the main aim is to prove, by scientific means, the effects and limitations of the experimental treatment. Therefore, some patient groups may serve as a baseline for comparison by not taking the test drug, or by receiving test doses of the drug large enough only to show that it is present, but not at a level that can treat the condition.

Researchers follow clinical trials guidelines when deciding who can participate, in a study. These guidelines are called Inclusion/Exclusion Criteria. Factors that allow you to take part in a clinical trial are called "inclusion criteria." Those that exclude or prevent participation are "exclusion criteria."

These criteria are based on factors such as age, gender, the type and stage of a disease, treatment history, and other medical conditions. Before joining a clinical trial, you must provide information that allows the research team to determine whether or not you can take part in the study safely. Some research studies seek participants with illnesses or conditions to be studied in the clinical trial, while others need healthy volunteers. Inclusion and exclusion criteria are not used to reject people personally. Instead, the criteria are used to identify appropriate participants and keep them safe, and to help ensure that researchers can find new information they need.

Risks and potential benefits 252

Clinical trials may involve risk, as can routine medical care and the activities of daily living. When weighing the risks of research, you can think about these important factors:

The possible harms that could result from taking part in the study

The level of harm

The chance of any harm occurring

Most clinical trials pose the risk of minor discomfort, which lasts only a short time. However, some study participants experience complications that require medical attention. In rare cases, participants have been seriously injured or have died of complications resulting from their participation in trials of experimental treatments. The specific risks associated with a research protocol are described in detail in the informed consent document, which participants are asked to consider and sign before participating in research. Also, a member of the research team will explain the study and answer any questions about the study. Before deciding to participate, carefully consider risks and possible benefits.

Potential benefits 253

Clinical Trials Information

Well-designed and well-executed clinical trials provide the best approach for you to:

Help others by contributing to knowledge about new treatments or procedures.

Gain access to new research treatments before they are widely available.

Receive regular and careful medical attention from a research team that includes doctors and other health professionals.

Risks 254

Risks to taking part in clinical trials include the following:

There may be unpleasant, serious, or even life-threatening effects of experimental treatment.

The study may require more time and attention than standard treatment would, including visits to the study site, more blood tests, more procedures, hospital stays, or complex dosage schedules.

What questions should I ask if offered a clinical trial? 255

If you are thinking about taking part in a clinical trial, you should feel free to ask any questions or bring up any issues concerning the trial at any time. The following suggestions may give you some ideas as you think about your own questions.

The study 256

What is the purpose of the study?

Why do researchers think the approach may be effective?

Who will fund the study?

Who has reviewed and approved the study?

How are study results and safety of participants being monitored?

How long will the study last?

What will my responsibilities be if I take part?

Who will tell me about the results of the study and how will I be informed?

Risks and possible benefits 257

What are my possible short-term benefits?

What are my possible long-term benefits?

What are my short-term risks, and side effects?

What are my long-term risks?

What other options are available?

How do the risks and possible benefits of this trial compare with those options?

Participation and care 258

What kinds of therapies, procedures and/or tests will I have during the trial?

Will they hurt, and if so, for how long?

How do the tests in the study compare with those I would have outside of the trial?

Will I be able to take my regular medications while taking part in the clinical trial?

Where will I have my medical care?

Who will be in charge of my care?

Personal issues 259

How could being in this study affect my daily life?

Can I talk to other people in the study?

Cost issues 260

Will I have to pay for any part of the trial such as tests or the study drug?

If so, what will the charges likely be?

What is my health insurance likely to cover?

Who can help answer any questions from my insurance company or health plan?

Will there be any travel or child care costs that I need to consider while I am in the trial?

Tips for asking your doctor about trials 261

Consider taking a family member or friend along for support and for help in asking questions or recording answers.

Plan what to ask ? but don't hesitate to ask any new questions.

Write down questions in advance to remember them all.

Write down the answers so that they?re available when needed.

Ask about bringing a tape recorder to make a taped record of what's said (even if you write down answers).

Ethical guidelines 262

The goal of clinical research is to develop knowledge that improves human health or increases understanding of human biology. People who take part in clinical research make it possible for this to occur. The path to finding out if a new drug is safe or effective is to test it on patients in clinical trials. The purpose of ethical guidelines is both to protect patients and healthy volunteers, and to preserve the integrity of the science.

Informed consent 263

Informed consent is the process of learning the key facts about a clinical trial before deciding whether to participate. The process of providing information to participants continues throughout the study. To help you decide whether to take part, members of the research team explain the study. The research team provides an informed consent document, which includes such details about the study as its purpose, duration, required procedures, and who to contact for various purposes. The informed consent document also explains risks and potential benefits.

If you decide to enroll in the trial, you will need to sign the informed consent document. You are free to withdraw from the study at any time.

IRB review 264

Most, but not all, clinical trials in the United States are approved and monitored by an Institutional Review Board (IRB) to ensure that the risks are minimal when compared with potential benefits. An IRB is an independent committee that consists of physicians, statisticians, and members of the community who ensure that clinical trials are ethical and that the rights of participants are protected. You should ask the sponsor or research coordinator whether the research you are considering participating in was reviewed by an IRB.

What happens after a clinical trial is completed? 265

After a clinical trial is completed, the researchers carefully examine information collected during the study before making decisions about the meaning of the findings and about the need for further testing. After a phase I or II trial, the researchers decide whether to move on to the next phase or to stop testing the treatment or procedure because it was unsafe or not effective. When a phase III trial is completed, the researchers examine the information and decide whether the results have medical

importance.

Results from clinical trials are often published in peer-reviewed scientific journals. Peer review is a process by which experts review the report before it is published to ensure that the analysis and conclusions are sound. If the results are particularly important, they may be featured in the news, and discussed at scientific meetings and by patient advocacy groups before or after they are published in a scientific journal. Once a new approach has been proven safe and effective in a clinical trial, it may become a new standard of medical practice.

Ask the research team members if the study results have been or will be published. Published study results are also available by searching for the study's official name or Protocol ID number in the National Library of Medicine's PubMed® database.

How does clinical research make a difference to me and my family? 266

Only through clinical research can we gain insights and answers about the safety and effectiveness of treatments and procedures. Groundbreaking scientific advances in the present and the past were possible only because of participation of volunteers, both healthy and those with an illness, in clinical research. Clinical research requires complex and rigorous testing in collaboration with communities that are affected by the disease. As research opens new doors to finding ways to diagnose, prevent, treat, or cure disease and disability, clinical trial participation is essential to help us find the answers.

For Parents and Children 267

Children are not little adults, yet they are often given medicines and treatments that were only tested

in adults. There is a lot of evidence that children?s developing brains and bodies can respond to medicines and treatments differently than how adults respond. The way to get the best treatments for children is through research designed specifically for them.

We have already made great strides in improving children's health outcomes through clinical research. Vaccines, treatments for children with cancer, and interventions for premature babies are just a few examples of how this targeted research can be helpful. However, there are still many questions to answer and more children waiting to benefit.

Should your child participate in a clinical study? 268

We understand that parents and caregivers have many questions when they are considering enrolling a child in a clinical study, and that children and adolescents also want to know what they will go through. The NIH remains committed to ensuring that families trying to decide whether to enroll their child in a clinical study get all the information they need to feel comfortable and make informed decisions. The safety of children remains the utmost priority for all NIH research studies.

Sexual & Gender Minority Research Office 269

The Sexual & Gender Minority Research Office (SGMRO) coordinates sexual and gender minority (SGM)?related research and activities by working directly with the NIH Institutes, Centers, and Offices. The Office was officially established in September 2015 within the NIH Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI).

Sexual and gender minority (SGM) populations include, but are not limited to, individuals who identify as lesbian, gay, bisexual, asexual, transgender, Two-Spirit, queer, and/or intersex.

Individuals with same-sex or -gender attractions or behaviors and those with a difference in sex development are also included. These populations also encompass those who do not self-identify with one of these terms but whose sexual orientation, gender identity or expression, or reproductive development is characterized by non-binary constructs of sexual orientation, gender, and/or sex.

Allies are critical to the mission of the SGMRO. To describe allyship at NIH, the Director authored a blog post in collaboration with the NIH Office of Equity, Diversity, and Inclusion (EDI). The post can be found along with others on the EDI 365 website.

What We Do 270

Coordinate SGM health research activities across NIH
Represent NIH at conferences and events on trans-NIH activities focused on SGM research
Coordinate and convene conferences and workshops to inform priority setting and research activities
Collaborate with NIH Institutes and Centers on the development of SGM health research reports
Manage information dissemination related to SGM research
Work with NIH Institutes and Centers to leverage resources and develop initiatives to support SGM health research

Strategic Goals 271

Advance rigorous research on the health of SGM populations in both the extramural and intramural research communities
Expand SGM health research by fostering partnerships and collaborations with a strategic array of internal and external stakeholders

Foster a highly skilled and diverse workforce in SGM health research

Encourage data collection related to SGM populations in research and the health research workforce

Accepts healthy volunteers 272

A type of eligibility criteria that indicates whether people who do not have the condition/disease being studied can participate in that clinical study.

Active comparator arm 273

An arm type in which a group of participants receives an intervention/treatment considered to be effective (or active) by health care providers.

Adverse event 274

An unfavorable change in the health of a participant, including abnormal laboratory findings, that happens during a clinical study or within a certain amount of time after the study has ended. This change may or may not be caused by the intervention/treatment being studied.

Age or age group 275

A type of eligibility criteria that indicates the age a person must be to participate in a clinical study. This may be indicated by a specific age or the following age groups: The age groups are: Child (birth-17) Adult (18-64) Older Adult (65+)

All-cause mortality 276

A measure of all deaths, due to any cause, that occur during a clinical study.

Allocation 277

A method used to assign participants to an arm of a clinical study. The types of allocation are randomized allocation and nonrandomized.

Arm 278

A group or subgroup of participants in a clinical trial that receives a specific intervention/treatment , or no intervention, according to the trial's protocol .

Arm type 279

A general description of the clinical trial arm. It identifies the role of the intervention that participants receive. Types of arms include experimental arm , active comparator arm , placebo comparator arm , sham comparator arm , and no intervention arm .

Baseline characteristics 280

Data collected at the beginning of a clinical study for all participants and for each arm or comparison group. These data include demographics, such as age, sex/gender, race and ethnicity, and study-specific measures (for example, systolic blood pressure, prior antidepressant treatment).

Canceled submission 281

Indicates that the study sponsor or investigator recalled a submission of study results before quality control (QC) review took place. If the submission was canceled on or after May 8, 2018, the date is

shown. After submission of study results, a study record cannot be modified until QC review is completed, unless the submission is canceled.

Certain agreements 282

Information required by the Food and Drug Administration Amendments Act of 2007 . In general, this is a description of any agreement between the sponsor of a clinical study and the principal investigator (PI) that does not allow the PI to discuss the results of the study or publish the study results in a scientific or academic journal after the study is completed.

Certification 283

A sponsor or investigator may submit a certification to delay submission of results information if they are applying for FDA approval of a new drug or device, or new use of an already approved drug or device. A sponsor or investigator who submits a certification can delay results submission up to 2 years after the certification/extension first submitted date, unless certain events occur sooner. See Delay Results Type in the Results Data Element definitions for more information about this certification.

Certification/extension first posted 284

The date on which information about a certification to delay submission of results or an extension request was first available on ClinicalTrials.gov. ClinicalTrials.gov does not indicate whether the submission was a certification or extension request. There is typically a delay between the date the study sponsor or investigator submitted the certification or extension request and the first posted date .

Certification/extension first submitted 285

The date on which the study sponsor or investigator first submitted a certification or an extension request to delay submission of results. A sponsor or investigator who submits a certification can delay results submission up to 2 years after this date, unless certain events occur sooner. There is typically a delay between the date the certification or extension request was submitted and the date the information is first available on ClinicalTrials.gov (certification/extension first posted).

Certification/extension first submitted that met QC criteria 286

The date on which the study sponsor or investigator first submitted a certification or an extension request that is consistent with National Library of Medicine (NLM) quality control (QC) review criteria. The sponsor or investigator may need to revise and submit a certification or extension request one or more times before NLM's QC review criteria are met. It is the responsibility of the sponsor or investigator to ensure that the study record is consistent with the NLM QC review criteria. Meeting QC criteria for an extension request does not mean that the National Institutes of Health (NIH) has determined that the request demonstrates good cause. The process for review and granting of extension requests by the NIH is being developed.

City and distance 287

In the search feature, the City field is used to find clinical studies with locations in a specific city. The Distance field is used to find studies with locations within the specified distance from a city in number of miles. For example, if you choose Illinois as the state , identifying "Chicago" as the city and "100 miles" as the distance will find all studies listing a location within 100 miles of Chicago.

Clinical study 288

A research study involving human volunteers (also called participants) that is intended to add to medical knowledge. There are two types of clinical studies: interventional studies (also called clinical trials) and observational studies .

Clinical trial 289

Another name for an interventional study .

ClinicalTrials.gov identifier (NCT number) 290

The unique identification code given to each clinical study upon registration at ClinicalTrials.gov. The format is "NCT" followed by an 8-digit number (for example, NCT00000419).

Collaborator 291

An organization other than the sponsor that provides support for a clinical study. This support may include activities related to funding, design, implementation, data analysis, or reporting.

Condition/disease 292

The disease, disorder, syndrome, illness, or injury that is being studied. On ClinicalTrials.gov, conditions may also include other health-related issues, such as lifespan, quality of life, and health risks.

Contact 293

The name and contact information for the person who can answer enrollment questions for a clinical study. Each location where the study is being conducted may also have a specific contact, who may

be better able to answer those questions.

Country 294

In the search feature, the Country field is used to find clinical studies with locations in a specific country. For example, if you choose the United States, you can then narrow your search by selecting a state and identifying a city and distance .

Cross-over assignment 295

A type of intervention model describing a clinical trial in which groups of participants receive two or more interventions in a specific order. For example, two-by-two cross-over assignment involves two groups of participants. One group receives drug A during the initial phase of the trial, followed by drug B during a later phase. The other group receives drug B during the initial phase, followed by drug A. So during the trial, participants "cross over" to the other drug. All participants receive drug A and drug B at some point during the trial but in a different order, depending on the group to which they are assigned.

Data Monitoring Committee (DMC) 296

A group of independent scientists who monitor the safety and scientific integrity of a clinical trial . The DMC can recommend to the sponsor that the trial be stopped if it is not effective, is harming participants, or is unlikely to serve its scientific purpose. Members are chosen based on the scientific skills and knowledge needed to monitor the particular trial. Also called a data safety and monitoring board, or DSMB.

Early Phase 1 (formerly listed as Phase 0) 297

A phase of research used to describe exploratory trials conducted before traditional phase 1 trials to investigate how or whether a drug affects the body. They involve very limited human exposure to the drug and have no therapeutic or diagnostic goals (for example, screening studies, microdose studies).

Eligibility criteria 298

The key requirements that people who want to participate in a clinical study must meet or the characteristics they must have. Eligibility criteria consist of both inclusion criteria (which are required for a person to participate in the study) and exclusion criteria (which prevent a person from participating). Types of eligibility criteria include whether a study accepts healthy volunteers , has age or age group requirements, or is limited by sex .

Enrollment 299

The number of participants in a clinical study. The "estimated" enrollment is the target number of participants that the researchers need for the study.

Exclusion criteria 300

A type of eligibility criteria . These are reasons that a person is not allowed to participate in a clinical study.

Expanded access 301

A way for patients with serious diseases or conditions who cannot participate in a clinical trial to gain access to a medical product that has not been approved by the U.S. Food and Drug Administration

(FDA) . Also called compassionate use. There are different expanded access types . For more information, see FDA Expanded Access: Information for Patients .

Expanded access status 302

Available: Expanded access is currently available for this investigational treatment, and patients who are not participants in the clinical study may be able to gain access to the drug, biologic, or medical device being studied. No longer available: Expanded access was available for this intervention previously but is not currently available and will not be available in the future. Temporarily not available: Expanded access is not currently available for this intervention but is expected to be available in the future. Approved for marketing: The intervention has been approved by the U.S. Food and Drug Administration for use by the public.

Expanded access type 303

Describes the category of expanded access under U.S. Food and Drug Administration (FDA) regulations. There are three types of expanded access: Individual Patients : Allows a single patient, with a serious disease or condition who cannot participate in a clinical trial, access to a drug or biological product that has not been approved by the FDA . This category also includes access in an emergency situation. Intermediate-size Population : Allows more than one patient (but generally fewer patients than through a Treatment IND/Protocol) access to a drug or biological product that has not been approved by the FDA . This type of expanded access is used when multiple patients with the same disease or condition seek access to a specific drug or biological product that has not been approved by the FDA . Treatment IND/Protocol : Allows a large, widespread population access to a drug or biological product that has not been approved by the FDA . This type of expanded access can only be provided if the product is already being developed for marketing for the same

use as the expanded access use.

Experimental arm 304

An arm type in which a group of participants receives the intervention/treatment that is the focus of the clinical trial.

Extension request 305

In certain circumstances, a sponsor or investigator may request an extension to delay the standard results submission deadline (generally one year after the primary completion date). The request for an extension must demonstrate good cause (for example, the need to preserve the scientific integrity of an ongoing masked trial). All requests must be reviewed and granted by the National Institutes of Health. This process for review and granting of extension requests is being developed. See Delay Results Type in the Results Data Element definitions for more information.

Factorial assignment 306

A type of intervention model describing a clinical trial in which groups of participants receive one of several combinations of interventions. For example, two-by-two factorial assignment involves four groups of participants. Each group receives one of the following pairs of interventions: (1) drug A and drug B, (2) drug A and a placebo, (3) a placebo and drug B, or (4) a placebo and a placebo. So during the trial, all possible combinations of the two drugs (A and B) and the placebos are given to different groups of participants.

FDAAA 801 Violations 307

Clinical Trials Information

A FDAAA 801 Violation is shown on a study record when the U.S. Food and Drug Administration (FDA) has issued a Notice of Noncompliance to the responsible party of an applicable clinical trial. A Notice of Noncompliance indicates that the FDA has determined the responsible party was not in compliance with the registration or results reporting requirements for the clinical trial under the Food and Drug Administration Amendments Act of 2007, Section 801 (FDAAA 801). The National Library of Medicine (NLM) is required by FDAAA 801 to add information to a study record about any FDAAA 801 Violation. This information is provided by the FDA. There are three categories of information that may be included: Violation: Shown when the FDA issues a Notice of Noncompliance and posts the Notice of Noncompliance on its designated webpage. There are three types of violations: Failure to submit required clinical trial information Submission of false or misleading clinical trial information Failure to submit primary and secondary outcomes Correction: Shown when the FDA confirms that the responsible party has updated the study record to correct the violation and posts the correction notice on its designated webpage. Because of the time for FDA review and processing, there may be a delay between the date when the study record was updated and the addition of correction information to the FDAAA 801 Violation information. Penalty: Shown when the FDA imposes a penalty for the violation and posts the penalty notice on its designated webpage.

First posted 308

The date on which the study record was first available on ClinicalTrials.gov after National Library of Medicine (NLM) quality control (QC) review has concluded. There is typically a delay of a few days between the date the study sponsor or investigator submitted the study record and the first posted date.

First submitted 309

The date on which the study sponsor or investigator first submitted a study record to ClinicalTrials.gov. There is typically a delay of a few days between the first submitted date and the record's availability on ClinicalTrials.gov (the first posted date).

First submitted that met QC criteria 310

The date on which the study sponsor or investigator first submits a study record that is consistent with National Library of Medicine (NLM) quality control (QC) review criteria. The sponsor or investigator may need to revise and submit a study record one or more times before NLM's QC review criteria are met. It is the responsibility of the sponsor or investigator to ensure that the study record is consistent with the NLM QC review criteria.

Food and Drug Administration Amendments Act of 2007, Section 801 (FDAAA 801) 311

U.S. Public Law 110-85, which was enacted on September 27, 2007. Section 801 of FDAAA amends Section 402 of the U.S. Public Health Service Act to expand ClinicalTrials.gov and create a clinical study results database . For more information on FDAAA 801, see the History, Policies, and Laws page on this site.

Funder type 312

Describes the organization that provides funding or support for a clinical study. This support may include activities related to funding, design, implementation, data analysis, or reporting. Organizations listed as sponsors and collaborators for a study are considered the funders of the study. ClinicalTrials.gov refers to four types of funders: U.S. National Institutes of Health Other U.S. Federal agencies (for example, Food and Drug Administration, Centers for Disease Control and Prevention, or U.S. Department of Veterans Affairs) Industry (for example: pharmaceutical and

device companies) All others (including individuals, universities, and community-based organizations)

Gender-based eligibility 313

A type of eligibility criteria that indicates whether eligibility to participate in a clinical study is based a person's self-representation of gender identity or gender (yes, no). Gender is distinct from sex .

Group/cohort 314

A group or subgroup of participants in an observational study that is assessed for biomedical or health outcomes.

Human subjects protection review board 315

A group of people who review, approve, and monitor the clinical study's protocol . Their role is to protect the rights and welfare of people participating in a study (referred to as human research subjects), such as reviewing the informed consent form . The group typically includes people with varying backgrounds, including a community member, to make sure that research activities conducted by an organization are completely and adequately reviewed. Also called an institutional review board, or IRB, or an ethics committee. For more information, see Participating in Studies on this site.

Inclusion criteria 316

A type of eligibility criteria . These are the reasons that a person is allowed to participate in a clinical study.

Informed consent 2 317

A process used by researchers to communicate to potential and enrolled participants the risks and potential benefits of participating in a clinical study. For more information, see Participating in Studies on this site.

Informed consent form (ICF) 318

The document used in the informed consent or process.

Intervention model 319

The general design of the strategy for assigning interventions to participants in a clinical study. Types of intervention models include: single group assignment , parallel assignment , cross-over assignment , and factorial assignment .

Intervention/treatment 320

A process or action that is the focus of a clinical study. Interventions include drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Interventions can also include noninvasive approaches, such as education or modifying diet and exercise.

Interventional study (clinical trial) 321

A type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the

study's protocol . Participants may receive diagnostic, therapeutic, or other types of interventions.

Investigator 322

A researcher involved in a clinical study. Related terms include site principal investigator, site sub-investigator, study chair, study director, and study principal investigator .

Last update posted 323

The most recent date on which changes to a study record were made available on ClinicalTrials.gov. There may be a delay between when the changes were submitted to ClinicalTrials.gov by the study's sponsor or investigator (the last update submitted date) and the last update posted date.

Last update submitted 324

The most recent date on which the study sponsor or investigator submitted changes to a study record to ClinicalTrials.gov. There is typically a delay of a few days between the last update submitted date and when the date changes are posted on ClinicalTrials.gov (the last update posted date).

Last update submitted that met QC criteria 325

The most recent date on which the study sponsor or investigator submitted changes to a study record that are consistent with National Library of Medicine (NLM) quality control (QC) review criteria. It is the responsibility of the sponsor or investigator to ensure that the study record is consistent with the NLM QC review criteria.

Last verified 326

The most recent date on which the study sponsor or investigator confirmed the information about a clinical study on ClinicalTrials.gov as accurate and current. If a study with a recruitment status of recruiting; not yet recruiting; or active, not recruiting has not been confirmed within the past 2 years, the study's recruitment status is shown as unknown .

Listed location countries 327

Countries in which research facilities for a study are located. A country is listed only once, even if there is more than one facility in the country. The list includes all countries as of the last update submitted date; any country for which all facilities were removed from the study record are listed under removed location countries .

Location terms 328

In the search feature, the Location terms field is used to narrow a search by location-related terms other than Country, State, and City or distance. For example, you may enter a specific facility name (such as National Institutes of Health Clinical Center) or a part of a facility name (such as Veteran for studies listing Veterans Hospital or Veteran Affairs in the facility name). Note: Not all study records include this level of detail about locations.

Masking 329

A clinical trial design strategy in which one or more parties involved in the trial, such as the investigator or participants, do not know which participants have been assigned which interventions. Types of masking include: open label, single blind masking, and double-blind masking.

NCT number 330

A unique identification code given to each clinical study record registered on ClinicalTrials.gov. The format is "NCT" followed by an 8-digit number (for example, NCT00000419). Also called the ClinicalTrials.gov identifier .

No intervention arm 331

An arm type in which a group of participants does not receive any intervention/treatment during the clinical trial.

Observational study 332

A type of clinical study in which participants are identified as belonging to study groups and are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to a specific interventions/treatment . A patient registry is a type of observational study.

Observational study model 333

The general design of the strategy for identifying and following up with participants during an observational study . Types of observational study models include cohort, case-control, case-only, case-cross-over, ecologic or community studies, family-based, and other.

Other adverse event 334

An adverse event that is not a serious adverse event , meaning that it does not result in death, is not life-threatening, does not require inpatient hospitalization or extend a current hospital stay, does not

result in an ongoing or significant incapacity or interfere substantially with normal life functions, and does not cause a congenital anomaly or birth defect; it also does not put the participant in danger and does not require medical or surgical intervention to prevent one of the results listed above.

Other study IDs 335

Identifiers or ID numbers other than the NCT number that are assigned to a clinical study by the study's sponsor, funders, or others. These numbers may include unique identifiers from other trial registries and National Institutes of Health grant numbers.

Other terms 336

In the search feature, the Other terms field is used to narrow a search. For example, you may enter the name of a drug or the NCT number of a clinical study to limit the search to study records that contain these words.

Outcome measure 337

For clinical trials , a planned measurement described in the protocol that is used to determine the effect of an intervention/treatment on participants. For observational studies , a measurement or observation that is used to describe patterns of diseases or traits, or associations with exposures, risk factors, or treatment. Types of outcome measures include primary outcome measure and secondary outcome measure .

Parallel assignment 338

A type of intervention model describing a clinical trial in which two or more groups of participants

receive different interventions. For example, a two-arm parallel assignment involves two groups of participants. One group receives drug A, and the other group receives drug B. So during the trial, participants in one group receive drug A "in parallel" to participants in the other group, who receive drug B.

Participant flow 339

A summary of the progress of participants through each stage of a clinical study, by study arm or group/cohort . This includes the number of participants who started, completed, and dropped out of the study.

Patient registry 340

A type of observational study that collects information about patients' medical conditions and/or treatments to better understand how a condition or treatment affects patients in the real world.

Phase 341

The stage of a clinical trial studying a drug or biological product, based on definitions developed by the U.S. Food and Drug Administration (FDA) . The phase is based on the study's objective, the number of participants, and other characteristics. There are five phases: Early Phase 1 (formerly listed as Phase 0) , Phase 1 , Phase 2 , Phase 3 , and Phase 4 . Not Applicable is used to describe trials without FDA-defined phases, including trials of devices or behavioral interventions.

Phase 1 342

A phase of research to describe clinical trials that focus on the safety of a drug. They are usually

conducted with healthy volunteers, and the goal is to determine the drug's most frequent and serious adverse events and, often, how the drug is broken down and excreted by the body. These trials usually involve a small number of participants.

Phase 2 343

A phase of research to describe clinical trials that gather preliminary data on whether a drug works in people who have a certain condition/disease (that is, the drug's effectiveness). For example, participants receiving the drug may be compared to similar participants receiving a different treatment, usually an inactive substance (called a placebo) or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.

Phase 3 344

A phase of research to describe clinical trials that gather more information about a drug's safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs. These studies typically involve more participants.

Phase 4 345

A phase of research to describe clinical trials occurring after FDA has approved a drug for marketing. They include postmarket requirement and commitment studies that are required of or agreed to by the study sponsor. These trials gather additional information about a drug's safety, efficacy, or optimal use.

Phase Not Applicable 346

Describes trials without FDA-defined phases , including trials of devices or behavioral interventions.

Placebo 347

An inactive substance or treatment that looks the same as, and is given in the same way as, an active drug or intervention/treatment being studied.

Placebo comparator arm 348

An arm type in which a group of participants receives a placebo during a clinical trial.

Primary completion date 349

The date on which the last participant in a clinical study was examined or received an intervention to collect final data for the primary outcome measure . Whether the clinical study ended according to the protocol or was terminated does not affect this date. For clinical studies with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all the primary outcome measures. The "estimated" primary completion date is the date that the researchers think will be the primary completion date for the study.

Primary outcome measure 350

In a clinical study's protocol , the planned outcome measure that is the most important for evaluating the effect of an intervention/treatment . Most clinical studies have one primary outcome measure, but some have more than one.

Primary purpose 351

The main reason for the clinical trial . The types of primary purpose are: treatment, prevention, diagnostic, supportive care, screening, health services research, basic science, and other.

Principal investigator (PI) 352

The person who is responsible for the scientific and technical direction of the entire clinical study.

Protocol 353

The written description of a clinical study. It includes the study's objectives, design, and methods. It may also include relevant scientific background and statistical information.

Quality control (QC) review 354

National Library of Medicine (NLM) staff perform a limited review of submitted study records for apparent errors, deficiencies, or inconsistencies. NLM staff identify potential major and advisory issues and provide comments directly to the study sponsor or investigator. Major issues identified in QC review must be addressed or corrected (see First submitted that met QC criteria and Results first submitted that met QC criteria). Advisory issues are suggestions to help improve the clarity of the record. NLM staff do not verify the scientific validity or relevance of the submitted information. The study sponsor or investigator is responsible for ensuring that the studies follow all applicable laws and regulations.

Randomized allocation 355

A type of allocation strategy in which participants are assigned to the arms of a clinical trial by chance.

Recruitment status 356

Not yet recruiting: The study has not started recruiting participants. Recruiting: The study is currently recruiting participants. Enrolling by invitation: The study is selecting its participants from a population, or group of people, decided on by the researchers in advance. These studies are not open to everyone who meets the eligibility criteria but only to people in that particular population, who are specifically invited to participate. Active, not recruiting: The study is ongoing, and participants are receiving an intervention or being examined, but potential participants are not currently being recruited or enrolled. Suspended: The study has stopped early but may start again. Terminated: The study has stopped early and will not start again. Participants are no longer being examined or treated. Completed: The study has ended normally, and participants are no longer being examined or treated (that is, the last participant's last visit has occurred). Withdrawn: The study stopped early, before enrolling its first participant. Unknown: A study on ClinicalTrials.gov whose last known status was recruiting; not yet recruiting; or active, not recruiting but that has passed its completion date, and the status has not been last verified within the past 2 years.

Registration 357

The process of submitting and updating summary information about a clinical study and its protocol , from its beginning to end, to a structured, public Web-based study registry that is accessible to the public, such as ClinicalTrials.gov.

Removed location countries 358

Countries that appeared under listed location countries but were removed from the study record by the sponsor or investigator.

Reporting group 359

A grouping of participants in a clinical study that is used for summarizing the data collected during the study. This grouping may be the same as or different from a study arm or group.

Responsible party 360

The person responsible for submitting information about a clinical study to ClinicalTrials.gov and updating that information. Usually the study sponsor or investigator.

Results database 361

A structured online system, such as the ClinicalTrials.gov results database, that provides the public with access to registration and summary results information for completed or terminated clinical studies. A study with results available on ClinicalTrials.gov is described as having the results "posted." Note: The ClinicalTrials.gov results database became available in September 2008. Older studies are unlikely to have results available in the database.

Results delayed 362

Indicates that the sponsor or investigator submitted a certification or extension request .

Results first posted 363

The date on which summary results information was first available on ClinicalTrials.gov after National Library of Medicine (NLM) quality control (QC) review has concluded. There is typically a delay between the date the study sponsor or investigator first submits summary results information (the results first submitted date) and the results first posted date. Some results information may be

available at an earlier date if Results First Posted with QC Comments .

Results first posted with QC comments 364

The date on which summary results information was first available on ClinicalTrials.gov with quality control review comments from the National Library of Medicine (NLM) identifying major issues that must be addressed by the sponsor or investigator. As of January 1, 2020, initial results submissions for applicable clinical trials (ACTs) that do not meet quality control review criteria will be publicly posted on ClinicalTrials.gov with brief standardized major comments. Accordingly, the Results First Posted with QC Comments date may be earlier than the Results First Posted date for an ACT with summary results information that is not consistent with NLM quality control review criteria.

Results first submitted 365

The date on which the study sponsor or investigator first submits a study record with summary results information. There is typically a delay between the results first submitted date and when summary results information becomes available on ClinicalTrials.gov (the results first posted date).

Results first submitted that met QC criteria 366

The date on which the study sponsor or investigator first submits a study record with summary results information that is consistent with National Library of Medicine (NLM) quality control (QC) review criteria. The sponsor or investigator may need to revise and submit results information one or more times before NLM's QC review criteria are met. It is the responsibility of the sponsor or investigator to ensure that the study record is consistent with the NLM QC review criteria.

Results returned after quality control review 367

The date on which the National Library of Medicine provided quality control (QC) review comments to the study sponsor or investigator. The sponsor or investigator must address major issues identified in the review comments. If there is a date listed for results returned after quality control review, but there is not a subsequent date listed for results submitted to ClinicalTrials.gov , this means that the submission is pending changes by the sponsor or investigator.

Results submitted to ClinicalTrials.gov 368

Indicates that the study sponsor or investigator has submitted summary results information for a clinical study to ClinicalTrials.gov but the quality control (QC) review process has not concluded. The results submitted date indicates when the study sponsor or investigator first submitted summary results information or submitted changes to summary results information. Submissions with changes are typically in response to QC review comments from the National Library of Medicine (NLM). If there is a date listed for results submitted to ClinicalTrials.gov, but there is not a subsequent date listed for results returned after quality control review , this means that the submission is pending review by NLM.

Secondary outcome measure 369

In a clinical study's protocol , a planned outcome measure that is not as important as the primary outcome measure for evaluating the effect of an intervention but is still of interest. Most clinical studies have more than one secondary outcome measure.

Serious adverse event 370

An adverse event that results in death, is life-threatening, requires inpatient hospitalization or extends a current hospital stay, results in an ongoing or significant incapacity or interferes

substantially with normal life functions, or causes a congenital anomaly or birth defect. Medical events that do not result in death, are not life-threatening, or do not require hospitalization may be considered serious adverse events if they put the participant in danger or require medical or surgical intervention to prevent one of the results listed above.

Sex 371

A type of eligibility criteria that indicates the sex of people who may participate in a clinical study (all, female, male). Sex is a person's classification as female or male based on biological distinctions. Sex is distinct from gender-based eligibility .

Sham comparator arm 372

An arm type in which a group of participants receives a procedure or device that appears to be the same as the actual procedure or device being studied but does not contain active processes or components.

Single group assignment 373

A type of intervention model describing a clinical trial in which all participants receive the same intervention/treatment.

Sort studies by 374

In Advanced Search, the Sort studies by option is used to change the order of studies listed on the Search Results page. You can sort by Relevance or Newest First: Relevance: Studies that best match your search terms appear higher in the search results list. This is the default display for all

searches. Newest First: Studies with the most recent First posted dates appear higher in the search results list.

Sponsor 375

The organization or person who initiates the study and who has authority and control over the study.

State 376

In the search feature, the State field is used to find clinical studies with locations in a specific state within the United States. If you choose United States in the Country field, you can search for studies with locations in a specific state.

Statistical analysis plan (SAP) 377

The written description of the statistical considerations and methods for analyzing the data collected in the clinical study .

Status 378

Indicates the current recruitment status or the expanded access status .

Study completion date 379

The date on which the last participant in a clinical study was examined or received an intervention/treatment to collect final data for the primary outcome measures , secondary outcome measures , and adverse events (that is, the last participant's last visit). The "estimated" study completion date is the date that the researchers think will be the study completion date.

Study design 380

The investigative methods and strategies used in the clinical study.

Study documents 381

Refers to the type of documents that the study sponsor or principal investigator may add to their study record . These include a study protocol , statistical analysis plan , and informed consent form .

Study IDs 382

Identifiers that are assigned to a clinical study by the study's sponsor , funders, or others. They include unique identifiers from other trial study registries and National Institutes of Health grant numbers. Note: ClinicalTrials.gov assigns a unique identification code to each clinical study registered on ClinicalTrials.gov. Also called the NCT number , the format is "NCT" followed by an 8-digit number (for example, NCT00000419).

Study record 383

An entry on ClinicalTrials.gov that contains a summary of a clinical study's protocol information, including the recruitment status ; eligibility criteria; contact information; and, in some cases, summary results. Each study record is assigned a ClinicalTrials.gov identifier, or NCT number .

Study registry 384

A structured online system, such as ClinicalTrials.gov, that provides the public with access to summary information about ongoing and completed clinical studies.

Study results 385

A study record that includes the summary results posted in the ClinicalTrials.gov results database . Summary results information includes participant flow , baseline characteristics , outcome measures , and adverse events (including serious adverse events).

Study start date 386

The actual date on which the first participant was enrolled in a clinical study. The "estimated" study start date is the date that the researchers think will be the study start date.

Study type 387

Describes the nature of a clinical study . Study types include interventional studies (also called clinical trials), observational studies (including patient registries), and expanded access .

Submitted date 388

The date on which the study sponsor or investigator submitted a study record that is consistent with National Library of Medicine (NLM) quality control (QC) review criteria.

Title 389

The official title of a protocol used to identify a clinical study or a short title written in language intended for the lay public.

Title acronym 390

The acronym or initials used to identify a clinical study (not all studies have one). For example, the title acronym for the Women's Health Initiative is "WHI."

U.S. Agency for Healthcare Research and Quality (AHRQ) 391

An agency within the U.S. Department of Health and Human Services. AHRQ's mission is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used.

U.S. Food and Drug Administration (FDA) 392

An agency within the U.S. Department of Health and Human Services. The FDA is responsible for protecting the public health by making sure that human and veterinary drugs, vaccines and other biological products, medical devices, the Nation's food supply, cosmetics, dietary supplements, and products that give off radiation are safe, effective, and secure.

Unknown 393

A type of recruitment status . It identifies a study on ClinicalTrials.gov whose last known status was recruiting; not yet recruiting; or active, not recruiting but that has passed its completion date, and the status has not been verified within the past 2 years. Studies with an unknown status are considered closed studies.

Diversity and Inclusion in Clinical Trials 394

Our health is a combination of physical and mental well-being, which is affected by our behavior,

biology, environment, societal policies, and importantly, our lived experiences. The lived experiences of people in the United States vary based on their race and ethnicity, socioeconomic status (SES), geographic location, sexual orientation, gender identity, and other sociodemographic characteristics.

Lived experiences also need to be understood in the context of the individual and structural social determinants of health.

How and where we live, learn, work and play, and our access to high quality health care, healthy foods, and quality education can enhance our health outcomes.

Similarly, negative experiences and exposures, such as pollution, violence, and structural racism and discrimination, can negatively affect our health.

Our health status reflects the interwoven effects of such factors.

A clinical trial is a type of clinical research that evaluates the effects of intervention(s), including drugs, devices, surgeries, diets, behavioral approaches, and lifestyle interventions, on health-related biomedical or behavioral outcomes.

To account for the diverse lived experiences and exposures of various populations, clinical research should be appropriately inclusive of racial and ethnic minority groups, as well as other populations experiencing health disparities, including sexual and gender minority or socioeconomically disadvantaged populations.

Clinical Trials Information

Why Are Clinical Trials Important? 395

Clinical trials can:

Determine if a new intervention is safe, works better, and/or has fewer side effects than an existing treatment or intervention.

Examine ways to detect a disease early, when it is potentially more treatable, or ways to prevent a health problem altogether.

Evaluate ways to improve the quality of life of people who have an illness or chronic medical condition.

Include testing of behavioral, social, environmental, and structural interventions.

Participating in clinical trials is voluntary. People volunteer to participate in clinical trials for a variety of reasons.

One of the most common reasons is altruism?the opportunity to contribute to science and the common good and/or help those with similar health issues.

People may volunteer when it allows them to receive an experimental intervention for life-threatening or disabling disease where no standard treatments are available or were already tried without success.

New interventions (e.g., weight loss or tobacco cessation interventions) that haven?t yet been approved by the U.S. Food and Drug Administration (FDA) may be tested for common conditions to understand if the intervention might help a condition in situations where current treatments or interventions don?t exist, don?t work well, or have unwanted side effects, or provide symptomatic relief, but offer no cure

The Importance of Diversity & Inclusion in Clinical Trials 396

Clinical Trials Information

People may experience the same disease differently. It?s essential that clinical trials include people with a variety of lived experiences and living conditions, as well as characteristics like race and ethnicity, age, sex, and sexual orientation, so that all communities can benefit from scientific advances.

Factors that can influence the risk and likelihood of developing a disease, experiencing a long-term health outcome, and responding to treatment include (but are not limited to):

Age

Biological sex

Pregnancy status

Life experiences (negatives, such as psychosocial stress and lack of basic resources, or positives, such as educational and employment opportunities)

Unhealthy behaviors (e.g., substance use, sedentary lifestyle, overeating, risky sexual activity)

Health-promoting behaviors (e.g., adequate sleep, obtaining recommended preventive services, physical activity, healthy eating)

Environmental conditions (e.g., pollution, access to health care or healthy foods, neighborhood segregation)

Genetic variation and geographic ancestry

Underlying medical problems or presence of comorbidities (i.e., additional diseases or conditions)

Historically, clinical trials did not always recruit participants who represented the individuals most affected by a particular disease, condition, or behavior. Often, these clinical trials relied almost exclusively on White male study participants. This shortcoming has created gaps in our understanding of diseases and conditions, preventive factors, and treatment effectiveness across populations. These gaps in knowledge can impede the quality of health care decision making, ability

to counsel people on ways to reduce their risk, optimal treatment responses, and even the development of more effective medications or interventions.

Clinicians and researchers should carefully consider the inclusion or exclusion criteria for their clinical trials. For example, a clinical trial excluding participants with high blood pressure or other comorbidities may end up excluding many people over 65 years old, who are more likely to have these conditions. The trial may then underrepresent certain groups in the study and make the results less applicable to groups who may benefit the most from the findings.

Real-World Examples of the Need for Inclusion in Clinical Trials 397

During the early stages of the pandemic, Coronavirus disease 2019 (COVID-19) disproportionately affected racial and ethnic minority populations, including African American, Hispanic/Latino, American Indian/Alaska Native, and Native Hawaiian and Pacific Islander population groups, with increased cases, hospitalizations and deaths.

It was critical that COVID-19 vaccine trials included sufficient representation across population groups to better understand vaccine effectiveness in populations who vary on environmental exposures and other lived experiences. By using inclusive recruitment practices in COVID-19 clinical trials, researchers have been able to show that vaccine safety and efficacy are similar across all racial and ethnic populations. Engaging diverse populations in planning and implementing such trials can also help increase public confidence that the vaccine is safe and effective. Asthma disparities are intricately linked with the environment. Living in a city may increase exposure to air pollution and risk for developing asthma. Exposure to tobacco smoke, chronic social stress, or unhealthy diets may also influence asthma risk or severity. Thus, it is vital for clinicians and researchers to consider where patients live, what they eat, and how they feel?as well as

characteristics like race, ethnicity, socioeconomic status, and age?to get a more thorough understanding of their patients? experience with asthma symptoms and identify the best preventative strategies or treatment option

What Are Clinical Trials and Studies? 398

By participating in clinical research, you can help scientists develop new medications and other strategies to treat and prevent disease. Many effective treatments that are used today, such as chemotherapy, cholesterol-lowering drugs, vaccines, and cognitive-behavioral therapy, would not exist without research participants. Whether you?re healthy or have a medical condition, people of all ages and backgrounds can participate in clinical trials. This article can help you learn more about clinical research, why people choose to participate, and how to get involved in a study.

Mr. Jackson's story 399

Mr. Jackson is 73 years old and was just diagnosed with Alzheimer?s disease. He is worried about how it will affect his daily life. Will he forget to take his medicine? Will he forget his favorite memories, like the births of his children or hiking the Appalachian Trail? When Mr. Jackson talked to his doctor about his concerns, she told him about a clinical trial that is testing a possible new Alzheimer?s treatment. But Mr. Jackson has concerns about clinical trials. He does not want to feel like a lab rat or take the chance of getting a treatment that may not work or could make him feel worse. The doctor explained that there are both risks and benefits to being part of a clinical trial, and she talked with Mr. Jackson about research studies ? what they are, how they work, and why they need volunteers. This information helped Mr. Jackson feel better about clinical trials. He plans to learn more about how to participate.

Clinical Trials Information

What is clinical research? 400

Clinical research is the study of health and illness in people. There are two main types of clinical research: observational studies and clinical trials.

Observational studies monitor people in normal settings. Researchers gather information from people and compare changes over time. For example, researchers may ask a group of older adults about their exercise habits and provide monthly memory tests for a year to learn how physical activity is associated with cognitive health. Observational studies do not test a medical intervention, such as a drug or device, but may help identify new treatments or prevention strategies to test in clinical trials.

Clinical trials are research studies that test a medical, surgical, or behavioral intervention in people. These trials are the primary way that researchers determine if a new form of treatment or prevention, such as a new drug, diet, or medical device (for example, a pacemaker), is safe and effective in people. Often, a clinical trial is designed to learn if a new treatment is more effective or has less harmful side effects than existing treatments.

Other aims of clinical research include:

Testing ways to diagnose a disease early, sometimes before there are symptoms
Finding approaches to prevent a health problem, including in people who are healthy but at increased risk of developing a disease
Improving quality of life for people living with a life-threatening disease or chronic health problem
Studying the role of caregivers or support groups
Learn more about clinical research from MedlinePlus and ClinicalTrials.gov.

Clinical Trials Information

Why participate in a clinical trial? 401

People volunteer for clinical trials and studies for a variety of reasons, including:

They want to contribute to discovering health information that may help others in the future.

Participating in research helps them feel like they are playing a more active role in their health.

The treatments they have tried for their health problem did not work or there is no treatment for their health problem.

Whatever the motivation, when you choose to participate in a clinical trial, you become a partner in scientific discovery. Participating in research can help future generations lead healthier lives. Major medical breakthroughs could not happen without the generosity of clinical trial participants ? young and old, healthy, or diagnosed with a disease.

Where can I find a clinical trial? 402

Looking for clinical trials related to aging and age-related health conditions? Talk to your health care provider and use online resources to:

Search for a clinical trial

Look for clinical trials on Alzheimer's, other dementias, and caregiving

Find a registry for a particular diagnosis or condition

Explore clinical trials and studies supported by NIA

After you find one or more studies that you are interested in, the next step is for you or your doctor to contact the study research staff and ask questions. You can usually find contact information in the description of the study.

Clinical Trials Information

Let your health care provider know if you are thinking about joining a clinical trial. Your provider may want to talk to the research team to make sure the study is safe for you and to help coordinate your care.

What happens in a clinical trial or study? 403

Here?s what typically happens in a clinical trial or study:

Research staff explain the trial or study in detail, answer your questions, and gather more information about you.

Once you agree to participate, you sign an informed consent form indicating your understanding about what to expect as a participant and the various outcomes that could occur.

You are screened to make sure you qualify for the trial or study.

If accepted into the trial, you schedule a first visit, which is called the ?baseline? visit. The researchers conduct cognitive and/or physical tests during this visit.

For some trials testing an intervention, you are assigned by chance (randomly) to a treatment group or a control group . The treatment group will get the intervention being tested, and the control group will not.

You follow the trial procedures and report any issues or concerns to researchers.

You may visit the research site at regularly scheduled times for new cognitive, physical, or other evaluations and discussions with staff. During these visits, the research team collects data and monitors your safety and well-being.

You continue to see your regular physician(s) for usual health care throughout the study.

How do researchers decide which interventions are safe to test in people? 404

Clinical Trials Information

Before a clinical trial is designed and launched, scientists perform laboratory tests and often conduct studies in animals to test a potential intervention?s safety and effectiveness. If these studies show favorable results, the U.S. Food and Drug Administration (FDA) approves the intervention to be tested in humans. Learn more about how the safety of clinical trial participants is protected.

What happens when a clinical trial or study ends? 405

Once a clinical trial or study ends, the researchers analyze the data to determine what the findings mean and to plan the next steps. As a participant, you should be provided information before the study starts about how long it will last, whether you will continue receiving the treatment after the trial ends (if applicable), and how the results of the research will be shared. If you have specific questions about what will happen when the trial or study ends, ask the research coordinator or staff.

What are the different phases of clinical trials? 406

Clinical trials of drugs and medical devices advance through several phases to test safety, determine effectiveness, and identify any side effects. The FDA typically requires Phase 1, 2, and 3 trials to be conducted to determine if the drug or device can be approved for further use. If researchers find the intervention to be safe and effective after the first three phases, the FDA approves it for clinical use and continues to monitor its effects.

Each phase has a different purpose:

A Phase 1 trial tests an experimental drug or device on a small group of people (around 20 to 80) to judge its safety, including any side effects, and to test the amount (dosage).

A Phase 2 trial includes more people (around 100 to 300) to help determine whether a drug is

effective. This phase aims to obtain preliminary data on whether the drug or device works in people who have a certain disease or condition. These trials also continue to examine safety, including short-term side effects.

A Phase 3 trial gathers additional information from several hundred to a few thousand people about safety and effectiveness, studying different populations and different dosages, and comparing the intervention with other drugs or treatment approaches. If the FDA agrees that the trial results support the intervention?s use for a particular health condition, it will approve the experimental drug or device.

A Phase 4 trial takes place after the FDA approves the drug or device. The treatment?s effectiveness and safety are monitored in large, diverse populations. Sometimes, side effects may not become clear until more people have used the drug or device over a longer period of time.

Clinical trials that test a behavior change, rather than a drug or medical device, advance through similar steps, but behavioral interventions are not regulated by the FDA. Learn more about clinical trials, including the types of trials and the four phases.

Questions to ask before participating in clinical research 407

Choosing to participate in research is an important personal decision. If you are considering joining a trial or study, get answers to your questions and know your options before you decide. Here are questions you might ask the research team when thinking about participating.

About the study

What is this study trying to find out?

What treatment or tests will I have? Will they hurt? Will you provide me with the test or lab results?

What are the chances I will be in the experimental group or the control group?

If the study tests a treatment, what are the possible risks, side effects, and benefits compared with

my current treatment?

How long will the clinical trial last?

Where will the study take place? Will I need to stay in the hospital?

Will you provide a way for me to get to the study site if I need it, such as through a ride-share service?

Will I need a trial or study partner (for example, a family member or friend who knows me well) to come with me to the research site visits? If so, how long will he or she need to participate?

Can I participate in any part of the trial with my regular doctor or at a clinic closer to my home?

How will the study affect my everyday life?

What steps are being taken to ensure my privacy?

Medical care

How will you protect my health while I participate?

What happens if my health problem gets worse during the trial or study?

Can I take my regular medicines while participating?

Who will be in charge of my care while I am in the trial or study? Will I be able to see my own doctors?

How will you keep my doctor informed about my participation?

If I withdraw from the trial or study, will this affect my normal care?

Costs and reimbursement

Will it cost me anything to be in the trial or study? If so, will I be reimbursed for expenses, such as travel, parking, lodging, or meals?

Will my insurance pay for costs not covered by the research, or must I pay out of pocket? If I don?t have insurance, am I still eligible to participate?

Will my trial or study partner be compensated for his or her time?

After the study ends

Will you follow up on my health after the end of the trial or study?

Will I continue receiving the treatment after the trial or study ends?

Will you tell me the results of the research?

Whom do I contact if I have questions after the trial or study ends?

How do researchers decide who will participate? 408

Clinical trials often test how a medical intervention affects people with a certain disease, family history, or lifestyle. Because of this focus, not everyone meets the criteria to participate in every trial. After you consent to participate, the research staff will ask questions and perform tests to see if you are eligible for the trial. The screening may involve blood and other laboratory tests, thinking and memory tests, and a physical examination. To be eligible to participate, you may need to have certain characteristics, called inclusion criteria. For example, a clinical trial may need participants to have a certain stage of disease, version of a gene, or family history. Some trials require that participants have a study partner who can accompany them to clinic visits.

Participants with certain characteristics may not be allowed to participate in some trials. These characteristics are called exclusion criteria. They include factors such as specific health conditions or medications that could interfere with the treatment being tested.

Many volunteers must be screened to find enough people who are eligible for a trial or study. Generally, you can participate in only one clinical trial at a time, although this is not necessarily the case for observational studies. Different trials have different criteria, so being excluded from one trial does not necessarily mean you will be excluded from another.

Clinical research needs participants with diverse backgrounds 409

Clinical Trials Information

When research only includes people with similar backgrounds, the findings may not apply to or benefit a broader population. The results of clinical trials and studies with diverse participants may apply to more people. That?s why research benefits from having participants of different ages, sexes, races, and ethnicities.Older Asian couple

Researchers need older adults to participate in clinical research so that scientists can learn more about how new drugs, tests, and other interventions will work for them. Many older adults have health needs that are different from those of younger people. For example, as people age, their bodies may react differently to certain drugs. Older adults may need different dosages of a drug to have the intended result. Also, some drugs may have different side effects in older people than in younger individuals. Having older adults enrolled in clinical trials and studies helps researchers get the information they need to develop the right treatments for this age group.

Researchers know that it may be challenging for some older adults to join a clinical trial or study. For example, if you have multiple health problems, can you participate in research that is looking at only one condition? If you are frail or have a disability, will you be strong enough to participate? If you no longer drive, how can you get to the research site? Talk to the research coordinator or staff about your concerns. The research team may have already thought about some of the potential obstacles and have a plan to make it easier for you to participate.