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MRCT CENTER
THE MULTI-REGIONAL
CLINICAL TRIALS CENTER OF
BRIGHAM AND WOMEN'S HOSPITAL
AND HARVARD

Clinical Research GLOSSARY

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Clinical Research Glossary

Helping you understand clinical research

This is the PDF version of the online Clinical Research Glossary. Access the online version here: https://mrctcenter.org/clinical-research-glossary/

The Clinical Research Glossary offers easy to understand clinical research definitions.

We want everyone to have clear information when deciding whether to join a research study, and throughout their participation.

All definitions are developed by the MRCT Center and a committed team of patient advocates and other professionals in medicine and research. Before definitions are released, they are reviewed by members of the public. The resulting definitions are what you find here on this site.

The Clinical Research Glossary is also a CDISC global standard for clear communication. This means that more and more groups are learning about and using this resource.

The Clinical Research Glossary started as a pilot project in 2020 and it keeps growing!

We're so glad you found us. We hope that the information helps you navigate your own clinical research journey.

Who Created this Glossary?

The MRCT Center is a research and policy center in Boston, Massachusetts with a team dedicated to developing health literacy resources to make research easier to understand.

We work with many different people and groups from the patient advocacy community and research industry, so all kinds of voices and perspectives are included in the work we do.

This glossary is the only one we know of that is:

- focused on clinical research,
- publicly available,
- developed with patients and participants, and
- reviewed by the community

Contact the MRCT Center Clinical Research Glossary Team

https://mrctcenter.org/glossary/contact-us/

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AND HARVARD

Clinical Research Glossary

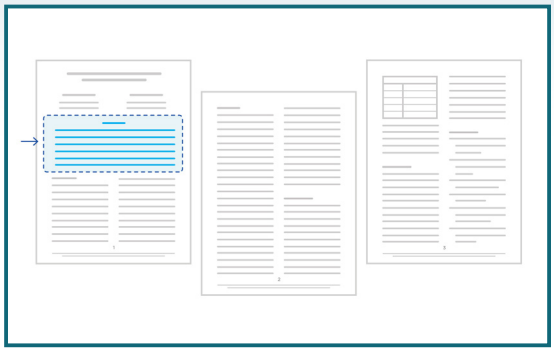
Terms of Use

Clinical Research Glossary

abstract (research)

cdisc

A short summary of an academic article or report.



Example of *abstract (research)* in a sentence

A journal article will often have an abstract at the beginning.

More Info

An abstract of a scientific journal article provides a short summary of the article and its main findings.

Reading an abstract can help someone decide whether they want to read the whole article.

Many other documents also begin with an abstract, including a protocol, results summary, scientific article, or study report.

Related Words

plain language summary (PLS)

Other info to think about when joining a study

You may see an abstract at the very beginning of a technical scientific document.

Articles about research studies usually start with an abstract. If you are looking for an article online, you may be able to read the abstract but not access the longer full text.

If you are trying to access an article about a study you participated in, your research team should be able to provide the text.

Other Resources

NCI Thesaurus

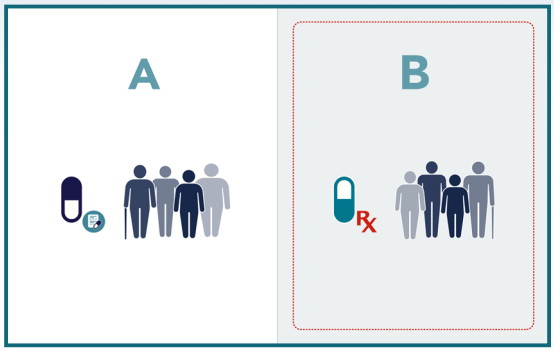
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

active comparator group (active control group)

cdisc

A group of study participants who receive the standard medicine or treatment for a disease or condition, and are compared to the group that receives the study treatment.



Example of *active comparator group (active control group)* in a sentence

An active comparator group is used when there is already an approved treatment for a disease or condition which could be used in the study instead of a placebo.

More Info

An active comparator is used in a research study when there are available treatments for a condition or disease. It is used instead of a placebo to compare the new treatment to the standard medicine or treatment. In the context of clinical research, a "standard medicine or treatment" is something that medical professionals agree is an acceptable way to treat a condition or disease.

Related Words

active comparator arm

active comparator group

Other info to think about when joining a study

You may see the term "active comparator" when you are looking through materials about a research study you are thinking of joining. Some research studies may even include "active comparator" in its title, letting people know what the new study treatment is being compared to.

You should feel free to ask the study team any questions you have about any product you may be given during the research study.

Other Resources

NCI Thesaurus

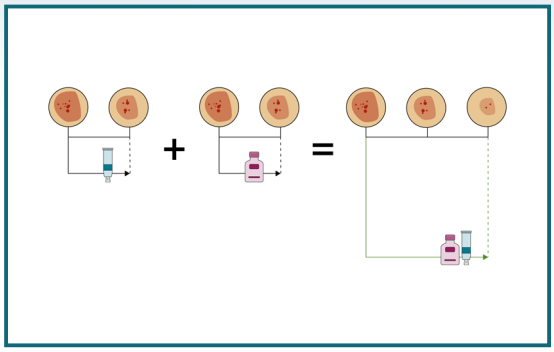
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

additive effect

cdisc

The combined effect when two or more things are used together.



Example of *additive effect* in a sentence

The additive effect of a combination drug is the sum of the effects of each drug acting alone.

More Info

For example, two vaccines may be combined into one shot because they do not interfere with each other and will still each have the same effect as if they were given as two separate shots.

So an additive effect means that 1+1 = 2

Related Words

synergistic effect

Other info to think about when joining a study

You may hear the words "additive effect" being used if you are part of a study that is studying two or more treatments being taken together.

You may want to find out more about why the two treatments are being given together and what the hoped effect could be.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

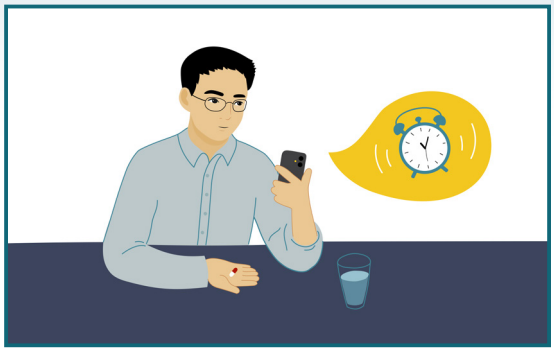
adherence

cdisc

Following the study directions and requirements.

Example of *adherence* in a sentence

Adherence to the study instructions is important so reliable information about the study treatment can be collected.



More Info

Adherence to the study protocol helps ensure the data from all study participants can be evaluated appropriately.

Reliable research results depend on both researchers and participants carefully following the protocol and study instructions.

The words 'adherence' and 'compliance' are often used in the same way.

Related Words

compliance

following

Other info to think about when joining a study

During study visits, someone from the study team may ask about your adherence to the study directions. That could mean following the exact directions for taking the investigational medicine or writing journal entries at specific time points.

When you are reading through the consent form you may see that it says you could be removed from the study by the investigator if you are unable to follow the study procedures.

You may wish to ask what you should do if you were unable to follow the study directions on a particular day. For example, if you forgot to take the study treatment at the right time.

If you have a hard time following the study procedures, let the study team know so they can help you.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

adverse event

cdisc

Any health problem that happens during a study.

Example of *adverse event* in a sentence

The study team needs to know about all adverse events that happen during the study.

More Info

Researchers track adverse events for safety reasons. They also want to find out whether any issues could be related to the study treatment.

Participants should tell the study team about any health problem that happens while they are in a study. Any event such as a fever, headache, cold, a mood change, or falling, should be reported.

Related Words

adverse reaction

side effect

Other info to think about when joining a study

You may see references to "adverse event" during the consent process when discussing procedures since many studies include specific time points to ask participants if they have experienced any health problems.

You may also see references to "adverse event" when discussing the risks of the study. Depending on the type of study you join, the risks you learn about are based on information participants in previous studies reported. It is important that you tell the study team about
any health problem that happens during the study, even if you don't think it's related to the research.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

adverse reaction

cdisc

A health problem that happens during a study and is reported as possibly caused by the study treatment.

Example of *adverse reaction* in a sentence

Adverse reactions are important to track so that the effects of the study treatment are known.

More Info

Adverse reactions are health problems that are related to the study treatment. A rash that develops only after taking a drug is an adverse reaction.

Related Words

adverse event

adverse drug reaction

side effect

Other info to think about when joining a study

While participating in a study, the study team may discuss adverse reactions with you. Adverse reactions are health issues that have been found to be related to the study treatment. It is important for you to report any health problem or issue that happens while you are in a study, even if you don't think it's related.

Other Resources

NCI Thesaurus

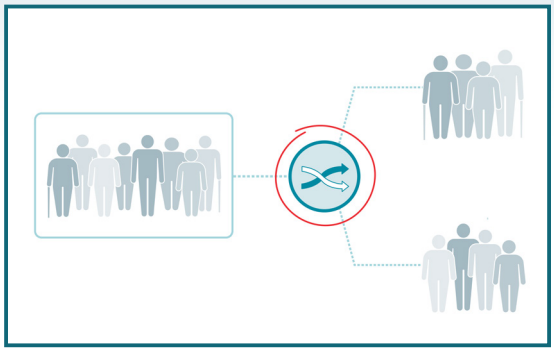
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

allocation (research)

cdisc

A way to assign participants to study treatment or control groups.



Example of *allocation (research)* in a sentence

A study's allocation method will be described in the protocol.

More Info

Allocation refers to the process of putting participants into different study groups.

Randomization is a form of allocation that supports balance between study groups.

Related Words

allotment

study arm

randomization

Other info to think about when joining a study

When you are thinking about joining a study, you may read or hear things about "participant allocation." If you have questions about what group you could be put into or what each group will be asked to do during the research, you should feel free to ask the study team before you give informed consent.

Other Resources

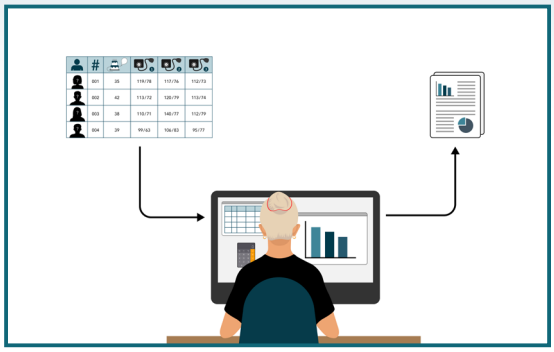
NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

analyze

To examine study data to answer a question and help reach conclusions.



Example of *analyze* in a sentence

Researchers analyze data to find out the results of a study.

More Info

In a research study, data are collected and then analyzed to answer the study questions.

A study statistician helps analyze the data. When they analyze the data, they interpret the information and try to come to conclusions about what the study results mean.

Related Words

evaluate
interpret
investigate
data analysis

Other info to think about when joining a study

You may often hear the term "analyze" used by the study team in the context of data. Someone on the research team will need to analyze the data collected in the research study.

You may want to ask how the data will be analyzed and what the researchers want to learn from the study.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

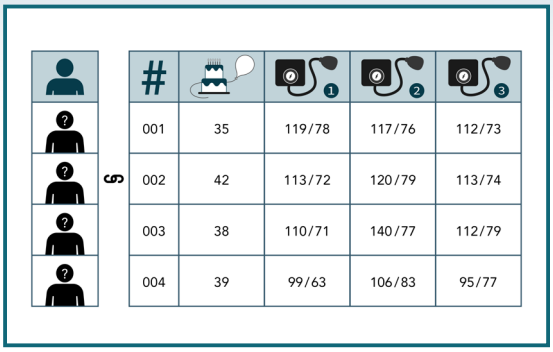
anonymize

cdisc

Remove, change, or hide personal details to protect participant privacy.

Example of *anonymize* in a sentence

When researchers anonymize data they remove all personal identifiers, so that the participant cannot be linked back to that data by anyone.



More Info

When data are anonymized, details such as name, birthdate, and address are removed so that any personal information is no longer available to anyone.

Related Words

unlink

mask

Other info to think about when joining a study

You may hear the term "anonymize" when the study team talks about the data they collect from you during the study and how that data will be protected. There are different ways to protect data. When data are anonymized, they cannot be linked back to any individual.

As a participant, you can ask the study team for more information about what data they will collect and how they will protect your personal information. You may also want to clarify if the information they collect from you will be anonymized.

Other Resources

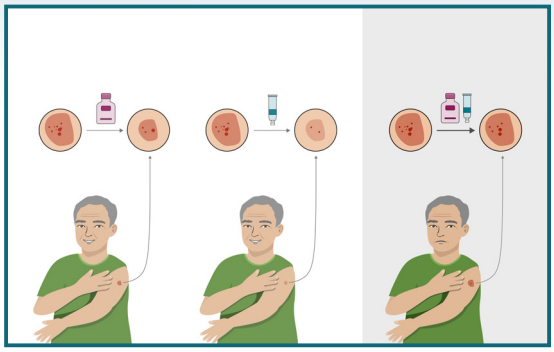
NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

antagonistic effect

cdisc

When one treatment or intervention works against another to reduce or block its effect.



Example of *antagonistic effect* in a sentence

An antagonistic effect means that one thing is lowering the effect of another.

More Info

An antagonistic effect is an example of how medicines interact with each other.

An antagonistic effect occurs when one substance or study treatment goes against the effect of another one. This can have a positive or negative impact.

For example, a medication that causes blood thinning could potentially be countered by taking Vitamin K, which has a clotting effect.

Another example for antagonistic effect is when a treatment is taken to reduce the side effects of another treatment. This is an overall positive outcome for the person taking these two treatments.

Related Words

Inhibiting effect

additive effect

synergistic effect

Other info to think about when joining a study

The term "antagonistic" is sometimes used to describe how two things that are used together actually have a weakened effect than when just one of them is used alone. It's like the two things work against each other to have less of an effect.

You may want to find out more about why the two treatments work against each other and whether that effect is a good thing or a bad thing for you. You might also want to know if it is possible to modify or reverse the effect.

Other Resources

NCI Thesaurus

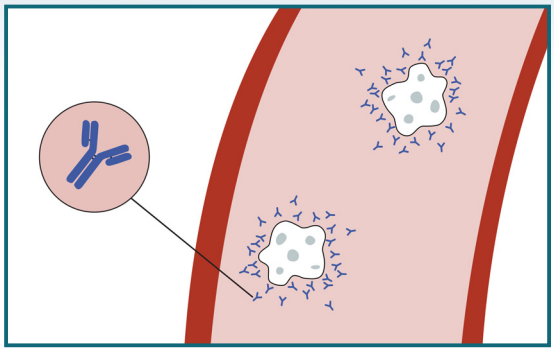
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

antibody

cdisc

A protein made by the body to fight an illness or infection.



Example of *antibody* in a sentence

Antibodies develop after an infection to help clear the infection and to prevent the infection from coming back.

More Info

An antibody is a protein that is produced by the body's immune system and causes an immune response.

Antibodies can be found in various areas of the body, including the blood, skin, lungs, tears, saliva, and even breast milk.

Antibodies can be produced in response to viruses, bacteria, parasites and even medications. Antibodies can sometimes recognize someone's own body tissues and cause disease.

In some cases, antibodies can also be used as a treatment/therapy. For example, antibodies are sometimes used to fight cancer cells.

Related Words

immune system
antigen
immunoglobulin
immunotherapy
protein

Other info to think about when joining a study

A research study may test whether a study treatment causes a person to develop antibodies to a disease. It may also test an antibody to see if it can treat a disease.

If you have any questions about antibodies or immune reactions, you can ask the study team.

Other Resources

NCI Thesaurus

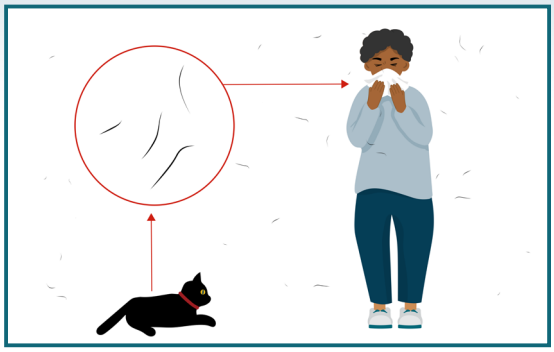
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

antigen

cdisc

A substance that causes the body's immune system to react.



Example of *antigen* in a sentence

An antigen is something that your body does not recognize and tries to fight.

More Info

The body reacts to an antigen like a virus, bacteria, parasite, or tumor.

Immune reactions include getting a fever, a rash or hives, or feeling sick.

One of the ways that the immune system protects itself from antigens is to produce antibodies.

Related Words

antibody

immune response

Other info to think about when joining a study

You may see the term "antigen" in different research study situations. For example you may see it in the title of a research study, in the consent form, or in other study information. During the Covid pandemic, there was a lot of information about antigen tests.

Feel free to ask a member of the study team for more information if you have questions about the term "antigen" being used in a research study.

Other Resources

NCI Thesaurus

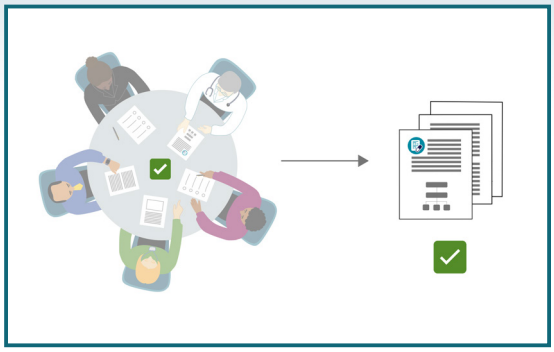
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

approval (IRB/ethics)

cdisc

Official decision by an ethics committee to allow a research study involving human participants to begin.



Example of *approval (IRB/ethics)* in a sentence

An ethics committee (EC) or Institutional Review Board (IRB) reviews a research study to check that participants will be protected and that there is a balance between the risks and benefits before granting approval.

More Info

Research studies that enroll participants are reviewed by an Ethics Committee or Institutional Review Board before approval is granted.

The IRB also reviews most ongoing research studies at least every year to ensure participants are protected and that the protocol has not changed.

Ethics approval is one of many different kinds of clinical research approvals.

Related Words

independent ethics board

Other info to think about when joining a study

You may see the word "approval" or "approved" used to describe that a research study went through a review process before being allowed to start.

If you have any questions about the approval process or would like to have the IRB's contact information, you can ask the study team. Their information should be listed in the informed consent form or found online.

You can always contact the EC or IRB that is overseeing the research study with any questions or concerns.

Other Resources

NCI Thesaurus

Mayo Clinical—Institutional Review Board (IRB)

FDA— Institutional Review Boards Frequently Asked Questions

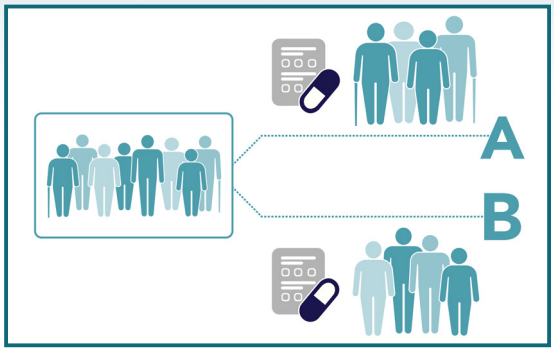
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

arm

cdisc

A group of participants in a research study who all receive the same study treatment.



Example of *arm* in a sentence

If a study has two arms, one group will receive one study treatment while a second group will receive a different study treatment such as a placebo or the standard of care.

More Info

Studies that compare two or more study treatments divide participants into separate arms to compare the effects of the different treatments.

Related Words

- study arm
- group
- study assignment
- randomization
- cohort
- treatment group

Other info to think about when joining a study

You may see the term "arm" in the consent form or when the study team is explaining the research study to you. They may mention that there will be different arms in the study you are joining. You may be randomized to one arm or another.

You can ask how many arms will be in a study. If there are arms, you can clarify how participants will be assigned to receive the different study treatments.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

assent

cdisc

Willingness to take part in a research study by someone who is not able to give legal consent.

Example of *assent* in a sentence

Some studies ask children, or people who have a guardian, to decide whether they agree to participate in research by giving their assent.

More Info

Assent can apply both to children and to adults who can't give legal informed consent. For example, an adult with severe dementia may no longer be able to give consent but could be asked to assent.

Confirming the assent of children and adults who are unable to give legal consent treats them with respect, even if not legally necessary.

Failing to object to being in a study is not considered assent. Assent can apply to children and adults who can't give legal informed consent. For example, in the case of an adult with dementia.

To leave a study, a participant may take back their assent, or the legal guardian or authorized decision maker may take back their consent.

Related Words

agreement

consent

Other info to think about when joining a study

The word "assent" may come up if minors are joining a study. When applicable, the parent or guardian may be signing to give consent, but the young person should be given the opportunity to assent to become a participant. The study team may also say that even if the guardian provides consent, the young person joining the study will need to give their assent before enrolling.

A minor who is enrolling in a study should feel free to ask as many questions about the research as necessary to feel comfortable becoming a participant.

Other Resources

NCI Thesaurus

MRCT Center - What is Assent?

MRCT Center - Assent to Consent

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

assent form

cdisc

A document used to explain the details of a research study to children or people who are unable to give legal consent.

Example of *assent form* in a sentence

An assent form provides information about the research in a way that is easy to understand.

More Info

An assent form provides research study information in a way that children and others who may have impaired decision-making can understand.

Giving children and people with impaired decision-making an assent form that is designed for them helps them to understand the research and decide how they feel about the study.

Related Words

assent
minor
guardian
consent
consent form

Other info to think about when joining a study

If you are the parent or guardian of a child, you will be deciding about the study and signing the consent form. You can ask the study team if there is an assent form for the child to understand the study.

A similar process can be followed if a study is enrolling adults who are not able to make decisions on their own about being in a research study.

You can use the assent form to guide a conversation to make sure the potential participant agrees with being in the research study.

Other Resources

NCI Thesaurus

MRCT Center - What is Assent?

MRCT Center - Assent to Consent

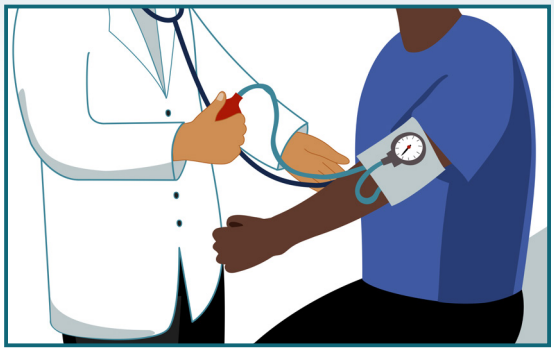
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

assessment

cdisc

Information that is collected and analyzed from a study participant.



Example of *assessment* in a sentence

A study often includes assessments, like surveys or medical tests.

More Info

An assessment is used in research to collect data that helps the researchers answer the study questions.

Related Words

test
survey
questionnaire
baseline assessment

Other info to think about when joining a study

You may hear the word "assessment" when the study team tells you about the study procedures that will be done during the study. An assessment could be a questionnaire you do on your own or a procedure that is done by someone on the study team (like getting a blood pressure reading).

Ask if you are not sure what the study assessment is for and what data are being collected. If the assessment involves any medical tests, you could ask if you need to do anything special to prepare.

Other Resources

NCI Thesaurus

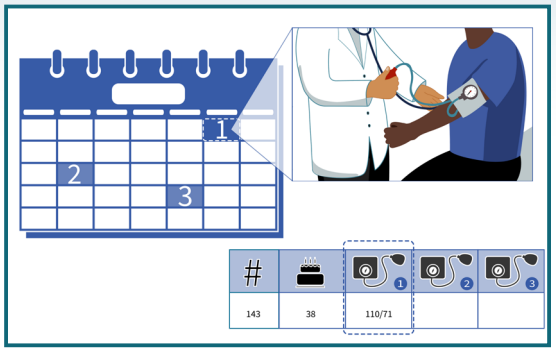
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

baseline assessment

cdisc

Information that is collected and analyzed from a study participant at the start of a study.



Example of *baseline assessment* in a sentence

A baseline assessment collects data about the participant's health status at the start of a study before any study treatment is given.

More Info

A baseline assessment is used to compare how the participant's health status changes during the study.

For example, if a study is measuring weight loss, the participant's weight must be taken at the start of the study to see if the participant loses weight while they are in the study.

A baseline assessment could include questionnaires, lab tests, or other medical information for the study.

Related Words

assessment
survey
questionnaire

Other info to think about when joining a study

You may hear the term "baseline assessment" when the study team tells you about what you need to do for the research study. They may ask you to complete a "baseline assessment" to collect information at the start of the study. Some baseline assessments are done by the participant (like a survey) while others might be done with a person from the study team (like a blood draw).

If you do not understand the baseline assessment at the start of the study, please ask the study team to clarify.

Other Resources

NCI Thesaurus

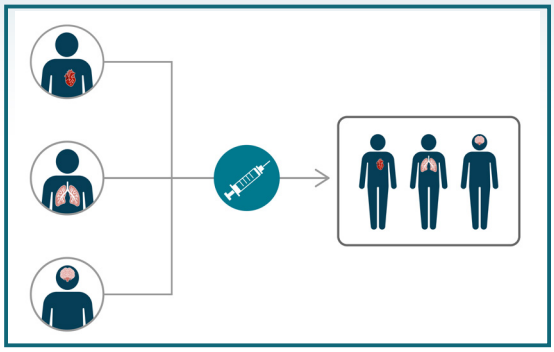
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

basket trial

cdisc

A research study that tests one study treatment for different diseases and conditions.



Example of *basket trial* in a sentence

A basket trial is done to see whether a study treatment can work for multiple different conditions that have something in common.

More Info

A basket trial is a type of platform or master protocol study.

A basket trial is done to find out whether one drug can treat multiple diseases.

A basket trial enrolls patients with different diseases that have something in common.

Related Words

Other info to think about when joining a study

You may hear about basket trials when you are learning about different types of study designs.

If you are thinking of joining a "basket trial" it means the study will be trying to find out if one treatment could help with a few different diseases or conditions.

If you are unclear what it means for a research study to be a basket trial, you should ask a member of the study team to clarify any of your questions.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

benefits of a research study

cdisc

The ways a research study might help the participant and others.

Example of *benefits of a research study* in a sentence

Learning about the possible benefits of a research study can help someone decide whether or not to enroll.

More Info

Research studies may have benefits for individuals and/or society. For example, a personal benefit of being in a research study might be regular health checks. A benefit to society may be helping future patients or the public, even if an individual participant does not directly benefit. Participants may not have any benefits from being in a research study.

Related Words

benefits of a clinical trial
benefits
advantages
pros

Other info to think about when joining a study

The consent form will include information about whether or not there will be direct benefits to you if you participate in a research study.

You should ask about more details of the benefits of the research, if there are any. You can also ask about the risks of participating in the study.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

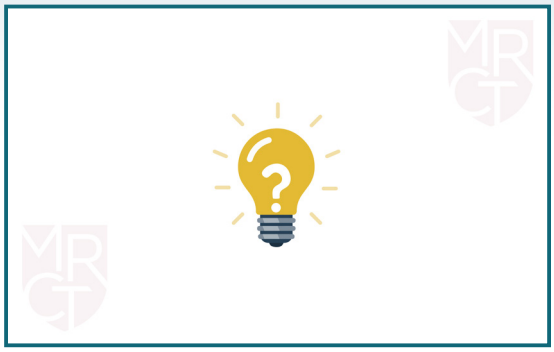
bias (research)

cdisc

Flaws in the way a study is designed, done, or analyzed that lead to one conclusion being favored over another.

Example of *bias (research)* in a sentence

Research bias can affect the results and outcomes of the research.



Do you have an idea for an image that could explain this concept? Contact us.

More Info

Bias in research can occur either on purpose or accidentally. Bias may cause false conclusions or misleading results.

All research study staff should be aware of, and reduce, potential sources of bias.

Research bias can occur when a study is being planned, conducted, or analyzed. Bias can happen based on data selection, study methods, individual experiences, or personal opinions.

Statistical or personal factors and can cause results or findings to lean one way over another. For example, if a researcher only recruits participants who speak English, people who speak another language would not be represented.

Related Words

prejudice
predisposition
tendency
favoritism
preference

Other info to think about when joining a study

The concept of "research bias" may come up when reading results and trying to interpret the way the study was conducted.

When you think about a study's results, you may have questions about whether there was any potential bias in the study, and how the researchers tried to avoid bias.

Bias is also something that you can discuss with the research team if you are considering being in a study or are currently a participant in a study.

Other Resources

NCI Thesaurus

Understanding Health Research - Common sources of bias

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

biobanking (research)

cdisc

Storing biological samples from participants for future research.

Example of *biobanking (research)* in a sentence

In biobanking, samples like blood, urine, and genetic material (DNA) are saved to be used in the future.

More Info

Many clinical research studies that collect samples include biobanking as an optional part of the study.

Any biobanking that could link the samples back to the participant should be described in the participant consent form.

Storing blood to be used in the future is an example of biobanking.

Related Words

biorepository
repository
sample bank

Other info to think about when joining a study

You may see the term "biobanking" if you are joining a study that is collecting biological samples and storing them for future research.

You should feel free to talk with the study team about how your samples and data will be used and protected.

You should also feel comfortable asking about whether it is possible to opt out of any future biobanking uses you might not agree with.

Other Resources

NCI Thesaurus

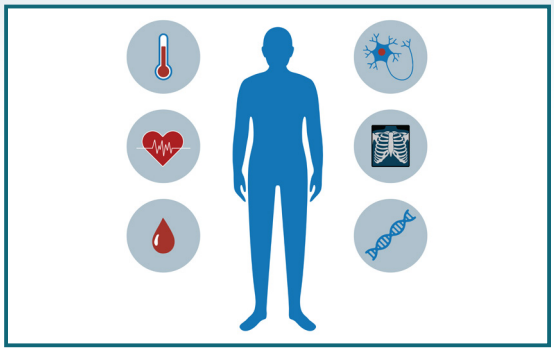
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

biomarker

cdisc

Something in the body that is measured as an indicator of personal health or disease.



Example of *biomarker* in a sentence

Many different types of biomarkers can be measured in the body.

More Info

Biomarkers can be found in blood, body fluids, or tissues. They are sometimes related to a particular disease or condition.

A biomarker can show how the body is working, and provide information about health.

Understanding biomarkers is important for developing new drugs and medical devices. Biomarkers are one way to figure out whether the drug or device is working as intended.

For example, one biomarker is cholesterol. Cholesterol levels are a useful biomarker for heart disease. A research study might try to find out if a medication is helping lower cholesterol to prevent heart disease.

Related Words

biological marker

Other info to think about when joining a study

A study that collects samples like blood or saliva from your body might be looking for biomarkers.

You can ask the study team any questions you have about the kinds of biomarkers that might be studied and whether any of the results will be returned to you.

Other Resources

NCI Thesaurus

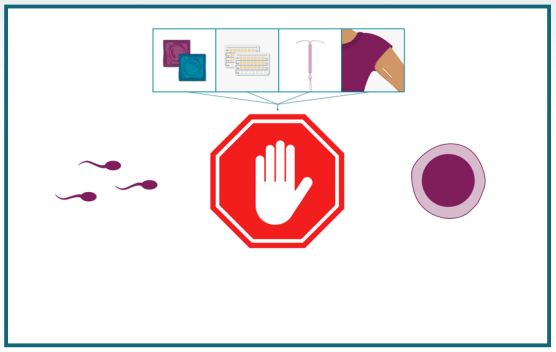
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

birth control

cdisc

A way to prevent pregnancy.



Example of *birth control* in a sentence

Using birth control may be required in some drug studies.

More Info

Birth control is any method, medicine, device, procedure, or behavior is used to prevent pregnancy.

Contraception is a form of birth control.

Sometimes birth control is needed in clinical trials if there is a possible risk to sperm or pregnancy development.

Related Words

- contraception
- pregnancy prevention
- condoms
- birth control pill
- abstinence
- hysterectomy
- vasectomy
- intrauterine device (IUD)

Other info to think about when joining a study

A study you are thinking about joining may say that you need to use a birth control method. Some studies require a sexual partner to also use birth control.

You can ask the study team to explain why birth control is needed. You could ask what kind of birth control the study will want you to be on. You could also ask what will happen if you do get pregnant while on the research study.

Other Resources

NCI Thesaurus

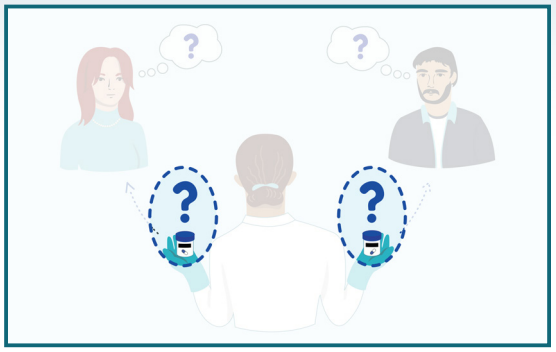
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

blinding

cdisc

A way to keep participants, and often study staff, from knowing which study treatment a participant is assigned.



Example of *blinding* in a sentence

Blinding is one way to reduce bias in a research study.

More Info

Blinding keeps participants and/or the study team from knowing which study arm a participant is randomized to.

Blinding is done for scientific reasons. It reduces the possible effect of participant and study team hopes and expectations on the results.

Some studies may be single-blinded (that is, the participant does not know what study treatment they are getting) or double-blinded (that is, neither the participant nor study staff know exactly which study treatment each participant is getting).

In the case of an emergency, however, the study team can follow a process to find out. This is called "unblinding."

Related Words

double-blind study
single-blind study
bias (research)
masking

Other info to think about when joining a study

If a study involves blinding, this will be described in the consent form that you will review and sign. You should feel free to ask any questions about the blinding so that you feel comfortable with not knowing exactly which study treatment you will get.

You can also ask why the research study uses blinding if you are unsure of the purpose.

If you are in a research study that involves blinding, you can ask if you will be able to find out what study treatment you received after your time in the study ends.

Other Resources

NCI Thesaurus

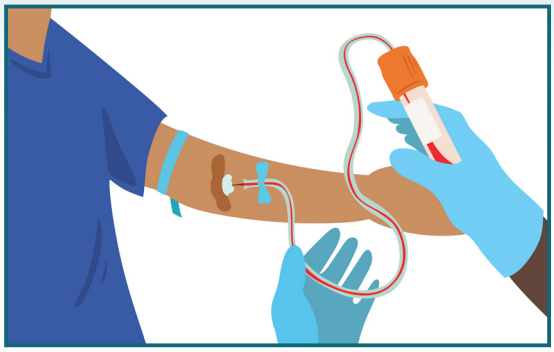
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

blood draw

cdisc

Taking a sample of blood by using a needle.



Example of *blood draw* in a sentence

A blood draw from a vein is often needed for lab tests.

More Info

If a study includes a blood draw, it means one (or more) samples of the participant's blood will be taken for the research.

Related Words

phlebotomy

blood sample

Other info to think about when joining a study

Some research studies require one or more blood draws. The blood draw could happen at any study visit depending on the study you join.

You can clarify if and when you need a blood draw during the study. You may also want to ask if you need to do anything to prepare, like skip a meal if it is a fasting blood draw.

Other Resources

NCI Thesaurus

Harvard Catalyst - Blood Draw for Research

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

case-control study

cdisc

Research that uses existing data to compare a group of participants with a disease or trait to a group without the same disease or trait.

Example of *case-control study* in a sentence

A case-control study tries to find out if specific events or situations that happened in the past might be related to a health outcome.

More Info

Case-control study is a type of observational study that generally uses data that already exists to answer a research question.

The group of participants that have the specific disease or trait ("case" group) is compared to those that do not ("control" group) to see if there is an event or exposure is related to an outcome.

For example, researchers might compare people with lung cancer to people without lung cancer to ask if smoking cigarettes was more common in one versus the other. Case control studies can show that the two are related, but they do not show that one causes the other.

Related Words

observational study

cohort study

blood sample

Other info to think about when joining a study

You might see the term "case-control study" used in study documents or consent forms.

During case-control studies, researchers may review your medical records for data. They could also ask you to complete surveys or provide a biological specimen like blood or saliva.

If you are asked to consent to a case-control study, you can ask how the study team plans to get your medical records and what information they will try to get from your records.

You could also ask if they may share any of this information and overall results with you.

Other Resources

NCI Thesaurus

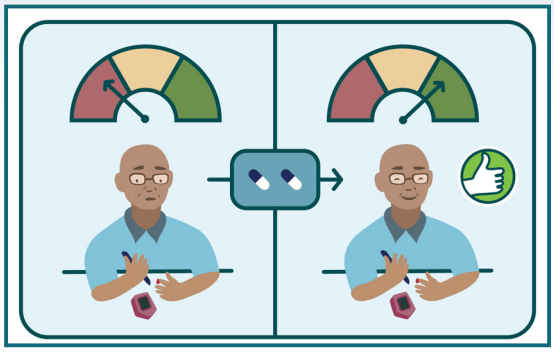
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

clinical benefit

cdisc

A health change that researchers measure to show that the study treatment helps the study participants.



Example of *clinical benefit* in a sentence

A study treatment may have *clinical benefit* if participants have some kind of improvement.

More Info

For example, the clinical benefit of a drug used in a diabetes study might be lowering and better controlling the blood sugar of participants.

Related Words

benefits of a research study
benefits
advantages
pros

Other info to think about when joining a study

You may see the term "clinical benefit" when researchers describe what the study is trying to find out. In many cases what matters most to participants is understanding whether a study treatment will lead to having a clinical benefit like improved quality of life. You might want to ask if the study is measuring the clinical benefit of the study treatment.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

clinical hold

cdisc

A pause to all or parts of a research study ordered by the government agency that oversees research in a country.

Example of *clinical hold* in a sentence

A clinical hold can be placed on studies involving a product (like a drug or device) by regulators like the FDA for many reasons, including safety concerns.

More Info

A clinical hold is a mandatory study suspension imposed by a government regulator.

Reasons for a clinical hold include concerns about participant safety, study quality, or insufficient information.

A complete clinical hold means all clinical study work is paused or delayed. A partial clinical hold means only a part of the clinical work must be paused or delayed.

In contrast, an "administrative hold" is a voluntary pause by the principal investigator. Ethics committees can also pause or stop research through a "suspension or termination of IRB approval."

Other countries have a similar process, though they may use different terminology.

Other info to think about when joining a study

If there is ever a clinical hold on a research study you are participating in, you can ask the study team, what caused it and if there are plans to respond to the clinical hold so the research can continue.

If there is a clinical hold, your study team will contact you to let you know. For your safety, please pay extra attention to any phone calls or messages you get about "clinical holds."

Related Words

study suspension

Other Resources

FDA — IND Application Procedures: Clinical Hold

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

clinical research

cdisc

A type of science that uses people's data to study health, illness, behaviors, or conditions in careful and defined ways.

Example of *clinical research* in a sentence

Clinical research is an organized way to find out about a condition or disease, how the condition progresses, how a treatment is given, or which treatments are safe and work best.

More Info

Clinical research includes many different types of studies, such as clinical trials, observational studies, and survey studies. Clinical research can be about individuals, populations, or public health.

Related Words

- health research
- medical research
- clinical trial
- clinical study
- research study
- observational study
- preclinical study

Other info to think about when joining a study

The term "clinical research" refers to any systematic way of studying health and illness. Clinical research is the way to learn more and find new medicines and treatments.

You may hear this term if a researcher asks you to take part in a clinical research study. For example, your doctor may ask if you want to be involved in research and consent to join a study.

Other Resources

- FDA - The Drug Development Process Step 3: Clinical Research
- NCI Thesaurus
- U.S. Department of Health and Human Services - What is Medical Research?

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

Clinical Research Coordinator (CRC) cdisc

A research staff member who helps manage studies.

Example of *Clinical Research Coordinator (CRC)* in a sentence

A Clinical Research Coordinator works with the study doctor to help conduct the study.

More Info

One or more CRCs is assigned by the Principal Investigator who is leading the research to take care of specific study tasks. Tasks include preparing study documents, scheduling study visits, and collecting data.

Related Words

project manager
study coordinator
research coordinator
research nurse

Other info to think about when joining a study

When enrolling in the study and going to study visits, you may meet with the clinical research coordinator. They may be the person explaining the study and consent process to you.

It may be useful to ask whether the clinical research coordinator is the person to contact if you have any questions about the study or any issues come up.

Other Resources

Harvard Catalyst - Meet the Research Team

NCI Thesaurus

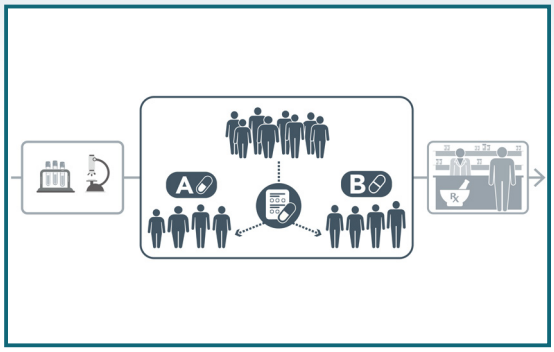
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

clinical trial

cdisc

A research study that tests drugs, devices and treatments to see if they are safe and work in people.



Example of *clinical trial* in a sentence

Participants in a clinical trial help the study doctor learn more about a new treatment.

More Info

A clinical trial could study ways to diagnose, treat, or even prevent illness. Some clinical trials look at just one study treatment. Others might compare the study treatment to another treatment, a placebo, or even to a group that is taking nothing in order to measure how well the study treatment works.

Related Words

- research study
- trial
- clinical study
- study
- interventional study
- clinical research study
- clinical research
- control
- placebo

Other info to think about when joining a study

The term "clinical trial" is used for studies of people with various diseases and conditions.

You might be asked if you want to take part in a clinical trial. You may also read it on flyers asking for study volunteers.

It is important to understand the risks and benefits of the clinical trial before you enroll.

Other Resources

NCI Thesaurus

FDA - Basics About Clinical Trials

Harvard Catalyst - What is a Clinical Trial?

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

clinician

cdisc

A health care provider.

Example of *clinician* in a sentence

A clinician has special medical training to care for patients.

More Info

Clinicians include people who are doctors, medics, nurses, pharmacists, psychologists, physical therapists, occupational therapists, psychiatrists, and others.

Related Words

allied health professional

healthcare provider

Other info to think about when joining a study

Any health care provider that you see regularly is a clinician. In health-related research studies, it may be a clinician who recruits and enrolls you. Additionally, a clinician may be in charge of a research study you join.

You can ask for the name and contact information of the clinician(s) running the research study. You may also want to discuss being in a research study with your own clinician before consenting to join a study.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

cohort

cdisc

A group of study participants that are similar in some way.

Example of *cohort* in a sentence

Data were collected from a cohort of people over the age of 65 to see if the participants developed health problems.

More Info

A cohort is usually a group of people who are in an observational study to see how a disease or condition develops. A cohort is also the group of people in a clinical trial testing a study treatment for a specific disease or condition.

Related Words

study cohort
study group
arm
observational study

Other info to think about when joining a study

You may hear the term "cohort" when the study team is describing the research study to you or when you are reading the study consent form. This term may come up when learning about the study groups and the different study treatments they may take or what different groups of participants may have to do differently.

It can be helpful to ask why a specific cohort was selected for the study you are joining and what the researchers would like to learn.

Other Resources

NCI Thesaurus

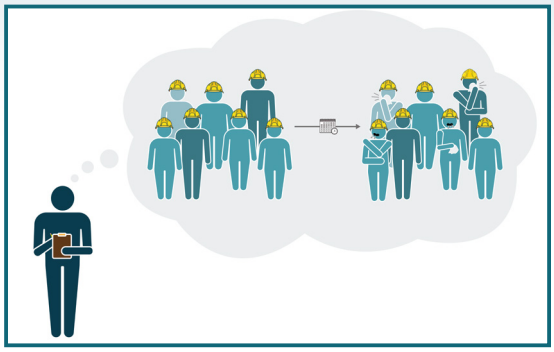
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

cohort study

cdisc

Research that collects data from or about a group of participants over time to see whether a specific outcome happens.



Example of *cohort study* in a sentence

The goal of a cohort study is to see if there is a relationship between risk factors or exposures and an outcome.

More Info

A cohort study is a type of observational study that can be prospective (collecting new data) or retrospective (like chart reviews) to answer a research question.

The participants can also be grouped in a cohort study. For example, people who smoke vs. people who don't smoke to see whether a particular health outcome occurs.

The Framingham Heart Study is an example of a cohort study. The study recruited participants and collected data about them over a period of time to see what may contribute to heart disease.

Related Words

observational study

longitudinal study

case-control study

Other info to think about when joining a study

You might see the term "cohort study" used in study documents or consent forms.

You could ask the study team how long they think this study is expected to continue. Some cohort studies last for years. You may also want to consider if you want to be in a study that could last a period of time.

You could also ask the study team how they plan to collect data. They may send you questionnaires or surveys. Additionally, the study team could also call you to ask questions over the phone.

Other Resources

GW Himmelfarb — Study Design 101: Cohort Study

NCI Thesaurus

NIH — Methodology Series Module 1: Cohort Studies

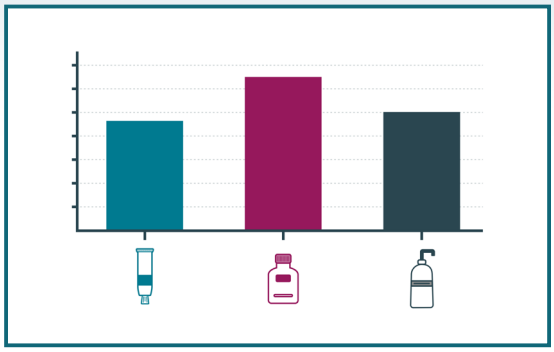
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

Comparative Effectiveness Research (CER)

cdisc

A study comparing two or more treatments.



Example of *Comparative Effectiveness Research (CER)* in a sentence

A comparative effectiveness research study compares at least two treatments to determine differences in outcomes.

More Info

Comparative effectiveness research compares treatments with drugs or devices, different ways to diagnose a condition, or how best to provide health care and services.

An example of a comparative effectiveness research study would be comparing Advil, Aleve, Tylenol, and Aspirin to see which is better for treating headaches. Generally, a placebo is not used in comparative effectiveness research.

Related Words

superiority trial

inferiority trial

Other info to think about when joining a study

If you are thinking about joining a comparative effectiveness research study, you should understand what study treatments are being compared and why.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

comparator

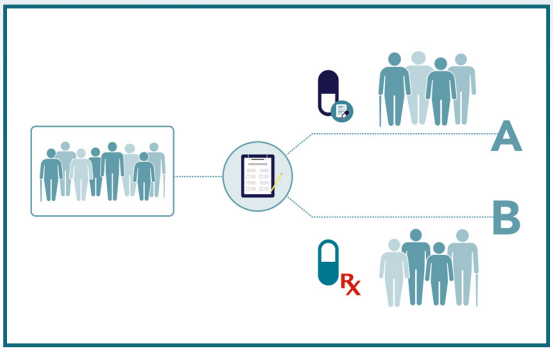
cdisc

Something that is compared to the study treatment.

Example of *comparator* in a sentence

A research study compares the outcomes of the treatment being tested to a comparator.

Studies with a comparator are usually trying to find out if there is a different outcome in the comparator group versus the group that gets the study treatment.



More Info

A comparator is also called a "control." The group that gets the comparator is the "control group."

The comparator can be an investigational or approved medicine, a placebo, or a different procedure or intervention.

For example, in a study of acupuncture for back pain, a comparator might be physical therapy or yoga.

Related Words

control
reference
benchmark
comparison
study treatment
test article

Other info to think about when joining a study

You may see the word "comparator" to describe another arm in the study. A comparator is often a treatment or intervention in common use and is used to see if the study treatment is worse, better, or somehow different. Feel free to ask any questions you might have about the comparator that is being used in a study.

Other Resources

NCI Thesaurus

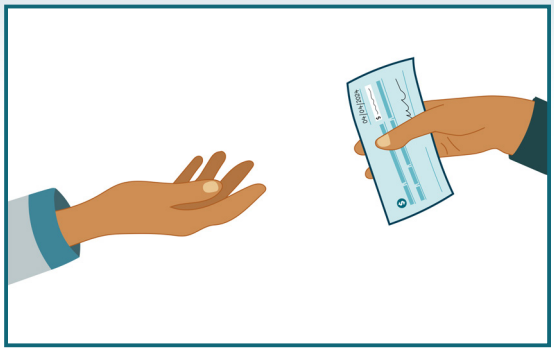
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

compensation (study)

cdisc

Money and other forms of payment that may be given to participants for completing study activities.



Example of *compensation (study)* in a sentence

Participants can ask the study team if compensation will be offered.

More Info

Some studies offer payment to participants. Study team members should explain any likely costs to participants for being in the research, and whether compensation or payment will be offered. This information may also be in the research consent form.

Compensation in research is meant to help cover out-of-pocket costs to study participants, such as transportation, parking, meals, childcare, and to offset time out of work. If the study is unable to provide compensation, study team members should explain why.

Related Words

reimbursement
payment
incentives

Other info to think about when joining a study

As a participant, you may hear or read about "compensation" when thinking about joining a study. This information about payments might be in the consent form, and a study team member may discuss this with you during the consent conversation.

If compensation is not mentioned, you should feel free to ask the study team if compensation or payment is provided. You may also ask how much compensation is provided, how the amount is determined, and what you need to do to ensure you can receive the compensation.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

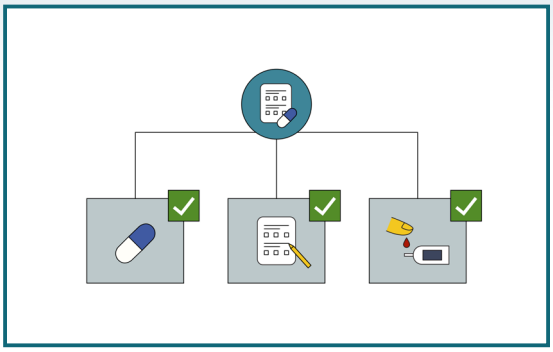
compliance

cdisc

Following research requirements.

Example of *compliance* in a sentence

Compliance with research rules and instructions improves the quality of a study.



More Info

Compliance in research refers to following regulations and guidelines about research. Researchers must be in compliance with research requirements and follow the approved protocol.

Compliance also applies to participants who should follow study procedures.

The words 'adherence' and 'compliance' are often used in the same way.

Related Words

adherence	following the rules or the law

Other info to think about when joining a study

The consent form may say that the study team could remove you from the study if they notice your participation does not meet compliance requirements. Feel free to ask the study team for assistance if you are struggling with compliance due to issues such as lack of transportation, a reading disability, or just using new technology as part of the study. Keep the study team updated so they are aware of your situation.

Both the researchers and participants need to be compliant with guidelines and protocols when they are taking part in the research. The study team will tell you that there are certain things you must do to be part of the research study. Following these rules means you are compliant with the study procedure.

If you are unsure of what you should be doing during the study, ask the study team for more information.

Other Resources

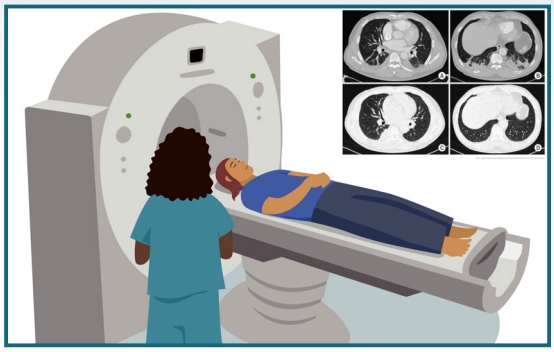
NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

Computerized Tomography (CT) scan

A way to take pictures of the inside of a person's body using a type of radiation and a computer.



Example of *Computerized Tomography (CT) scan* in a sentence

A CT scan is able to show specific changes in a person's body (like changes in the brain, other tissues, organs or bones).

More Info

A CT scan is a type of imaging study.

Related Words

imaging study

MRI

X-ray

Other info to think about when joining a study

A CT scan may be needed in a research study.

If you know you have to get a CT scan for the research study, you can ask how the information will help the study. Also, you can ask if the CT scan results will be shared with you or your regular doctor, and how much radiation you will receive. This information could help you decide if you want to receive radiation from a CT scan done for research purposes.

Other Resources

NCI Thesaurus

Harvard Catalyst - CT Scans for Research

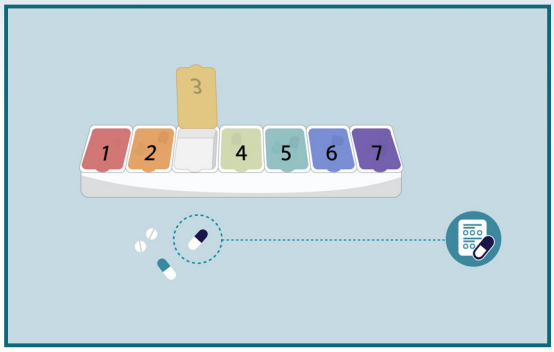
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

concomitant medications

cdisc

Non-study medicines that are allowed to be taken at the same time as the study treatment.



Example of *concomitant medications* in a sentence

Researchers need to know about any concomitant medications a participant is taking while in a research study.

More Info

In research, concomitant medications are medicines that a participant takes at the same time as taking the study treatment.

Concomitant medications are not the study treatment.

The study team needs to know about all the medicines that are being taken to make sure that they do not interfere with the research.

For example, if a participant takes a blood pressure medication, they should tell the study team and ask if is okay to keep taking it in the research study.

Related Words

usual medications

con-meds

Other info to think about when joining a study

Concomitant medications are reviewed by the study team to ensure that they are safe to take during the study.

It is important to tell the study team about your other medications to ensure it is safe to take them while on the study. If you join a research study and need to start a new medication, contact the study team first. If any new health issues arise, be sure to discuss them with the study team.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

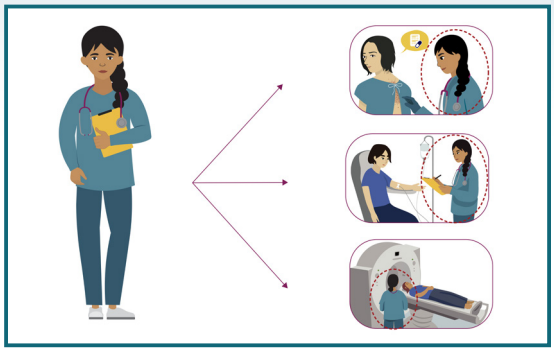
conduct

cdisc

To do a study or procedure.

Example of *conduct* in a sentence

The study team helps conduct the research.



More Info

Depending on the study, the researcher may conduct a physical exam, survey, or interview to collect data for the research.

Related Words

perform
run
execute
implement
carry out

Other info to think about when joining a study

The term "conduct" may come up in the consent form you are given when you're thinking about joining a study. It may mention that the study team is conducting this research or that your participation may help them conduct the research.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

confidence interval

cdisc

The defined range of numbers used to describe where the results are expected to fall.

Example of *confidence interval* in a sentence

A confidence interval is the range of values that a result is expected to fall in if the test is done again.

This graphic represents math and statistics terms in this glossary.

More Info

A confidence interval is a measure of variability. It is the likelihood that a measurement, when repeated, will fall within a given range. It can help researchers know how much to trust that a result can be repeated.

The smaller the confidence interval, the more certain the results are.

The term "confidence interval" is often abbreviated as "CI."

Related Words

margin of error

estimate

probability

Other info to think about when joining a study

The term "confidence interval" will usually appear in publications about research studies when the article discusses the statistics and results.

The results section may provide more description about the confidence interval as well as define what it is for the specific study written about in the publication.

The confidence interval could also be included in the Plain Language Summary explaining the study results.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

confidentiality

cdisc

Protecting personal information from people who should not have access.

Example of *confidentiality* in a sentence

Confidentiality in research means researchers keep participant information private.

More Info

Researchers protect confidentiality by not sharing personal details about study participants with people who do not need to know as part of their work on the research.

Related Words

privacy
data
non-disclosure

Other info to think about when joining a study

Confidentiality is very important in healthcare and clinical research. When talking or reading about the data that you will provide during the study, the study team may mention how they will protect your confidentiality.

You can always ask more about how the study team plans to protect your data and who will have access to it. Before you join a study, make sure you feel comfortable with how your data will be used and protected.

Other Resources

NCI Thesaurus

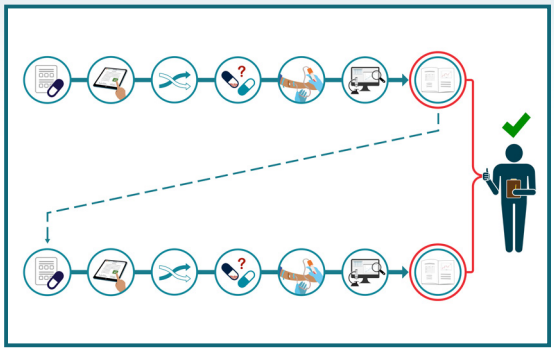
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

confirmatory clinical trial

cdisc

A type of clinical research that is done to see if earlier study results can be repeated and learn more about how well a study treatment works.



Example of *confirmatory clinical trial* in a sentence

A confirmatory clinical trial usually enrolls more participants and lasts longer than earlier studies to make sure that the treatment works.

More Info

Confirmatory clinical trials are a type of randomized controlled trial that confirm and validate earlier, similar studies of the same treatment. They also often expand the type of participants enrolled. For example, the later, confirmatory trial may include older or younger people and they may also find new safety issues.

Related Words

confirmatory trial
randomized controlled trial
registration trial
pivotal trial
phase 3

Other info to think about when joining a study

A confirmatory study is designed to learn more about whether and how well a study treatment works.

If you are asked to participate in a randomized controlled trial, you may want to find out more about the past results. You may also want to learn more about whether a placebo or other treatment is being used for comparison.

Other Resources

EUPATI — Confirmatory studies

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

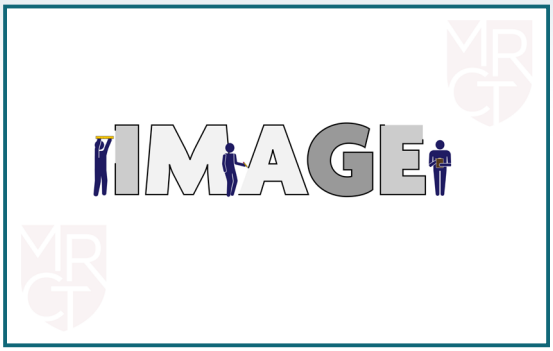
confounding

cdisc

When the study outcome is influenced by outside conditions that were not expected by the study researchers.

Example of *confounding* in a sentence

Researchers try to be aware of possible confounding factors that can affect their study results.



This graphic indicates that a new image is being developed. Check back again soon!

More Info

Confounding suggests there is a correlation between two or more things when really there is none.

For example, alcohol use is associated with lung cancer. Alcohol is not known to be related to lung cancer, but people who smoke often consume alcohol. Smoking is the confounder here, related to lung cancer and associated with alcohol use.

Related Words

correlation
causation
cause and effect
dependent and independent variables

Other info to think about when joining a study

Researchers design studies to try to avoid the amount of confounding that could impact the study results. If you are thinking about enrolling in a new study, you might ask the study team how the study was designed to try to prevent confounding.

Pregnancy is often considered a confounding factor for research. Some studies are designed to not allow pregnant people to participate because they aren't sure how the pregnancy would impact the results. If you are planning to become pregnant and are thinking about joining a study that does not allow pregnancy you should discuss this with the study team.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

consent form

cdisc

A document used to explain the planned research before a person decides whether or not to join a study.

Example of *consent form* in a sentence

A person signs the consent form when they choose to take part in a study but only after they understand the information.

More Info

A consent form for a research study explains the research, potential risks and benefits, and all the details of a study. The consent form also includes information about other treatment options, the rights of participants, and the rules that the researchers need to follow.

A consent form can be on paper or an electronic document.

Related Words

informed consent form

informed consent

Other info to think about when joining a study

Most clinical research studies require a person to read and sign a consent form. A member of the study team should explain the study in detail and answer any questions you have.

You can ask for and keep a copy of the consent form from the study. Take the time to get your questions answered if anything is unclear so you understand what you will have to do during the study and how long the study is. Even after signing a consent form to join a study, remember you can withdraw from the study too. Just make sure to discuss with the study team so you can leave the study safely.

Other Resources

NCI Thesaurus

U.S. Department of Health and Human Services - Informed Consent for Research: What to Expect

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

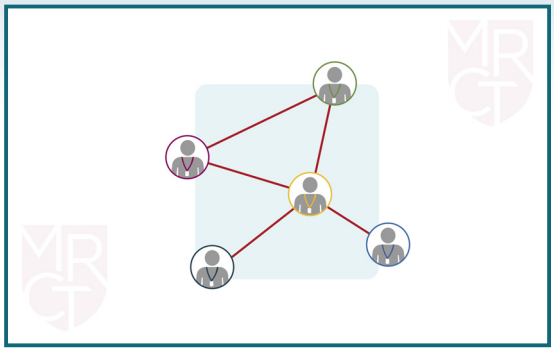
Contract Research Organization (CRO)

cdisc

A group that is paid by the study sponsor to support research studies.

Example of *Contract Research Organization (CRO)* in a sentence

A Contract Research Organization helps the sponsor run a study.



This graphic represents the groups in a research network that are involved in the conduct of research studies.

More Info

A Contract Research Organization (CRO) can be a commercial, academic, or other group that is contracted by the sponsor to perform one or more research functions.

A CRO works with the study teams and often helps coordinate multiple sites.

Related Words

sponsor

clinical research coordinator (CRC)

Other info to think about when joining a study

When reviewing the consent form, it may say that there is a Contract Research Organization (CRO) involved.

You could ask for more details about what the CRO is doing and what part they play in the study.

You can also ask whether any participant information is shared with the CRO.

Other Resources

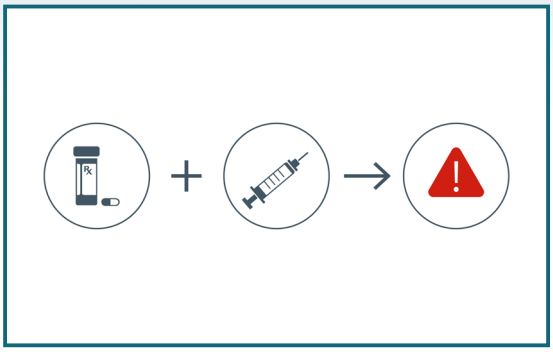
NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

contraindicated

When things should not be used or done together because of possible harm.



Example of *contraindicated* in a sentence

Researchers make sure that study procedures are not contraindicated before a participant enrolls in a study.

More Info

Researchers carefully check whether participants are receiving treatment or have a condition that would be contraindicated for the study intervention.

For example, a study of high-protein diets is contraindicated in people with kidney failure because high protein might harm the participant's kidneys.

An action or procedure could also be contraindicated in certain situations. For example, an MRI is contraindicated in someone who has anything metal in their body.

Related Words

harmful

Other info to think about when joining a study

The study team may tell you there are certain medications you cannot take or foods you cannot eat while you are participating in the study because they are contraindicated. For your safety you may not be allowed to join a study because you have a condition that may be contraindicated.

Be sure to ask for clarification if you are unsure about what may be contraindicated. See if there is a list that you can keep that reminds you of what is contraindicated.

Other Resources

NCI Thesaurus

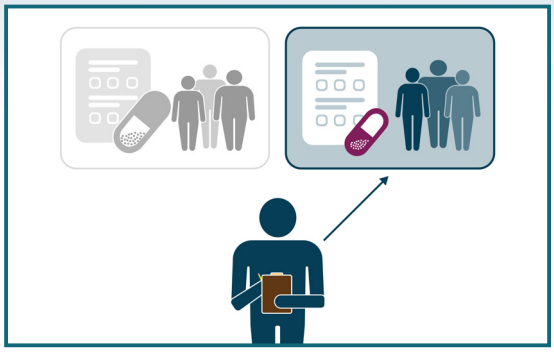
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

control group

cdisc

The people in a study who do not receive the study treatment or do not have the condition being studied.



Example of *control group* in a sentence

A control group is used as a comparison to see the effect of the study treatment.

More Info

Participants in the control group receive something different during the research study compared to the intervention group. The control group might receive a different dose, standard of care, a placebo or no treatment at all.

Related Words

control arm

comparison group

Other info to think about when joining a study

Whether a research study has a control group is important to understand. You could ask if the study you are thinking about joining will have a control group. If there is, you could ask what being in the control group will involve. For example, being in the control group could mean getting a placebo or the standard of care for the disease the study is looking at. You can also ask how participants will be assigned to the control group. This is often decided randomly, using randomization.

Other Resources

NCI Thesaurus

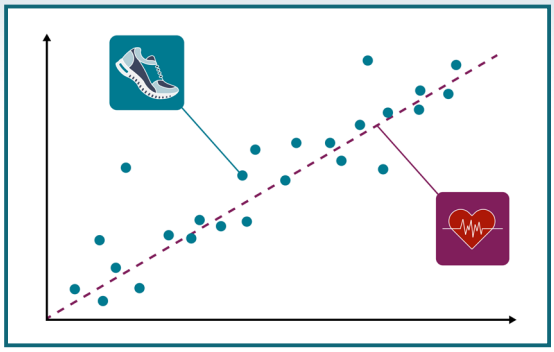
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

correlation

cdisc

When two or more measures are linked.



Example of *correlation* in a sentence

There is a correlation between height and weight in that taller people tend to be heavier.

More Info

A correlation means that two things are associated. It does not mean that the one of the two things is caused by the other.

A strong correlation means that two things are highly related.

A weak correlation means that two things are not very related.

An inverse correlation means that as one thing increases, the other decreases.

Related Words

relationship

association

Other info to think about when joining a study

The term "correlation" may be used to discuss how certain conditions or situations relate to each other. You may also hear about correlations in the context of how study results are presented and discussed. For example, a study may try to find out whether the study intervention is correlated with some specific outcomes.

Other Resources

NCI Thesaurus

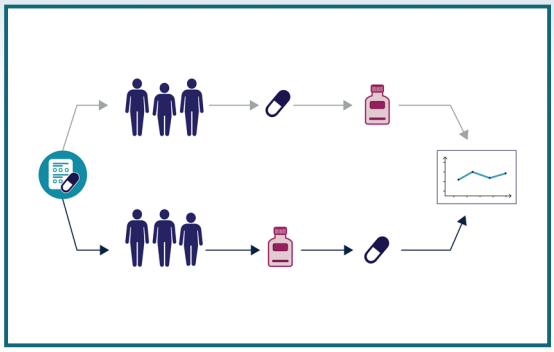
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

crossover trial

cdisc

A type of study where each participant receives all the study treatments but in a randomly assigned order.



Example of *crossover trial* in a sentence

In crossover trials, all participants receive the same interventions but the order that they are given is randomly assigned.

More Info

In a crossover trial, one group of participants receives study treatment A first followed by study treatment B, while the other group of participants receives study treatment B followed by study treatment A. There is sometimes a washout period in between.

The order in which the study treatments are given is randomized.

A benefit of this is that confounding may be reduced as each participant serves as their own "control."

Related Words

study design

Other info to think about when joining a study

The type of research study is often described in the consent form. If you are considering joining a crossover trial, there should be information about what this is and what the study treatments are.

If you are deciding whether to join a crossover trial, you may want to ask the research team more about how long the trial will take and if there is a washout period between taking each study treatment.

Before joining the trial, you could also ask the study team what the process might be if you think one study treatment is working better for you than another.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

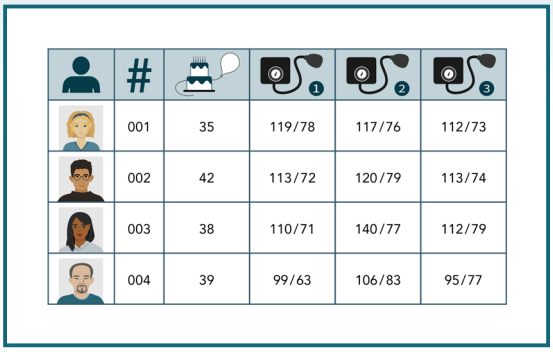
data

cdisc

Information collected from or about people taking part in a research study.

Example of *data* in a sentence

Researchers use data to answer study questions.



	#				
	001	35	119/78	117/76	112/73
	002	42	113/72	120/79	113/74
	003	38	110/71	140/77	112/79
	004	39	99/63	106/83	95/77

More Info

There are many different types of data including:
personal information like age and date of birth, questionnaires, blood test results, imaging scans and their interpretations, health insurance status and so on.

The types of data collected depend on the study.

Related Words

information
assessment
questionnaire

Other info to think about when joining a study

Analyzing data is the way research questions are answered. You will usually hear the term "data" when researchers talk about the information they will be collecting about you during the study.

You may want to clarify what data the study team will collect from you and how the data will be used for the research. You can also ask how the data will be protected and whether the data could be used for any other future uses.

Other Resources

NCI Thesaurus

Harvard Catalyst - Information about Data

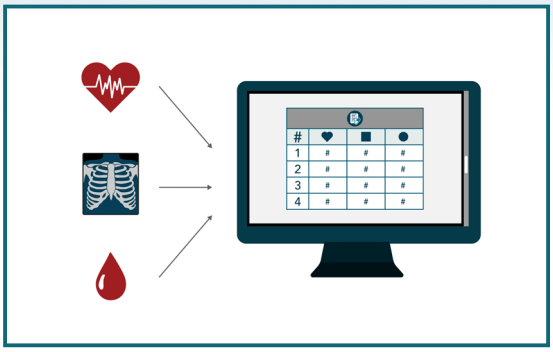
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

database (research)

cdisc

Information that has been collected and organized to be used for research.



Example of *database (research)* in a sentence

A research database stores study information so that researchers can use it to answer study questions.

More Info

Participants are usually given a code during the study so their identifiers are not saved in the same place as the other study data. A research database usually has coded information about the participants to protect their privacy. A database can be used in the present or in the future to answer new questions.

Related Words

data bank

repository

registry

Other info to think about when joining a study

You will hear the term "database" used in many different ways during the research process.

In research studies you may hear or read about the term "database" when the study team or consent form is describing how they will store data that is collected from the study. A database may also store personal information, like participant contact information.
This information should be stored in a secure, protected way.

You may want to ask how your data will be stored if you join the study. You can also ask the study team who has access to the database and what information they will keep in the database. Additionally, you may want to ask how they will keep the database safe and secure.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Data Monitoring Committee/Data and Safety Monitoring Board (DMC/DSMB) cdisc

An independent group of experts that reviews study data to make sure that patient safety is protected.

Example of *Data Monitoring Committee/Data and Safety Monitoring Board (DMC/DSMB)* in a sentence

A Data Monitoring Committee advises the study sponsor if any concerns about participant safety are found.

More Info

Data Monitoring Committees (DMCs) are also called Data and Safety Monitoring Committees (DSMC) or Data and Safety Monitoring Boards (DSMB).

Studies that are randomized controlled trials, higher risk, or enrolling vulnerable populations (e.g. children) usually include DMCs to review the data at specific timepoints, especially for adverse events that can affect participant safety.

The DMC reviews unblinded data on a regular schedule and as needed until the end of the study and advises on next steps in the event of adverse event(s).

The DMC also looks at whether a study should be stopped early (for example, for safety reasons or if there is no benefit to the study treatment).

Related Words

DSMB

DSMC

Other info to think about when joining a study

You may see or hear about a Data Monitoring Committee (DMC) if you are enrolled in a study that has one. The DMC looks at all study data and may request that the study team give you important new information that is learned. If there are any safety concerns, the DMC may advise that the study should be ended early.

Other Resources

NCI Thesaurus

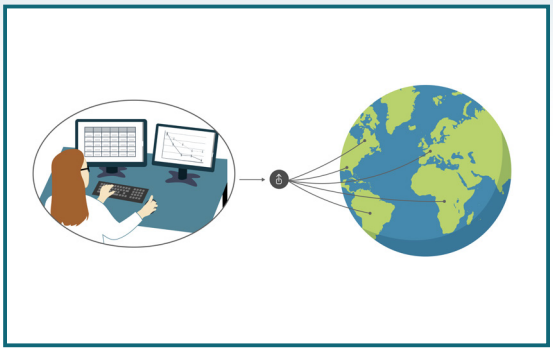
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

data sharing (research)

cdisc

Making information collected during a study available for future use.



Example of *data sharing (research)* in a sentence

Data sharing lets study data be used to answer new research questions in the future.

More Info

In clinical research, data can be shared to do more research. Data sharing reduces the number of new participants that are needed since data are already available.

In addition to new research, data sharing improves transparency because the published data can be reviewed and even reanalyzed.

Data sharing at the end of a study is done in ways that protect participant privacy. For example, the data do not include direct identifiers, such as your name and address.

When data are shared amongst the different sites of the same research study, that is typically not considered "data sharing (research)" in this context. That is considered normal activities needed to conduct research.

Related Words

data

pseudonymized

anonymized

Other info to think about when joining a study

You can ask the study team if there are plans to share research data and what data they plan on sharing.

You can also ask the study team how they will protect your privacy if your data are shared and how users will access the data.

In some cases, you may be able to ask if you can opt out of data sharing.

You can also ask if the study team will share the data they collect during a study with you and your regular doctors.

Other Resources

NCI Thesaurus

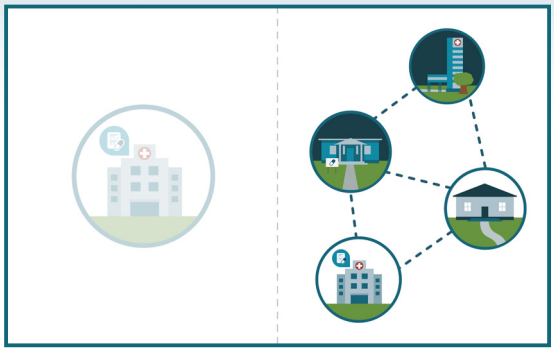
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

decentralized clinical trial

cdisc

A type of research study where some or all of the participant's study-related activities happen at places other than a single study site.



Example of *decentralized clinical trial* in a sentence

In a decentralized clinical trial, there could be remote data collection, like measuring heart rate through a device provided to the participant.

More Info

In a decentralized clinical trial (DCT), some or all of the study activities take place away from a central study site.

For example, participants may go through the consent process virtually or have remote visits with their study team using a phone or computer. There could also be home visits by members of the study team.

In a DCT, the participant might also be able to go to a local lab or pharmacy to get a blood draw, instead of going to a single study site for every procedure.

The consent form usually describes which parts of the study are allowed to be done in different locations.

Related Words

study site

Other info to think about when joining a study

If you are thinking about joining a decentralized clinical trial, the consent form will explain what will happen in the study and where study procedures could take place. You should feel free to ask the study team any questions about what is expected and what they will provide in order to be in the study.

You can ask questions about how you will interact with the study team during the study and how you can get help with being in the study if needed. For example, if the decentralized clinical trial uses a device or new technology to collect data, you should ask who to contact if they aren't working for you.

You can also ask if there are any options to meet the study staff in person if necessary.

Other Resources

NCI Thesaurus

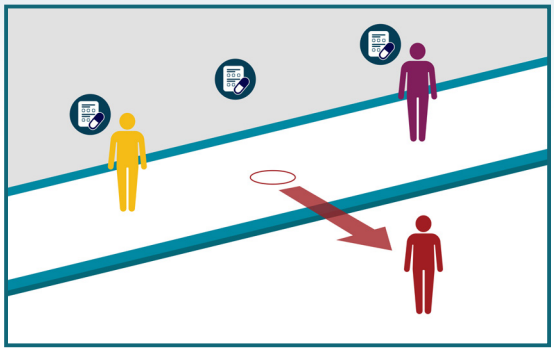
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

discontinue (participant)

cdisc

To remove a study participant from a study.



Example of *discontinue (participant)* in a sentence

If a participant wants to stop being in a study, they should have a conversation with the study team about how to discontinue safely.

More Info

A participant can decide to discontinue being in a study. Sometimes a participant is discontinued by the researchers for safety or other reasons. Reasons for discontinuing and the transition from the study should be discussed with the participant before they leave the study.

Related Words

withdraw

Other info to think about when joining a study

The term "discontinue" can be used in research to describe either leaving the study or stopping the study treatment. If you decide to discontinue any part of being in a study, please discuss with the study team how to do so safely first. This is to make sure that there are no likely health risks from ending study participation.

Other Resources

NCI Thesaurus

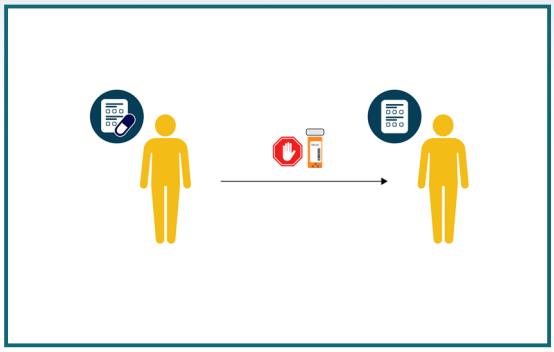
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

discontinue (study treatment)

cdisc

To stop a study treatment in a participant.



Example of *discontinue (study treatment)* in a sentence

If a participant wants to stop the study treatment, they should first have a conversation with the study team about how to discontinue safely.

More Info

A participant can decide to discontinue a study treatment. Sometimes a study treatment can be discontinued by the researchers for safety or other reasons. Reasons for discontinuing should be discussed before the study treatment is stopped.

Related Words

withdraw

Other info to think about when joining a study

The term "discontinue" can be used in research to describe leaving the study or stopping the study treatment. If you decide to stop taking the study treatment, please discuss this with the study team first. This is to make sure that there are no likely health risks from stopping the study treatment. Please also discuss how stopping the study treatment affects your participation in the study itself.

Other Resources

NCI Thesaurus

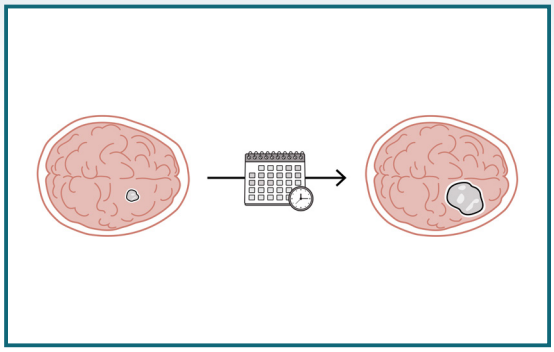
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

disease progression

cdisc

An illness getting worse over time.



Example of *disease progression* in a sentence

Disease progression refers to a disease or condition getting worse for a patient.

More Info

Disease progression can refer to a disease or symptoms getting worse. It can also refer to a person's functional abilities declining.

Related Words

Other info to think about when joining a study

Depending on the kind of study you are considering or reading about, you may see or hear references to "disease progression" during the informed consent process or other informational study materials. Disease progression may be used to explain the purpose of a study or explain the reason for particular procedures and tests. For example, a study could be collecting data on whether the disease progresses after taking a treatment.

If you have any questions about what it means for a study to look at disease progression, you should ask the study team.

Other Resources

NCI Thesaurus

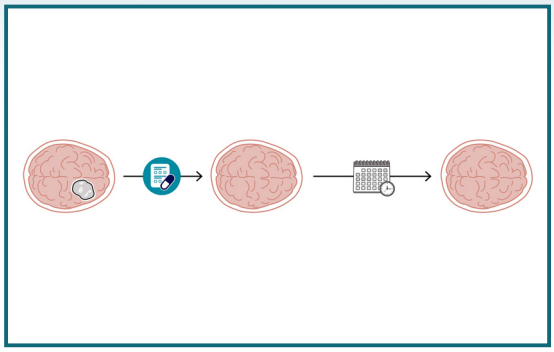
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

disease-free survival

cdisc

The length of time after treatment without the illness coming back.



Example of *disease-free survival* in a sentence

Some studies look at disease-free survival to see if the drug keeps a disease from coming back.

More Info

Disease-free survival can be used to describe the length of time an individual or a group of participants within a study are free of their disease.

Not every person in a study will necessarily have the same response to the study treatment.

Related Words

relapse-free survival

remission

Other info to think about when joining a study

Depending on the kind of study you are considering or reading about, you may see or hear references to "disease-free survival" during the informed consent process or other informational study materials.

Disease-free survival" may be used to explain the purpose of a study or explain the reason for particular procedures and tests. For example, a study could be collecting data on disease-free survival after participants take a certain treatment.

If you have any questions about what it means for a study to look at disease-free survival, you should ask the study team.

Other Resources

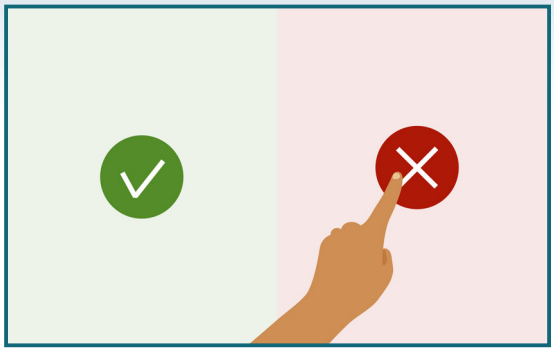
NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

dissent

Refusing to be part of a research study.



Example of *dissent* in a sentence

A child can dissent or refuse to participate even if their parent or guardian has consented for them to participate in a study.

More Info

Children and adults who are unable to give legal consent may dissent to participate at any point during the research. Researchers should honor dissent whether it is communicated in a verbal or non-verbal way.

A participant can dissent and withdraw from most research at any time. Sometimes, when the research is likely to provide benefit to the individual receiving the intervention, dissent may not be honored, but every effort should be made to explain the reason to the participant.

Related Words

object
say no
refuse
decline
disagree

Other info to think about when joining a study

The term "dissent" may be discussed when a parent or guardian reviews the consent form. You should know that even if a guardian provides consent, they have to ask the person who will be in the study if they want to be in the study or not. The person will either want to be in the study and assent or they may not want to be and dissent.

You can ask if there is an assent process and what that process will be like. You may want to also ask what happens if the guardian gives consent but the potential participant dissents.

Other Resources

NCI Thesaurus

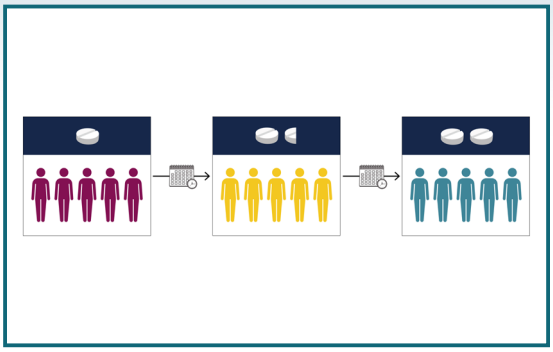
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

dose escalation study

cdisc

A kind of study where increasing amounts of a study treatment are given to different groups to find the best dose.



Example of *dose escalation study* in a sentence

In a dose-escalation study, the dose of a study treatment is increased one group at a time to find the best dose.

More Info

In a dose-escalation study, the first participant (or group of participants) gets the lowest dose of study medication.

The amount is increased with each participant or group to find the dose that gives the greatest benefit with the fewest side effects.

This process can help researchers choose the best dose for future studies.

Related Words

Therapeutic Index

Other info to think about when joining a study

If you are considering participating in a dose escalation study, you may have questions about how the dose levels were determined and what safety information already exists.

Other Resources

NCI Thesaurus

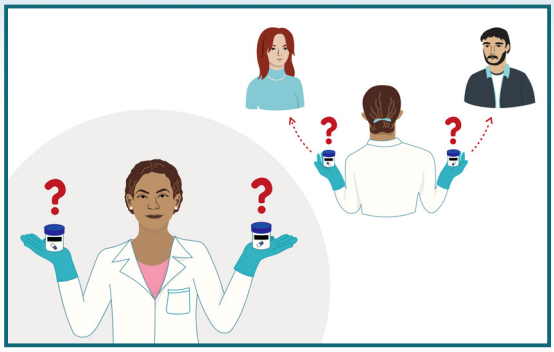
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

double-blind study

cdisc

A study that is set up so that the study treatment that each participant receives is not known by the participants or the researchers.



Example of *double-blind study* in a sentence

In a double-blind study, the study participants and the study doctor don't know which treatment each participant is getting.

More Info

Double blind studies are done to minimize bias that can affect the study results.

Bias can occur when participants or researchers know which study treatment participants are getting.

Participants can ask to find out which study treatment they received after the study ends.

Related Words

masked study
blinded study
masking
blinding
bias
single-blind study
randomization

Other info to think about when joining a study

If you are considering joining a double-blind study you can ask questions about how your safety will be monitored. If there is an emergency, it is possible to find out what study treatment you are taking so you can receive the medical care you need.

Other Resources

NCI Thesaurus

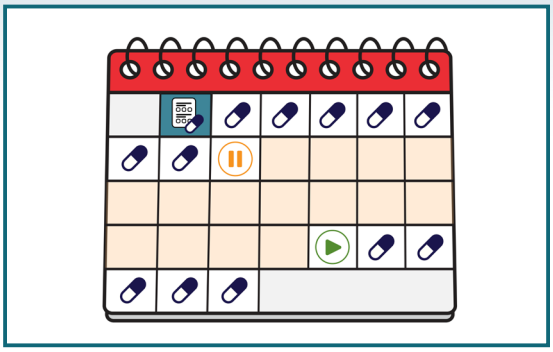
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

drug holiday

cdisc

A time period decided between the participant and study team when a medication is stopped and then re-started.



Example of *drug holiday* in a sentence

A person should always check with the study team and their doctor before stopping any medicine or taking a drug holiday.

More Info

A drug holiday is a planned break from taking a medicine or study treatment.

People may take a drug holiday for study reasons, a health issue, or personal reasons. For example, having surgery may mean that all current medications, including any study treatments, need to be paused.

A person should not stop taking any prescription or study medications without first discussing with their doctor and the study team first.

Related Words

medication vacation

Other info to think about when joining a study

If you are in a research study and would like to take a planned "drug holiday" to stop taking the study treatment you should first discuss it with the study team.

Any time you plan to pause any of your prescribed medications you should ensure this is safe with your regular doctor and discuss how to stop taking your medications safely.

Feel free to ask any questions you have about taking a drug holiday.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

drug therapy

cdisc

The use of medicine to treat a disease, condition, or symptom.

Example of *drug therapy* in a sentence

Clinical trials are done to learn more about the risks and benefits of a drug therapy.

More Info

There are many different types of drug therapy that can have multiples different purposes.

A drug therapy could be used to:

- make symptoms better,
- treat a condition or disease,
- lower the risk of getting a disease in the future,
- or destroy harmful cells, like cancer cells.

Related Words

Pharmacotherapy
Pharmaceutical therapy
Biologic
drug

Other info to think about when joining a study

If a research study is testing a drug therapy it is important to understand the possible risks and benefits.

You can ask questions during the consent process, but also anytime during the study if any new questions come up. The study team is there to make sure you stay safe while you are taking a drug therapy.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

e-consent (form)

cdisc

An electronic version of an informed consent form.

Example of *e-consent (form)* in a sentence

An e-consent form can be useful in studies that are being conducted remotely.

More Info

E-consent is a method of obtaining informed consent through the use of an electronic system instead of a paper consent form.

Participants may sign the form electronically and then they may be able to get a copy emailed to them or download it themselves.

Related Words

electronic informed consent

digital consent

consent form

decentralized clinical trials

Other info to think about when joining a study

A study may have an e-consent form to join a study.

You could ask if you get a copy of the e-consent form and how you will get that copy. You could also ask if there is a paper version of the consent form for you if you want one.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

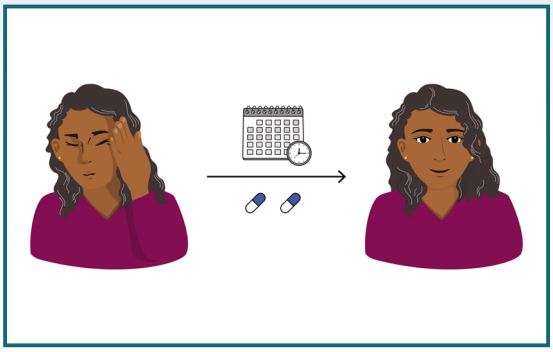
effectiveness

cdisc

How well a treatment works.

Example of *effectiveness* in a sentence

Effectiveness refers to how well a treatment, medicine or vaccine works in people who use it after it has been approved.



More Info

Effectiveness refers to how well a treatment works in the real world, not in a planned clinical trial. Usually effectiveness is assessed after approval by health or government authorities.

Related Words

efficacy

Other info to think about when joining a study

The word effectiveness commonly comes up in the context of already approved medications. In contrast, efficacy, refers to how well a study treatment works in a study. The words "effectiveness" and "efficacy" are sometimes used to mean the same thing even though they have slightly different meanings.

Other Resources

NCI Thesaurus

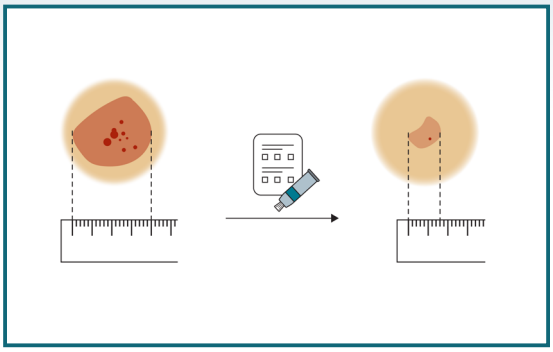
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

efficacy

cdisc

How well a study treatment works in the study.



Example of *efficacy* in a sentence

A study tests efficacy to see how well a new treatment works.

More Info

Efficacy is different from "effectiveness" which refers to how well the treatment works in the real world outside a study.

Related Words

effectiveness

Other info to think about when joining a study

The word "efficacy" can be used to describe how well the investigational intervention works in the controlled setting of a study. This term may be used when researchers describe an objective in the study. For example, a study could be testing the efficacy of a new intervention.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

eligibility criteria

cdisc

The reasons a person can be included in, or excluded from, a study.

Example of *eligibility criteria* in a sentence

A study has eligibility criteria to make sure only people who fit the study requirements join as participants.

More Info

The eligibility criteria for a study are made up of inclusion criteria and exclusion criteria. For example, a study may be looking to include only people of a certain age or with a certain health condition.

Related Words

inclusion criteria

exclusion criteria

Other info to think about when joining a study

If you are interested in joining a clinical trial, the study team will ask you some questions and possibly do some medical tests to make sure you meet the eligibility criteria. This is for your safety and for scientific reasons so participants all meet specific criteria.

If you do not meet the eligibility criteria for one study, you can ask the study team if there are other studies that you could be a good fit for.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

Emergency Use Authorization (EUA) cdisc

A process to make a treatment or vaccine available during a public health emergency, before all research is complete, and before full approval is granted.

Example of *Emergency Use Authorization (EUA)* in a sentence

Regulators decide whether to allow an Emergency Use Authorization.

This graphic represents concepts that follow a regulatory review process.

More Info

An Emergency Use Authorization (EUA) makes medical treatments and vaccines available when the public's health is at risk, such as during a pandemic.

Under an EUA, medicines and vaccines are still being tested but the approval process is fast-tracked in order to make interventions available more quickly.

An EUA applies to the USA only. Other countries have different rules and regulations.

Related Words

Other info to think about when joining a study

The term "Emergency Use Authorization" may be something you heard during the COVID pandemic. If a treatment or vaccine is made available under an EUA, you may hear that there are still research studies to collect more data about the product.

Other Resources

NCI Thesaurus

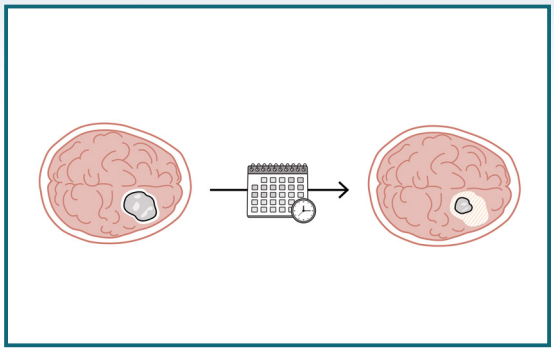
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

endpoint

cdisc

A measure of the expected effect of the study treatment.



Example of *endpoint* in a sentence

An endpoint is one of the main questions the study is trying to answer.

More Info

A study could have more than one endpoint. Some examples of endpoints that are used in studies include finding out more about a disease or condition, participant quality of life, or symptoms.

Related Words

clinical endpoint
outcome
primary endpoint
secondary endpoint
surrogate

Other info to think about when joining a study

The term "endpoint" is used to describe what the study will be looking at to see if the study treatment had an effect. You could see this term in consent documents or other descriptions of the study, including study results reports.

In general, the endpoint is reported as an average of all the data collected in the study. You may not have the same results as the overall study found. For example, a study treatment may have lowered blood pressure overall for study participants, but your blood pressure may not have changed while taking the study treatment.

If you have any questions about the study endpoint, you can ask the study team.

Other Resources

NCI Thesaurus

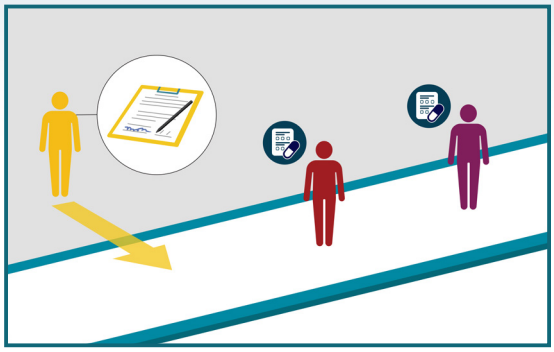
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

enroll

cdisc

The action of a participant joining the study after providing informed consent.



Example of *enroll* in a sentence

If you enroll in a study, it means you decided to volunteer to be a participant.

More Info

In order to enroll in a study, a person must meet the eligibility criteria.

Study participation is your choice. It is voluntary.

If the study includes randomization, this would be occur after the participant enrolls.

Related Words

join
informed consent
consent form
eligibility criteria
inclusion criteria
exclusion criteria
randomization

Other info to think about when joining a study

You may hear the term "enroll" when the study team is asking if you want to join the research study. You may need to provide your informed consent by signing a consent form before you can enroll in the study.

Do your best to understand everything you will be asked to do if you enroll in a study. Feel free to ask the study team any questions you have about the study. In many cases, you will be able to take the time to go home and think about it before deciding to enroll in a study.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

epidemiologist

cdisc

A person who studies where, why, how often, and to what populations health concerns and diseases happen.

Example of *epidemiologist* in a sentence

An epidemiologist analyzes data to look for patterns and causes of diseases or other health conditions in large groups of people.

More Info

Some studies include epidemiologists because they help search for the cause of a disease and identify who might be at risk.

Epidemiologists also help figure out how to control or stop the spread of a disease.

Related Words

Disease detective

Other info to think about when joining a study

An epidemiologist tends to look at population health rather than individual health. If you learn that an epidemiologist is a member of the study team, this means there is someone looking at how the disease or condition being studied affects large groups of people.

Other Resources

NCI Thesaurus

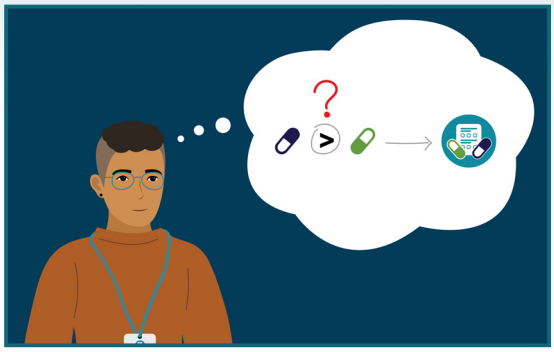
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

equipoise

cdisc

An ethical reason for doing research when researchers do not know if one treatment is better than another for a disease or condition



Example of *equipoise* in a sentence

When study treatments are given in a randomized clinical trial there is equipoise because researchers have real questions about whether one is better than another.

More Info

Equipoise is important in any study that compares one treatment or intervention with another. Research is ethical if there is genuine uncertainty about which treatment or intervention is better.

If there is good evidence that one treatment is better than another, it would be wrong for researchers to give the less effective one. Equipoise means all treatments in the study are reasonable choices based on what is known.

Related Words

clinical research
clinical trial
randomization
comparator

Other info to think about when joining a study

You could see the word "equipoise" in the study description or when learning about clinical research more generally.

Equipoise is when there is a real question about whether one study treatment is better than another. It is required for study teams to conduct ethical research.

You can talk to the study team about why they are studying a certain treatment and why they set up the study in the way they did.

Other Resources

NCI Thesaurus

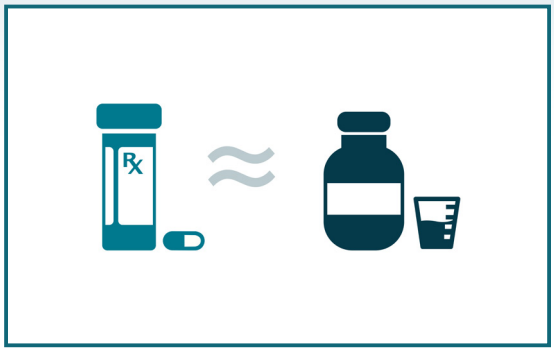
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

equivalence

cdisc

When two or more things in a study are about the same.



Example of *equivalence* in a sentence

In clinical research, equivalence often refers to whether two study treatments are almost the same.

More Info

Treatments, therapies, vaccines, evaluation methods and study groups do not have to be exactly equal in order to have equivalence.

Instead, equivalence means that the treatments are about the same in terms of how they work for patients.

Related Words

- similarity
- resemblance
- equivalence study
- non-inferiority study
- equal

Other info to think about when joining a study

You may see the word "equivalence" when a study is trying to see if two or more study treatments have the same effect, or if a study has shown there is equivalence between study treatments.

You may want to ask about whether there are any known possible differences between study treatments that would be important for you to understand given your own personal health concerns and issues.

Other Resources

NCI Thesaurus

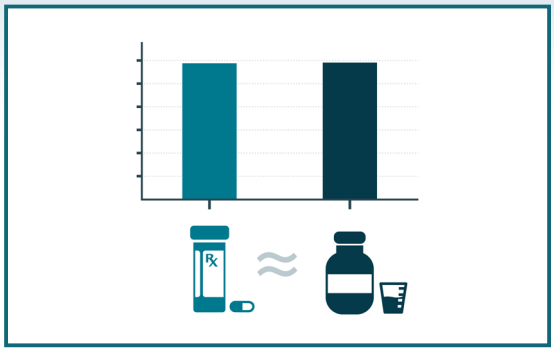
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

equivalent (effect)

cdisc

The same or almost the same result.



Example of *equivalent (effect)* in a sentence

In research, an equivalent effect means that different study treatments or medication doses have about the same effect on patients.

More Info

An equivalent effect doesn't mean two treatments are exactly equal. Two treatments are equivalent if they have about the same risks and benefits.

Related Words

same
similar
equal outcome

Other info to think about when joining a study

The word "equivalent effect" could be used to explain that one study treatment has a similar effect as another one.

You may want to ask about whether there are any known possible differences between study treatments that would be important for you to understand given your own personal health concerns and issues.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

eSignature

cdisc

A way for a person to sign their name using a computer or device, instead of signing on paper.

Example of *eSignature* in a sentence

An electronic device can be used to get a participant's eSignature to confirm their agreement to join a research study.

More Info

eSignature can have different meanings in different contexts or countries.

There are a few different ways to provide an eSignature:

- a participant could be asked to provide an eSignature by using their finger or a stylus to sign their name on a digital form instead of a piece of paper.
- a participant could be asked to type their name into an electronic document as their eSignature.

Related Words

informed consent

consent form

Other info to think about when joining a study

You might hear about or see the term "eSignature" being used in a research study you are thinking about joining.

You can ask any questions about the documents you are signing, whether it be an ink signature or an eSignature.

You have the right to understand the information before you sign a clinical research consent form. You can also ask for the study team to give you a copy of the signed consent form.

Other Resources

NCI Thesaurus

EFGCP—eConsent Initiative

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

evaluate

To examine, review, and understand.

Example of *evaluate* in a sentence

A study team member will evaluate the effect of the study treatment at participant study visits.

More Info

The study doctor evaluates the participant's response and safety in order to decide whether to continue the participation in a research study. The researchers also evaluate the quality of the data from a study to analyze the outcome.

Related Words

- assess
- check
- check out
- learn
- judge
- appraise

Other info to think about when joining a study

You may see the term "evaluate" if you look up your study on clinicaltrials.gov or in the consent form. You may hear about participants being evaluated during the study based on certain measurements. This term may also come up when talking about evaluating the safety or efficacy of a new therapy or device.

If the consent form talks about evaluating the participant, you may want to ask how they will evaluate you. Additionally, if the researchers are evaluating the efficacy or safety of a study treatment or device, you may want to know more about how they are going to do this and how the data will answer the study questions.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

exclusion criteria

cdisc

A list of reasons a person cannot be included in a study.

Example of *exclusion criteria* in a sentence

If someone wants to join a study, they can not have any of the exclusion criteria.

More Info

Exclusion criteria are reasons that researchers cannot include a person in a research study. For example, if a study is only enrolling adults with diabetes, a person who does not have the condition could not take part.

Related Words

eligibility criteria

inclusion criteria

Other info to think about when joining a study

You may see the term "exclusion criteria" when learning about reasons why you might not be able to be included in a research study.

The study team will ask you some questions and possibly do some medical tests to confirm you can be included. This is for your safety and for scientific reasons to make sure you do not meet the exclusion criteria.

If you are unable to join one study, you can ask the study team if there are other studies that could be a better fit for you.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

expanded access

cdisc

A process for a doctor to request an unapproved treatment for a seriously ill patient.

Example of *expanded access* in a sentence

Doctors can seek approval to use a study treatment outside of research via an Expanded Access application.

This graphic represents concepts that follow a regulatory review process.

More Info

Expanded Access is a path for a patient with an immediately life-threatening or serious disease or condition to access an investigational medical product (like a drug, biologic, or medical device). Expanded Access can make treatment outside of clinical trials possible when no other treatments are available and there is no clinical trial for the patient to join.

Expanded Access is also called "compassionate use." Expanded Access is a program for doctors to request treatments that are not yet approved for seriously ill patients. This request is made by a patient's doctors using the Expanded Access application. The company that makes the experimental drug also has to approve the request.

Related Words

compassionate use
emergency use
pre-approval access

Other info to think about when joining a study

The concept of "Expanded Access" may be discussed if you are seriously ill or have a life-threatening condition, and the available treatments do not work for you.

"Expanded Access" may also be discussed with you if there is no clinical trial for you to enroll in.

You can always discuss with your doctor if there is a new unapproved treatment that could be requested via expanded access. It is important to note that Expanded Access is for treatment; it is not considered research.

Other Resources

NCI Thesaurus

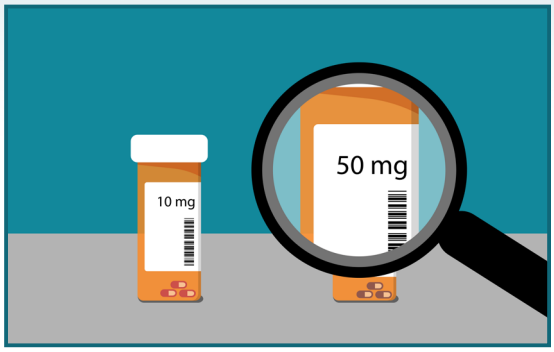
FDA - Expanded Access

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

experimental

Something that is being tested in research but not yet proven.



Example of *experimental* in a sentence

An experimental medicine is studied before it is approved.

More Info

Experimental treatments go through research studies to make sure the risks and benefits to participants are better understood.

Before a drug, vaccine, or device is approved by regulators for a particular use, disease, or group of patients it is considered to be experimental.

Related Words

investigational

Other info to think about when joining a study

Clinical research is designed to find out more about health, disease, prevention and treatment.

The word "experimental" may be used to describe what a research study is testing, for example an experimental treatment. This means that the treatment has not yet been proven or approved but there is reason to believe that it might work well.

Through research, experimental treatments can become approved treatments. If you have any questions about anything experimental in a research study, you should ask the study team.

Other Resources

NCI Thesaurus

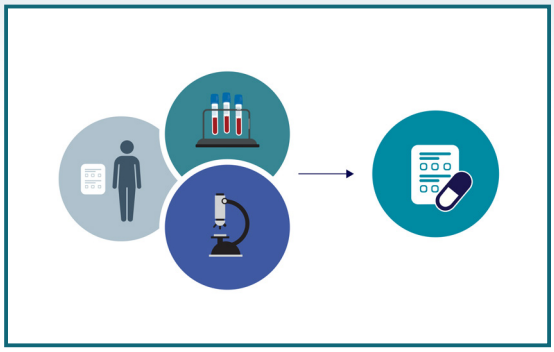
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

exploratory research

cdisc

A process to find facts that can guide the design of future studies.



Example of *exploratory research* in a sentence

Exploratory research is helpful to find out how to approach future research questions.

More Info

Exploratory research clarifies the question to be solved. It does not result in final conclusions or solutions.

Exploratory research can test whether a method or study design can be used, or whether an outcome can be measured in a reliable way.

Sometimes exploratory research is done using samples stored in biobanks.

Related Words

pilot

preliminary studies

Other info to think about when joining a study

You may see the term "exploratory research" to describe early research that was done to figure out processes and inform the next study.

If you are thinking about joining a research study, you can always ask what exploratory research informed the design of the study, or what exploratory research might be conducted with the data that is collected during the study.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

focus group

cdisc

A group interview to learn what people think about a topic.

Example of *focus group* in a sentence

A focus group offers participants a chance to discuss their experiences with each other and the researcher.

More Info

A focus group is a way to get many different people together to hear about what they think about a certain topic. A focus group is usually led by a member of the study team. Since focus groups collect information from a few people at the same time it is important to respect everyone's privacy when participating and not share details about the other people outside the study.

Related Words

group interview

Other info to think about when joining a study

You may be asked to participate in a "focus group" as part of a study. You may ask any questions about the focus group such as what information will be collected, how data will be collected, whether the focus group will be recorded, whether there will be a note taker, and how many people will be in the room.

You can also ask how the data will be used and/or shared, and how your privacy will be protected. Feel free to ask any questions you have about being in a focus group.

Other Resources

NCI Thesaurus

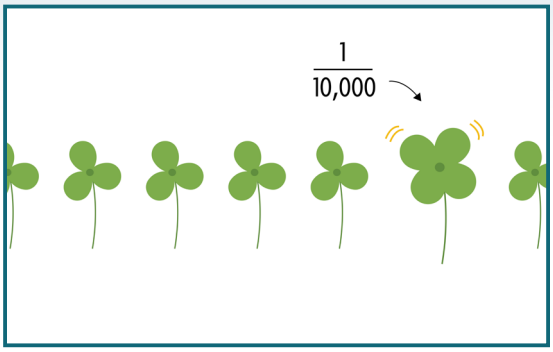
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

frequency

cdisc

How often something happens over a period of time.



Example of *frequency* in a sentence

The frequency of study visits should be clear to anyone joining a research study.

More Info

Frequency refers to how many times something will happen. It also describes the number of times something occurs in a specific period of time.

Related Words

number
prevalence
recurrence
repeat
incidence

Other info to think about when joining a study

The word "frequency" can be used in many different situations. For example, this term could be used to talk about the "frequency of study visits" you may have to make if you participate in the study. This term could also be used to talk about how often you have to take the study treatment or how often you need to fill out a questionnaire. If you experience some type of symptom while taking the investigational product, the study team may ask about the frequency of these symptoms.

If you have any questions about how often you have to do something in order to participate in the study, please ask the study team.

Other Resources

NCI Thesaurus

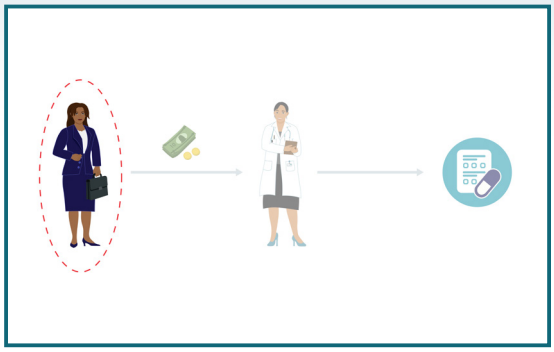
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

funder (research)

cdisc

A person or group that provides money and other resources to do a research study.



Example of *funder (research)* in a sentence

The funder provides money and resources for the research but is not involved in the study conduct.

More Info

There are many different types of funders, such as:

- Sponsors, like pharmaceutical companies that can be both the sponsor and funder for a research study.
- Government agencies that give research grants.
- Foundations and organizations interested in studies that are important to them and their patient communities.
- Non-profit organizations, like the Gates Foundation.
- Individuals, like philanthropists, who give or raise money to cover the costs of specific research.

Funders could provide the money necessary to run a research study but they can also provide other things like the study treatment, comparators, the placebo, or other resources necessary to run a research study.

The funder is not ultimately responsible for the study conduct; it is the sponsor and the principal investigator who are ultimately responsible.

Related Words

sponsor

Other info to think about when joining a study

You might see the term "funder" in a consent form or protocol about a study, and also on clinical trial recruitment websites.

You can feel free to ask the study team who or what organization is funding the study.

Other Resources

NCI Thesaurus

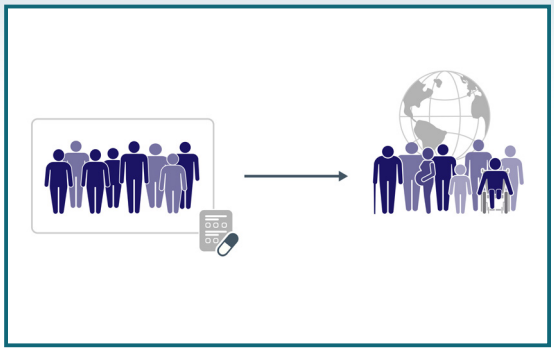
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

generalizability

cdisc

How research results can apply to people who were not part of the study.



Example of *generalizability* in a sentence

A study has generalizability if the results are useful and can apply beyond the original study participants.

More Info

Ideally, research findings should have generalizability to people outside of the study.

Good generalizability means research results can be broadly applied to a large number of people who are similar in some way .

Poor generalizability means that the results can only be applied to the study population or very specific situation.

Related Words

usefulness

meaning

Other info to think about when joining a study

You may hear the term "generalizability" when the study team is describing what they hope the outcome of the research study will be.

You could ask the study team at the beginning of the study if they expect the research results to have generalizability to larger groups. You can also ask how generalizable the results are likely to be.

The word may also be used in publications about research, especially in the "discussion" section.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

genetic testing

cdisc

A medical test that could identify a health risk to a person or their biological family members by looking at their genes (DNA).

Example of *genetic testing* in a sentence

Genetic Testing is done on cells from blood, tissues, and other fluids from the body.

This graphic represents genetic terms in this glossary.

More Info

In clinical research, genetic testing looks for changes in DNA that are different from what is most common.

Genetic testing is done on DNA, which is the genetic material found in cells. DNA provides instructions for how the body grows and develops. Changes or differences in DNA are called variants. Some variants may be linked to increased risk for a disease and affect personal health. However, not every variant is understood or has a known health effect, and more could be learned about its effect in the future.

Related Words

variant
mutation
SNP

Other info to think about when joining a study

You may hear the term "genetic testing" from both your regular doctors and researchers involved in studies. You may even hear about genetic testing kits that you can buy yourself.

Some research studies may have genetic testing as part of the study or offer it to participants if they are interested. If genetic testing is part of a research study, you may want to ask more questions, including what information could be learned during testing, what different results could mean for you or your biological family members, and if there are any risks associated with the testing. Sometimes differences are found but whether those differences are important is unclear. Discussing these possibilities with the study team could be helpful.

You may want to ask if you will receive the results from genetic testing and if these results will be shared with anyone else besides the study team. You may also want to ask if there will be a genetic counselor to explain the results to you if the study team shares this information with you.

Other Resources

NCI Thesaurus

NIH—Talking Glossary of Genomic and Genetic Terms

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

hazard ratio

cdisc

A measure of risk that compares two treatments in the same study.

Example of *hazard ratio* in a sentence

Studies with more than one group use hazard ratios to compare whether one group has more adverse events than the other.

This graphic represents math and statistics terms in this glossary.

More Info

The hazard ratio is the relative risk of an event happening in one group compared to another.

For example, in a drug study, the group getting the study treatment may have headaches two times more than the control population. The hazard ratio would be 2, meaning that the study treatment group has twice the chance of getting headaches compared to the comparison group.

Related Words

progression-free survival

relative risk

Other info to think about when joining a study

You might see the word "hazard ratio" in research reports and articles that describe the results of research studies. This is a technical math term and will not usually be used in materials designed especially for patients and participants.

If you see this word in a study document for a study you are considering, enrolled in, or completed, you can ask the researcher or study team any questions you might have.

Other Resources

NCI Thesaurus

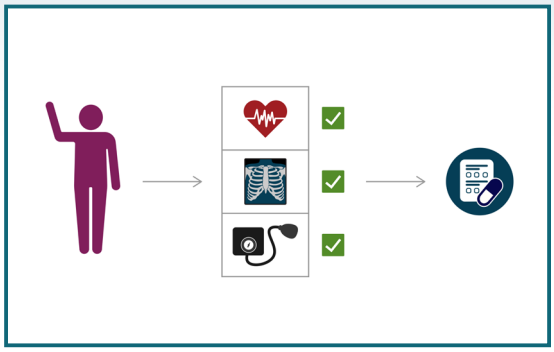
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

healthy volunteer

cdisc

A study participant who does not have a disease or condition, including the one being studied.



Example of *healthy volunteer* in a sentence

A healthy volunteer should not have any known diseases or conditions.

More Info

A healthy volunteer may test the study treatment's safety or be the comparison (control) during the study.

Related Words

- participant
- subject
- study participant
- research participant
- research subject
- study subject
- healthy control

Other info to think about when joining a study

Some studies recruit healthy volunteers. You may see the term "healthy volunteer" in the consent form or other information about the study.

If you are healthy and wish to volunteer for a study, you will be screened to make sure you meet the study criteria. Feel free to ask the researchers any questions you might have about what the study is about and what you will be asked to do if you join.

Other Resources

NCI Thesaurus

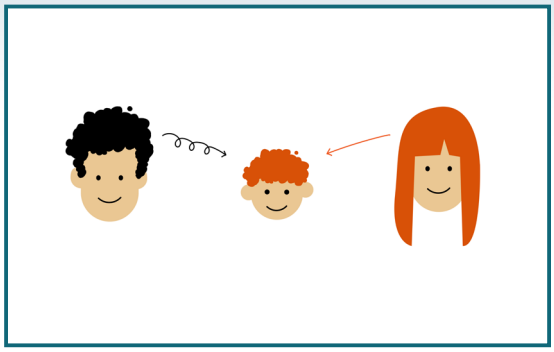
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

hereditary

cdisc

A parent's features and traits being passed to their biological children before birth.



Example of *hereditary* in a sentence

A parent's features and traits being passed to their biological children before birth.

More Info

Some physical or behavioral traits are hereditary. This means the traits are transferred from the parents to their biological children through genes and before the children are born.

Related Words

genotypic
phenotypic
mental health
physical info
traits (the manifestation of genetic information)

Other info to think about when joining a study

You may see the term "hereditary" used in a variety of different situations. It could be used when explaining why a disease might develop or a study to look at hereditary condition.

For example, hereditary may be used in a consent form to describe a type of disease that is being studied.

If you are confused or have questions, you should feel free to ask your study team for more information.

Other Resources

NCI Thesaurus

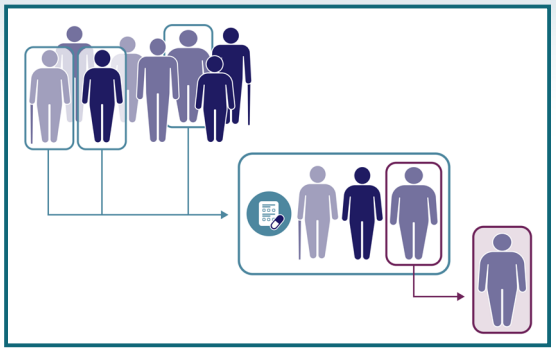
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

human subject

cdisc

A person who participates in a research study.



Example of *human subject* in a sentence

The term human subject is sometimes used in legal research documents instead of 'study participant.'

More Info

A human subject is a person in a research study.

The term "human subject" was first used in research regulations in the 1970s. Since then, there has been a growing appreciation that 'human subjects' should be called 'participants' because they are active partners in the research. Participants share in the experience of advancing science and medicine.

Although the term "human subject" is still used in some legal or regulatory documents, the term "study participant" is more respectful.

Related Words

- study participant
- participant
- study subject
- subject
- research participant
- research subject
- volunteer
- healthy volunteer

Other info to think about when joining a study

If you are planning to join a research study, you may see the term "human subject" used in some of the formal documents you are given to review and sign. This is often because there is still some legal language that uses the term instead of "participant."

Your contribution to science is very important. Please know that regardless of what term is used to describe study participation, the scientific community is grateful if you choose to join a study.

If you have any questions about participating in a study, you should feel free to ask the study team and talk with someone you trust about whether to enroll."

Other Resources

NCI Thesaurus

NIH— Definition of Human Subjects Research

FDA— Comparison of FDA and HHS Human Subject Protection Regulations

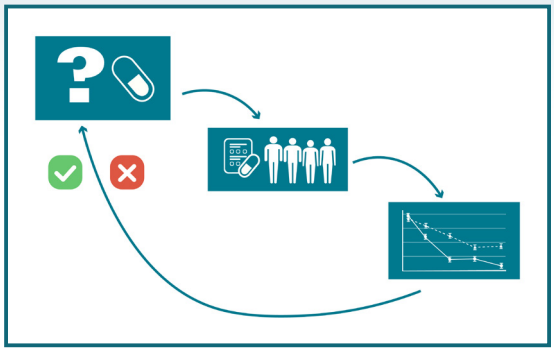
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

hypothesis

cdisc

An idea that is tested in a research study.



Example of *hypothesis* in a sentence

The hypothesis in a research study is tested to see if it is true or not.

More Info

A hypothesis is sometimes described as an educated guess, idea, or question that is a starting point for research. The hypothesis is usually presented as a statement, that is tested during the research.

For example, a research study may have the hypothesis that one treatment causes fewer side effects than another. The study would be designed to test whether that
is true.

Related Words

premise
supposition
thesis
theory

Other info to think about when joining a study

The word "hypothesis" may be used in discussions about what researchers are trying to learn through the study. You may see this word in the title of the study you are thinking of participating in or in the background information

You may also hear the study team talking about testing their hypothesis through the research. The word "hypothesis" can also appear in publications about the statistics and data collected from the study.

You can always ask the study team about the hypothesis that is being tested through the research.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

immune response

cdisc

The body's reaction to a substance, illness, or infection.

Example of *immune response* in a sentence

An immune response is the body's way to fight something it thinks might be harmful.

More Info

The immune response is how the body identifies and defends itself against germs like bacteria, viruses, and substances that seem to be harmful. An immune response helps the body stay safe.

For example, a vaccine works by causing an immune response so that the body can fight off the germ, and remember to attack it if the germ ever comes back.

Related Words

Immune system
antibody
antigen

Other info to think about when joining a study

You may see the term "immune response" used in a variety of ways in the research study context. For example, a study may be researching participants' immune responses to certain things or how different investigational products may affect a person's immune response.

If you have questions about a study that is looking at immune response, be sure to ask your study team for more information.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

incentive

Something that supports or encourages research participation.

Example of *incentive* in a sentence

An incentive to join research might be to help researchers learn more about a condition or find a new treatment.

More Info

Incentives for research participation can be feeling good personally, receiving a gift card or payment, or getting entered into a raffle.

Incentives can also include payment beyond the costs of participating or access to free medication. Incentives often help enrollment.

A participant should never feel that an incentive pressures them to join the study or remain in the study.

Related Words

offer

motivation

Other info to think about when joining a study

You may hear the term "incentive" before you enroll in a study. The study team may provide incentives for you showing up to study visits or when you complete the study.

You may want to ask if study incentives could impact your eligibility for any social benefits if you are using things like SNAP or are on disability. Incentives can be in the form of money and may need to be reported on your taxes.

You should feel free to discuss with the study team whether any kind of incentive will be offered and in what form."

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

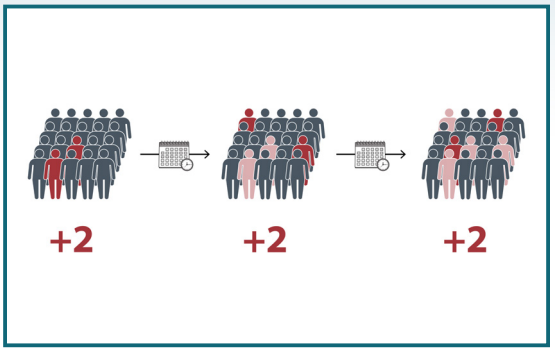
incidence

cdisc

Number of new cases or events during a period of time.

Example of *incidence* in a sentence

The incidence rate tells us how many new cases of a specific disease or condition develop during a certain period of time.



More Info

Measuring the incidence is a way to keep track of how many new cases or events happen in a population at risk during a given time period.

The incidence is generally reported as a rate.

For example, in a study with 10 participants, if 3 people report headaches after taking the study medication and 7 do not, the incidence of headaches is 30% (3/10 = .3 or 30%).

Related Words

frequency
prevalence
rate

Other info to think about when joining a study

You might see the word "incidence" used to describe the frequency of a disease or condition.

The word can also be used to describe the expected or actual number of adverse events in a study.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

inclusion criteria

cdisc

A list of requirements a person must meet to take part in a study.

Example of *inclusion criteria* in a sentence

If someone wants to join a study, they must meet all the inclusion criteria.

More Info

For example, if a study is for adults only, a person can only consider joining if they are 18 years of age or older.

Related Words

eligibility criteria

exclusion criteria

Other info to think about when joining a study

You may hear the term "inclusion criteria" when researchers talk about who can join a study.

There may be reasons why a person cannot be included in a research study.

Before you join a study, the study team will ask you some questions and possibly do some medical tests. This is for your safety and for scientific reasons to confirm that you meet the requirements of the study.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

informed consent

cdisc

The process of learning and discussing the details of a research study before deciding whether to take part.

Example of *informed consent* in a sentence

Informed consent is required for most research studies before a person can join as a participant.

More Info

Informed consent is an ongoing conversation that occurs before someone can participate in a study and whenever information about the study changes.

A consent form is used as part of the informed consent process.

Related Words

consent

consent form

Other info to think about when joining a study

You may hear about "informed consent" often before you join a research study, and throughout your participation. A member of the study team will explain the research and answer any questions you have.

Before you agree to join a study, you should understand what the research is about and what you will need to do if you enroll.

Do not be afraid to ask as many questions as you need to. Someone from the study team should answer and clarify anything that is confusing. You can also take time to think about whether you want to join a study or not.

Other Resources

NCI Thesaurus

FDA - Informed Consent for Clinical Trials

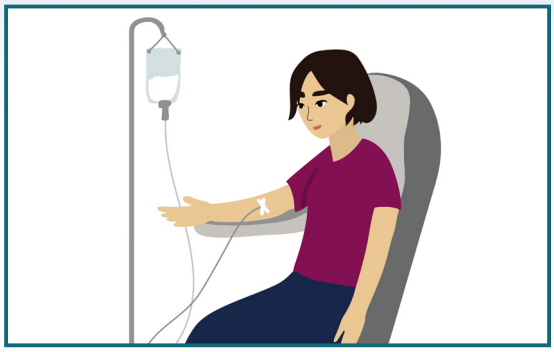
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

infusion

cdisc

A way to give a fluid to the study participant, usually through a vein.



Example of *infusion* in a sentence

A study treatment given to a participant through their vein is an infusion.

More Info

In an infusion, the fluid could be a study treatment or other liquids, like ones that are given for hydration.

Related Words

intravenous infusion
intravenous injection
intervention

Other info to think about when joining a study

The term "infusion" will be used if there is a study treatment that is given through an infusion. If you are thinking about joining a study that has one or more infusions, you can ask what the infusion is for and what it contains.

You can always ask the study team to clarify any study procedures.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

Institutional Review Board (IRB)

cdisc

A team of people who review studies to protect the rights and welfare of study participants.

Example of *Institutional Review Board (IRB)* in a sentence

Participants can only enroll in a study after an IRB reviews and approves the study protocol.

More Info

An IRB must approve a research study before it starts. The IRB uses rules and regulations to make sure the research is ethical and the participants who enroll are protected. An IRB is sometimes also called an Ethics Committee.

The IRB members are not part of the study team. They are separate and conduct an independent review. IRB members come from different backgrounds and have medical, scientific, and non-scientific experience.

IRBs were created in the 1970s to respond to unethical research. They protect the rights and welfare of participants.

Related Words

committee for the protection of human subjects

independent ethics committee

independent review board

research ethics committee

ethics committee

Other info to think about when joining a study

You may see the term "institutional review board" in the consent form in a section about which group approved the study.

You may also hear members of the study team talk about the IRB and getting the IRB's approval before any study activities can take place.

The contact information of the IRB that is overseeing a study should be included in the consent form. You can reach out to the IRB if you have any concerns or complaints about your experience being in a research study.

Other Resources

NCI Thesaurus

HHS - How IRBs Protect Human Research Participants

If you know of other resources we should link to to help explain this word, please contact us.

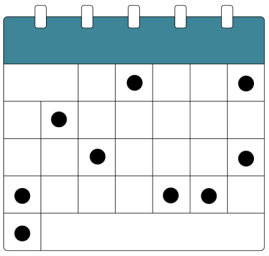
Clinical Research Glossary

intermittent

Not regular or predictable.

Example of *intermittent* in a sentence

The participant reported intermittent dizzy spells since the last study visit.



More Info

When something is intermittent, it means that it happens more than once, but does not happen on a schedule, is not planned, and is not predictable.

Related Words

- time to time
- randomly
- occasionally
- on and off
- every so often
- infrequently

Other info to think about when joining a study

The term "intermittent" may come up when discussing adverse events that could happen during a research study. You can always discuss with the study team any questions you have about the possible adverse events in a study.

Other Resources

NCI Thesaurus

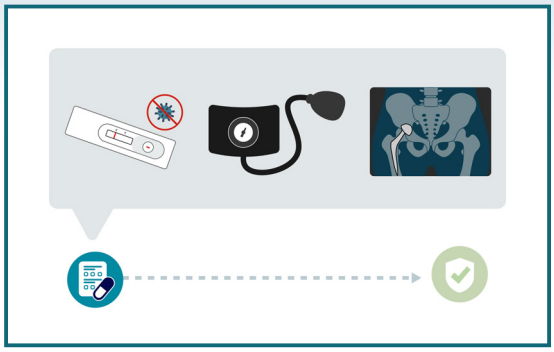
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

investigational device

cdisc

A medical tool, instrument, or test that has not yet been approved for the reason being studied in the research.



Example of *investigational device* in a sentence

An investigational device can be studied to find out how safe it is and how well it works.

More Info

In healthcare, investigational devices can include things like new thermometers, new genetic test, tests to diagnose an illness, or even computer programs.

Some investigational devices that are used inside the body, like insulin pumps, pacemakers, and deep brain stem stimulators.

There are also investigational devices that are used outside the body, like hearing aids, genetic tests, insulin readers, and "smartwatch" wearables.

Researchers get approval before using an investigational device in a research study that enrolls people.

Related Words

implantable device

medical test

Investigational Device Exemption (IDE)

Other info to think about when joining a study

You might see the word "investigational device" in a research consent form.

If you have an investigational device inserted into your body as part of a research study, it is important to understand the risks and benefits, as well as what will happen to the device when the study is over.

If the research involves randomization, you can ask to find out more about what each study group will receive.

You can also clarify if the investigational device will be removed from you and returned back to the researchers when your time in the study is over.

If the device will not be removed, you can find out more about who to contact with questions about maintaining the device or how the device could affect your future medical care.

Even for investigational devices that are outside the body, you could still ask if you will get to keep it. For example, if you will be able to keep using an insulin reader from a study, or will have to return it.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

Investigational Device Exemption (IDE) cdisc

An approval given by the United States Food and Drug Administration to use a medical tool, instrument, test, or method in a study that enrolls people.

Example of *Investigational Device Exemption (IDE)* in a sentence

Researchers submit an Investigational Device Exemption application to the FDA to get permission to study a device's safety and find out how well it works in people.

More Info

The Investigational Device Exemption (IDE) application is specific to the United States (US).

Researchers submit an IDE application to the US Food and Drug Administration (FDA) for approval to study its effectiveness and safety. After approval, the research is said to be done "under an IDE."

Some, but not all, investigational devices need an IDE before they can be studied in people. High-risk devices require an IDE before they can be used in a study.

Related Words

investigational device

implantable device

Other info to think about when joining a study

You may see or hear the term "investigational device exemption" if you are thinking about joining a study that is using a medical object or medical test that has not yet been approved by the US FDA.

If you join a study that is testing a device under an IDE, you can learn more about the device and ask what safety information the study team already has. Because there is an IDE, these devices could be riskier, so you can always ask what potential risks the study team already knows about and how they plan to keep participants safe.

If an investigational device is put into your body, you may want to learn more about what will happen to it when the study is over.

You can also ask about what kind of care you will have access to if any harm or injury occurs that was possibly caused by the investigational device.

Other Resources

NCI Thesaurus

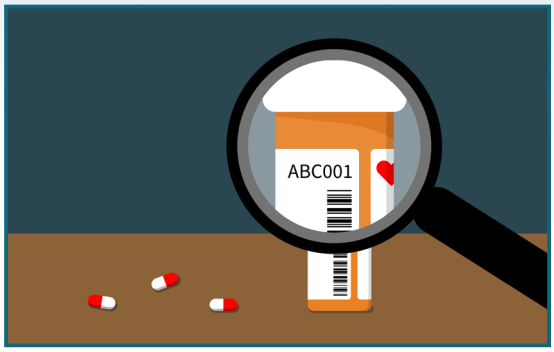
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

investigational medicine

cdisc

A treatment or drug that is not yet approved for the condition being studied.



Example of *investigational medicine* in a sentence

Being in a research study is one way a patient might have access to an investigational medicine.

More Info

Every country has health authorities or government agencies that review and approve studies of investigational medicines. They then use the study data on risks and benefits to decide whether the investigational medicine is safe and effective and whether it can be approved for the condition or purpose.

Related Words

- investigational use
- experimental drug/ medicine
- study treatment
- intervention
- investigational product
- investigational drug
- study medication
- study medicine
- drug candidate

Other info to think about when joining a study

You may learn about an "investigational medicine" if you are thinking about joining a study that is looking at a treatment that is not yet approved. Your doctor or the study team may mention the investigational medicine in discussions or in the consent form.

You could ask the study team to explain more about why the investigational medicine is being studied. You may also want to ask about how the investigational medicine has been studied before and what the study objectives are.

Other Resources

NCI Thesaurus

University of Rochester - Using Investigational Medicines

FDA - Understanding Investigational Drugs

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

Investigational New Drug (IND) application

cdisc

An application to the United States Food & Drug Administration (FDA) to get permission to use a drug in a research study that enrolls people.

This graphic represents concepts that follow a regulatory review process.

Example of *Investigational New Drug (IND) application* in a sentence

Researchers submit an Investigational New Drug application to the FDA to get permission to study a new use for a drug.

More Info

The Investigational New Drug (IND) application is specific to the United States (US). Researchers testing a new drug, or an approved drug for a new use, must get approval of an IND from the US Food and Drug Administration (FDA). The FDA is a government agency that regulates drugs and devices that are used in patients. Once approval is obtained, the research is often said to be conducted "under an IND."

Similar processes exist elsewhere in the world. For example, in Europe approval is obtained via a Clinical Trial Application (CTA).

Other info to think about when joining a study

If you join a study that is testing a medicine under an Investigational New Drug (IND) application you should feel free to ask about what safety information about the study treatment is already known, and why this particular medicine is being tested. You can also find out more about the risks and what kind of care you can expect to receive if there are any adverse events.

Related Words

investigational medicine

Other Resources

NCI Thesaurus

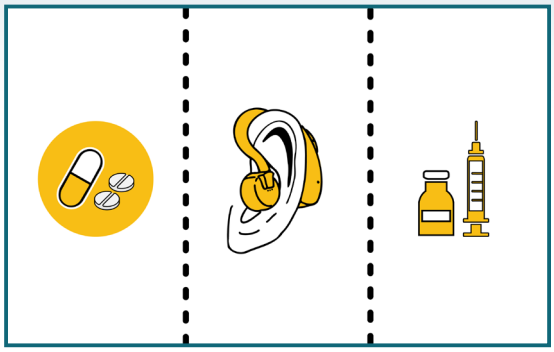
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

investigational product

cdisc

A drug, device, vaccine, or other treatment being tested in a study.



Example of *investigational product* in a sentence

The investigational product is what is studied in a clinical trial.

More Info

If a study is using an investigational product it means the product has not been approved yet or is not yet approved for the condition or disease being studied.

An investigational product can be a medication, device or vaccine.

Related Words

investigational treatment
intervention
study treatment

Other info to think about when joining a study

You may hear about an "investigational product" when learning about a new research study. If a study is testing the effect of an investigational product you should have a good understanding of what the product is and what the study will be measuring.

You may want to ask if will be able to access the investigational product after your study participation is over if you felt you had some improvement during the study.

Other Resources

NCI Thesaurus

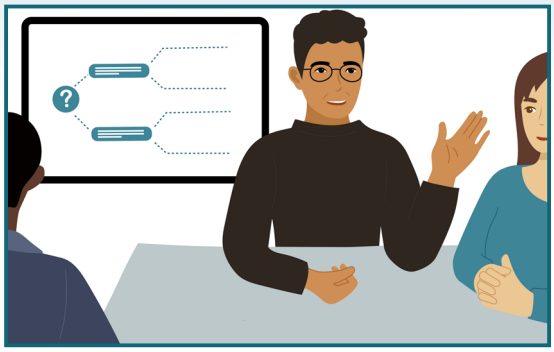
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

investigator

cdisc

A person who leads a research study.



Example of *investigator* in a sentence

The investigator is responsible for making sure the study is carried out as planned.

More Info

A study can have many investigators. An investigator could be a doctor, scientist, or other health professional.

A principal investigator is in charge of making sure the whole research study is being conducted correctly.

Related Words

researcher
study doctor
principal investigator
sub-investigator
co-investigator
coordinating investigator
site investigator

Other info to think about when joining a study

You may hear the term "investigator" when you learn about the different people involved in doing a study. The investigator who is running the study may be listed in the consent form.

You can ask for the investigator's name and also find out who you should contact in case you have any problems or questions during the study. It may be someone other than the investigator.

Other Resources

NCI Thesaurus

Harvard Catalyst - Meet the Research Team

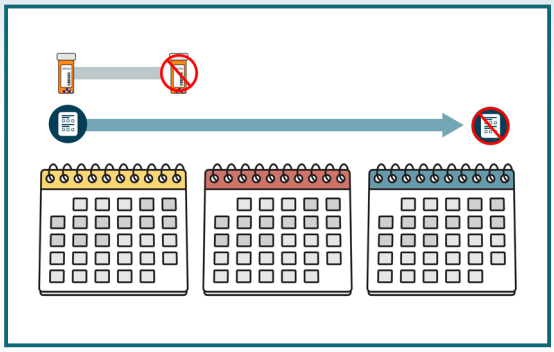
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

long-term follow-up (research)

cdisc

When researchers continue to collect data from study participants after initial research activities are completed.



Example of *long-term follow-up (research)* in a sentence

During long-term follow-up, participants may continue to have appointments with the study team to answer questions about their health.

More Info

Long-term follow-up usually follows a period of active treatment in a research study.

Long-term follow-up is done to collect data on the possible long-term effects of a study treatment that may not have happened during the initial research study.

For example, a member of the study team may call a participant every few months to see how they are doing and ask them questions about their health.

In some situations, long-term follow up is necessary or suggested after an intervention, like gene therapy.

Related Words

post-market surveillance

questionnaire

Other info to think about when joining a study

Before joining a study, you should ask the study team if there will be long-term follow-up. If there is, you can confirm how long it will be and what will be involved in the ongoing data collection. For example, will you be sent questionnaires that you have to answer and return back to the study team?

If you are in a study that involves long-term follow-up, feel free to ask questions about what happens if you move away from the study site.

It may also be important for you to ask how they will stay in touch with you during long-term follow-up as the appointments may have more time between them.

Other Resources

NCI Thesaurus

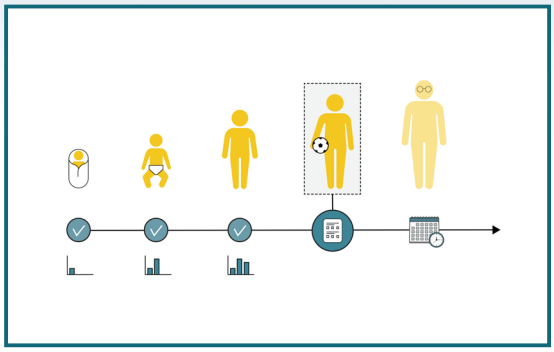
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

longitudinal study

cdisc

Research that collects data from the same participants over a long time.



Example of *longitudinal study* in a sentence

A longitudinal study collects information from a group of participants over a given period of time.

More Info

Longitudinal studies help researchers see how specific factors about participants change over time.

Longitudinal studies can be many weeks, months or years, depending on the topic being studied.

For example, enrolling 3 year old children to see whether a specific early childhood education program affects later learning is a longitudinal study. Another example is finding out whether a study treatment prevents a disease from getting worse over time.

Related Words

Other info to think about when joining a study

If you are considering joining a longitudinal study you should ask questions about how long the commitment is and what will be expected. A research study may have the term "longitudinal" in its title or used to describe follow-up study visits.

If you have questions about how this term is used, ask the study team before deciding to join this study.

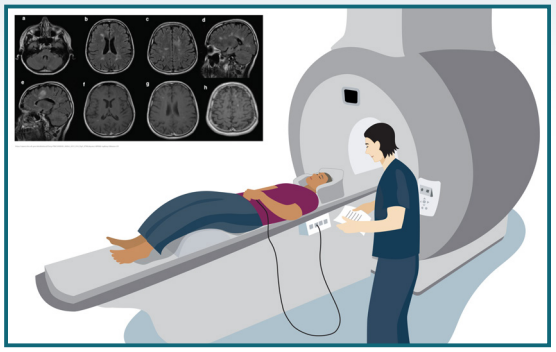
Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Magnetic Resonance Imaging (MRI) cdisc

A way to take pictures of the inside of a person's body with a machine that uses strong magnets and radio waves.



Example of *Magnetic Resonance Imaging (MRI)* in a sentence

Magnetic Resonance Imaging (MRI) is most often used to take pictures of bones, tissues, organs or the brain.

More Info

During an MRI, powerful magnets and radio waves are used to create very detailed pictures of the inside of a person's body. MRIs do not involve radiation.

An MRI may be done as part of screening, or as a way to collect data about a participant throughout the study.

Related Words

imaging study

X-ray

CT scan

Other info to think about when joining a study

You may have heard the term "MRI" when talking to your regular doctor. Some research studies may involve getting an MRI. If you have an MRI you will not be exposed to any radiation.

You can ask why a study is using MRIs. You may also want to know if the study team will share your MRI pictures with you or your regular doctors. In general, MRI research scans are done for the research and not to identify specific health problems. If you have concerns about your health, please discuss them with your regular doctor.

Other Resources

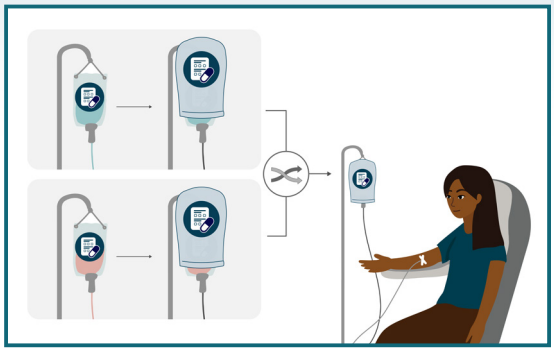
NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

masking (study treatment)

cdisc

Hiding or covering what the study treatments look like so participants cannot tell the difference.



Example of *masking (study treatment)* in a sentence

Masking is done so what the different study treatments look like is hidden.

More Info

Masking keeps participants and study staff from knowing which intervention a participant is assigned to and receiving.

Masking is done because knowing what each participant receives can influence or bias the results.

For example, if a study treatment is a pink liquid, and the comparator is clear, masking would cover both treatments so no one can tell the difference.

Related Words

blinding

Other info to think about when joining a study

You might see the term "masking" in the consent form or used to describe how a study treatment will be covered, so you can't tell what it looks like.

Masking is sometimes also used in place of the words "blinding" or "blinded" to describe the study design, and how participants may be kept from knowing what study treatment they are receiving. Masking helps make the study as controlled as possible and helps minimize the effect of what you hope or expect the effect to be.

Please ask any questions you have about masking or blinding and what it means in the context of the study you are joining."

Other Resources

NCI Thesaurus

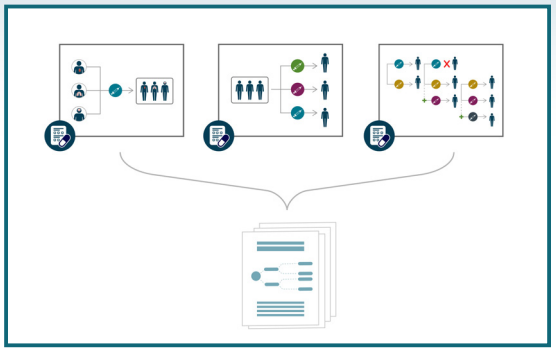
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

master protocol

cdisc

An overall research plan that guides sub-studies that have their own research questions.



Example of *master protocol* in a sentence

A master protocol includes information about more than one study and allows the research to happen more quickly.

More Info

A Master Protocol is the main protocol that guides sub-studies that can each be done at the same time.

Master Protocols are used because they can help get answers more quickly and efficiently. They generally need fewer participants and offer more study options.

Basket Trials, Umbrella Trials, and Platform Trials are all types of Master Protocols.

Related Words

basket trial

platform trial

umbrella trial

Other info to think about when joining a study

You may see studies refer to a "Master Protocol."

These studies will have sub-studies that participants join. You can ask all about how the studies are designed, whether you can choose which sub-study you will be in, and how your experience in one sub-study may be different from other sub-studies.

Other Resources

NCI Thesaurus

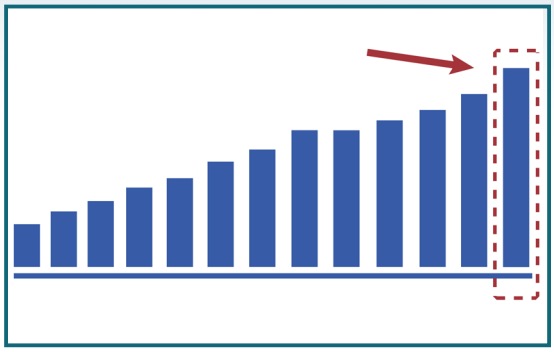
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

maximum

cdisc

The most or largest amount.



Example of *maximum* in a sentence

A study treatment should have the maximum benefit without causing serious side effects.

More Info

The word "maximum" can refer to anything that is measured. In a study, it may be the "maximum age" of participants eligible for the study, or the "maximum dose" permitted, or the "maximum amount of blood" that may be taken at any one time.

Related Words

most
greatest
largest

Other info to think about when joining a study

You may see the term "maximum" used in a variety of different ways. For example, the study team may talk about the maximum dose of a medication you can take. Or they may talk about the maximum number in a range of results from some type of research test.

If you are unclear about how the study team is using the word, please ask them to explain more.

Other Resources

NCI Thesaurus

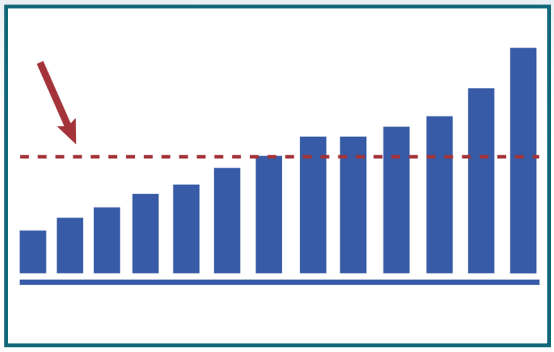
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

mean

cdisc

The average.



Example of *mean* in a sentence

In math, the mean is the average value of a set of numbers.

More Info

The mean is calculated by adding all the numbers in a set together, and dividing by the number of values.

For example, in a group of four people who are aged 10, 20, 30, and 40, the mean (or average) age of the group members is 25.

This is calculated by first adding all four numbers together, and then dividing by 4.

So, 10 + 20 + 30 + 40 = 100. And 100/4 = 25. Thus, the mean, or average age, is 25.

Related Words

average

median

Other info to think about when joining a study

You may see the term "mean" used to describe an average of all the study data using numbers. You may see this term used in study results reports.

If you receive study results that report the mean of any data and you have questions about that information, you can reach out to the study team to learn more.

Other Resources

NCI Thesaurus

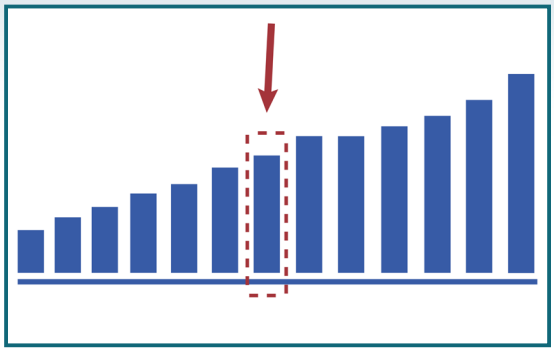
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

median

cdisc

The middle number in a set of numbers when listed in order from lowest to highest.



Example of *median* in a sentence

In math, the median is the middle number in a set of numbers.

More Info

The median is the middle, and it is not the same as the mean or average.

For example, 5 is the median in the set of numbers 2, 3, 5, 30, and 50, because 5 is in the middle when the numbers are ordered from lowest to highest.

Finding out the median can be useful if there are data that are outside the expected range. In the example above, 5 is the median, and that is far lower than the mean of 18 (that is, 2+3+5+30+50= 90; 90/5=18), showing that the data are not evenly spread out.

Related Words

middle

Other info to think about when joining a study

You might see the term "median" used to describe the middle number in a set of data. You may see this term used in study results reports.

If you receive study results that report the median of a data set and you have questions about that information, you can reach out to the study team to learn more.

Other Resources

NCI Thesaurus

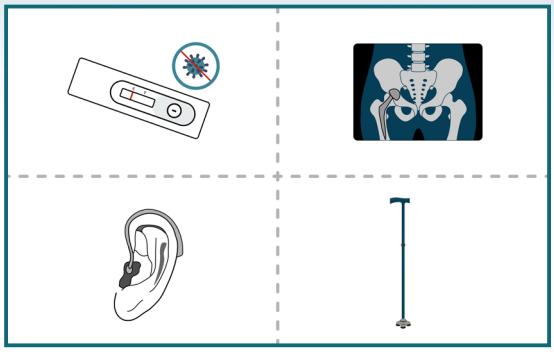
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

medical device

cdisc

A test kit, implant, or other item that can be used, worn, or inserted to prevent, diagnose, monitor, or treat a disease, condition, or symptom.



Example of *medical device* in a sentence

Medical devices are studied just like drugs and vaccines to find out whether they are safe and work as intended.

More Info

A medical device is used on or in a person's body.

For example, a medical device can be:

- a cane used to walk;
- a splint used on a twisted ankle,
- a pacemaker to help the heart, or
- a test to find out if someone has the flu.

In some cases, a medical device can be used with a drug or other therapy to help bring a medicine into the body. For example, an insulin pump is a device (the pump) that delivers a drug (insulin) for people with diabetes. Smart watches, and some computer programs or software are also medical devices when used in health care.

Research testing medical devices that are high risk is overseen by regulatory agencies (like the FDA) and ethics committees.

Other info to think about when joining a study

You might see or hear the term "medical device" if you are joining a study that is testing a medical device or using a medical device in the study.

You may also hear about a medical device when talking to your usual doctors outside of the research setting.

Since a medical device could be used inside or outside of your body, you should ask any questions you have about what is already known about the device and the possible risks and benefits of using it.

In studies that use medical devices, you can ask the study team if you will get to keep the medical device after the study is over or if you will be required to return it.

Related Words

investigational device

Investigational Device Exemption (IDE)

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

methods (research or study)

cdisc

The process followed to collect and analyze research data.

Example of *methods (research or study)* in a sentence

A study method for a research study about anxiety may involve participants filling out a questionnaire about any worry or anxiety they are feeling.

More Info

Study methods use specific procedures to collect information in a standard way. The information is used to answer the research questions.

Different studies use different methods depending on the research question.

Study methods also include information on how the data will be analyzed.

Related Words

methodologies

Other info to think about when joining a study

Before joining a study, you should make sure you understand what study methods will be followed during the study. For example, are data collected through surveys you will have to fill out? Are you joining a study where you are randomly assigned to a study treatment so that the study team can compare different treatments? You should feel free to ask the study team any questions you have about the methods.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

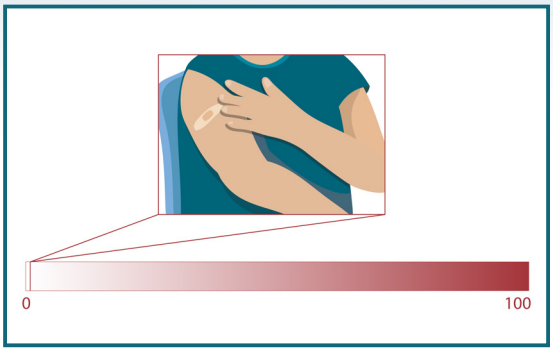
minimal

cdisc

Very small.

Example of *minimal* in a sentence

A participant must report every adverse reaction even if the impact on their lives seems minimal.



More Info

The risks of a study are minimal or very small if they are about the same as the risks of daily living. Adverse events may be described as minimal if they don't last very long or are mild.

Some research is considered to be minimal risk, meaning the risk to participants should not be very high.

Related Words

limited

negligible

Other info to think about when joining a study

You may hear the term "minimal" when discussing whether a study is minimal risk or not.

If you have any questions about the risk of the study or otherwise how the word "minimal" is being used, you should feel free to discuss it with the study team.

Other Resources

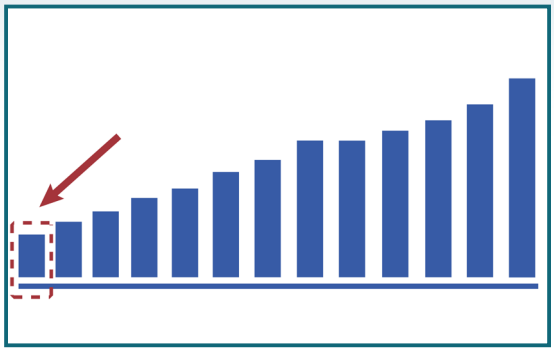
NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

minimum

The smallest or least amount.



Example of *minimum* in a sentence

A research study needs a minimum number of participants so enough data can be collected to answer the study questions.

More Info

The word "minimum" can refer to anything that can be measured.

For example, in a research study the "minimum age" in eligibility criteria is the youngest age that is allowed for a person to be enrolled.

Related Words

least

lowest

Other info to think about when joining a study

The term "minimum" may be used in a variety of contexts. For example, the study team share information about the minimum amount of time you have to do a study task. They might also talk about the minimum age for study participants.

If you are unclear about how the study team is using the word, please ask them to explain more.

Other Resources

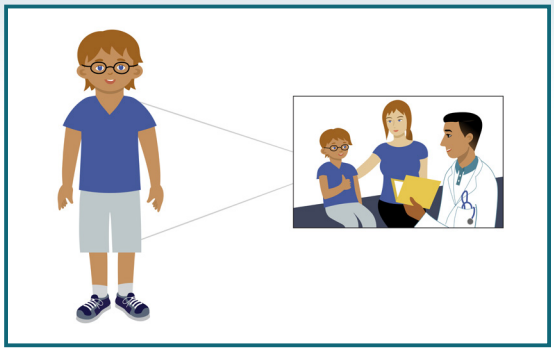
NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

minor

Someone considered too young to give legal consent.



Example of *minor* in a sentence

A minor is a person who is under the legal age of majority in a specific place.

More Info

Studies that enroll children need to have processes in place to ensure a parent or a guardian gives consent. The minor, when appropriate, is asked for their agreement before they are enrolled in the study. This is called assent.

Related Words

assent
child
young person

Other info to think about when joining a study

"Minor" is another word for child or pediatric participant. If you are a parent or guardian with a child who may join a research study, you can ask any questions, such as whether if there is a separate assent process for the child and whether there are additional protections for children.

Other Resources

NCI Thesaurus

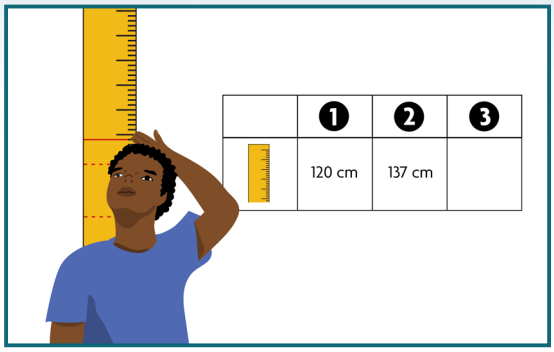
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

monitor

cdisc

To observe, check or evaluate something in a study over time.



Example of *monitor* in a sentence

In ongoing studies, researchers have a responsibility to monitor the study participants.

More Info

Participants might have their health and safety monitored depending on what type of study they are in.

Data can be monitored as well to make sure they are being collected and stored correctly.

Related Words

audit
investigate
assess
watch
oversee
observe
evaluate

Other info to think about when joining a study

The word "monitor" is often used to describe the steps and processes that will be followed to make sure participant safety is being protected and the study is being conducted properly.

You can always ask the study team about how your safety and well-being will be monitored and how the study team will monitor the overall study.

Other Resources

NCI Thesaurus

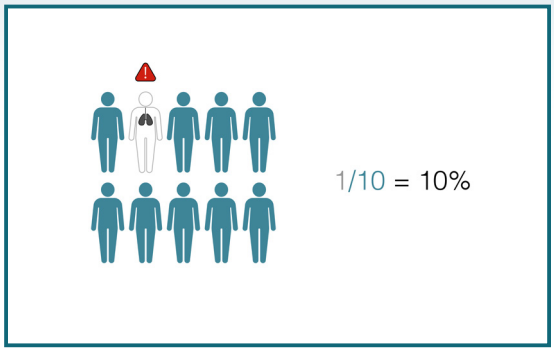
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

morbidity (rate)

cdisc

The number of people who develop a disease or illness in a group over time.



Example of *morbidity (rate)* in a sentence

The morbidity rate in a study refers to how many people have or develop a condition.

More Info

The morbidity rate is calculated by counting how many new cases or illnesses occur in a given number of people in a certain amount of time.

Morbidity can also refer to medical problems caused by a treatment.

For example, if 100 people get a rash from a new medication in a study of 1000 people, the morbidity rate of rash is 10% (e.g., 100/1000=1/10 or 10%).

Related Words

illness rate

mortality

Other info to think about when joining a study

In the clinical research context, the term "morbidity rate" can be found in study descriptions. A study could be looking at ways to decrease the number of people developing a disease or illness.

Sometimes you might see the term "morbidity rate" used in study results as well to describe how many participants develop new diseases or illnesses, or even how the morbidity rate of the study compares with the general public or other groups.

If you see this term when you are reviewing a research document, you can always ask the study team about how it might be important for your participation in the study.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

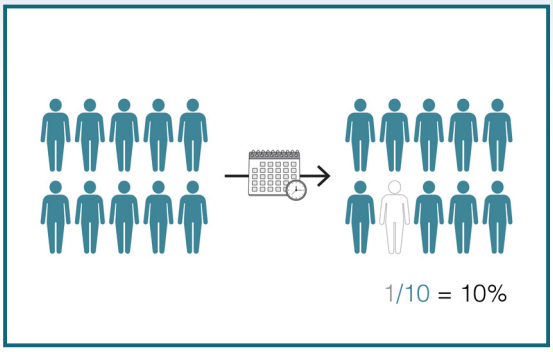
mortality (rate)

cdisc

The number of deaths in a group of people over time.

Example of *mortality (rate)* in a sentence

The mortality rate in a study refers to how many people died over the course of the study.



More Info

The mortality rate is calculated by counting how many deaths occur in a group of people during an amount of time.

For example, if 6 people died in a study of 200 people, the mortality rate would be 3% (e.g., 6/200=3/100=3%).

Related Words

death rate

morbidity

Other info to think about when joining a study

In the clinical research context, the term "mortality rate" can be found in study descriptions. A study may look at ways to decrease the number of deaths ("mortality rate") in a group of people or from a specific cause. The term may also be used to describe how many participants died over the course of the study.

If you see this term when you are reviewing a research document, you can always ask the study team about how it might be important for your participation in the study.

Other Resources

NCI Thesaurus

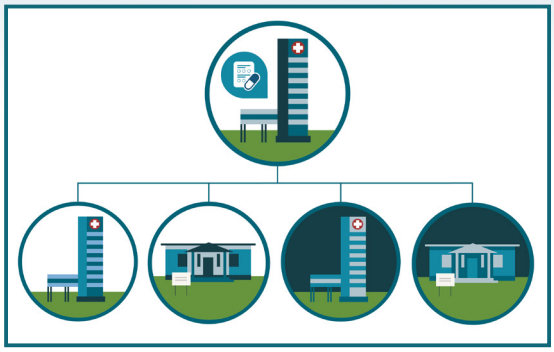
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

multicenter trial

cdisc

A study that takes place at more than one research center.



Example of *multicenter trial* in a sentence

A multicenter trial can be done in many locations in a country or even around the world.

More Info

A multicenter study is a way to conduct research at more than one research center or site to make sure there are enough participants and people from many different backgrounds. A research center can be hospital, clinic, or research institution.

Related Words

multi-site study

investigator

Other info to think about when joining a study

You may hear the term "multicenter study" when the study team describes what kind of research study you could join or when you are reading the consent form.

If a study is multi-center, you could ask what the other study locations there are. You may want to clarify who the investigator is at your research center and who to contact if you have questions.

Other Resources

NCI Thesaurus

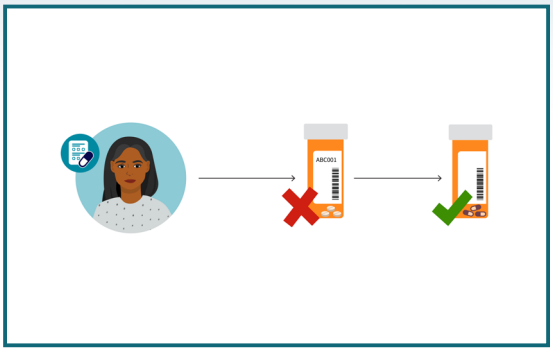
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

n-of-1 study

cdisc

A research study testing one or more study treatments in a single participant to find the best treatment for that person.



Example of *n-of-1 study* in a sentence

In an n-of-1 study, a participant may try several different study treatments to see which one works best for them.

More Info

N-of-1 studies may be conducted in rare diseases or conditions where there are fewer patients or individual responses may be unique. N-of-1 studies may also be. conducted in chronic diseases or conditions. This type of study design tries to see which study treatment is best for the individual participant, while still collecting data to support general learning.

N-of-1 studies can still be randomized and blinded.

N-of-1 studies can also be used to collect information about health technologies and devices, not just study treatments.

In n-of-1 studies, data from multiple individuals could also be combined to support more general conclusions. There may be analyses of the data collected from the individuals to see if they can be applied more broadly to the population level.

Related Words

n-of-1 trial

personalized study

personalized trial

Other info to think about when joining a study

An "n-of-1 study" is a type of personalized medicine that collects data during the process of trying out different treatments.

If you are thinking about joining an n-of-1 study, you may ask the study team about the study treatments that will be used and what order they will be given. You can also ask how being part of the study could affect your overall healthcare and treatment for your condition, like if you will be able to keep using the treatment that worked best for you.

Other Resources

Columbia — N-of-1 Trials

NCI Thesaurus

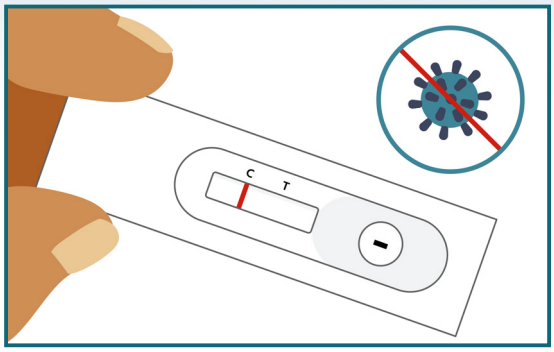
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

negative test result

cdisc

A test result that shows a person does not have what was tested for.



Example of *negative test result* in a sentence

A negative COVID test means that the person most likely does not have COVID.

More Info

A negative test result for a disease, condition, genetic marker, or biomarker means that a person likely does not have the condition being tested for.

A "false negative" means that the test incorrectly found someone to be negative when they are actually positive. Tests try to reduce the number of false negatives.

Related Words

sensitivity

specificity

false negative

Other info to think about when joining a study

You may see the term "negative test result" in the context of study screening or a study procedure. You may want to ask if you will get the test result and if yes, how long it will take for the results to be ready. If you have any questions about this test result you should discuss with the study team.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

negligible

cdisc

So small that it has little to no impact.

Example of *negligible* in a sentence

Some research results are negligible in terms of what they mean for patient care.

More Info

If an event, effect, or result is negligible, it is not considered important or impactful.

Related Words

unimportant
insignificant
inconsequential
minor
minimal

Other info to think about when joining a study

The word "negligible" could be seen in the context of clinical research study results to describe that a difference between data or outcomes is so small that it is unlikely to have an impact on patient care.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

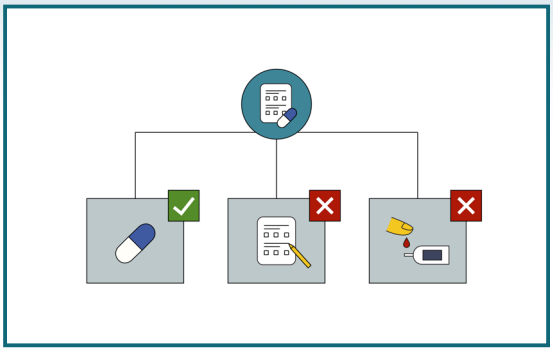
non-compliance

cdisc

Not following research requirements.

Example of *non-compliance* in a sentence

Non-compliance with the research protocol can impact the outcomes of the research.



More Info

Non-compliance can apply to either researchers or participants not following the study requirements. Researchers must comply with the laws and regulations of research and the protocol as written. Participants must comply with study procedures.

Participant non-compliance could result in the principal investigator removing a participant from the study for not following the study instructions.

Regulators, sponsors or the IRB could check a research team for non-compliance with research laws and regulations.

Related Words

Other info to think about when joining a study

You might hear the term "non-compliance" when study team tells you about things you should do while in the study in order for the data to be complete. If you do not do these things, non-compliance could be an issue. For example, the study team may say you have to take an investigational medicine 3 times a day. If you only take it twice a day, it would
be considered non-compliance with the study procedures. There may also be things you cannot do while you are in the study and if you do them, that is also considered non-compliance.

Before signing up for a study, be sure to ask for clarification if you are unsure about what you need to do while you are in the study and what you cannot do. You may also want to ask what will happen if you are non-compliant. For example, if you have to take the investigational medicine once a day but you forget to, you can ask the study team what you should do in that situation.

Other Resources

NCI Thesaurus

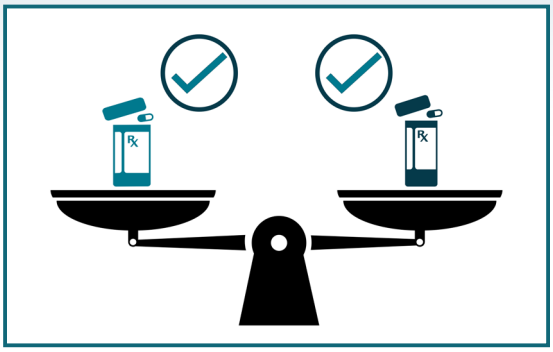
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

non-inferiority trial

cdisc

A study to test if a study treatment works about as well as another treatment for the same condition.



Example of *non-inferiority trial* in a sentence

One example of a non-inferiority trial would be to test whether a new medicine for asthma works as well as one that some patients already use.

More Info

Non-inferiority trials are done to find more treatment options that work as well as ones that are already approved for a specific disease or condition.

Related Words

- non-inferiority study
- superiority trial
- equivalence trial
- control

Other info to think about when joining a study

If you are considering joining a non-inferiority trial this means that the study will be looking at whether one treatment is as good as another. You should ask the study team any questions you have about the treatments being studied or how you will be assigned to a study arm.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

objective

cdisc

A purpose or goal of a study.

Example of *objective* in a sentence

The research objective is the scientific question to be answered by the study.

This graphic represents concepts related to what a study is designed to find out.

More Info

The study protocol always includes the objective(s) of the research.

For example, an objective could be to find out whether a study treatment causes a certain symptom to get better.

Related Words

study objective
goal
aim
purpose

Other info to think about when joining a study

You might see the word "objective" in the consent form or study protocol. You could also hear about the objectives when speaking with the study team.

The objective of the study refers to what the study is trying to find out. If you participate in a study you should understand the objective and ask the study team any questions you might have.

Other Resources

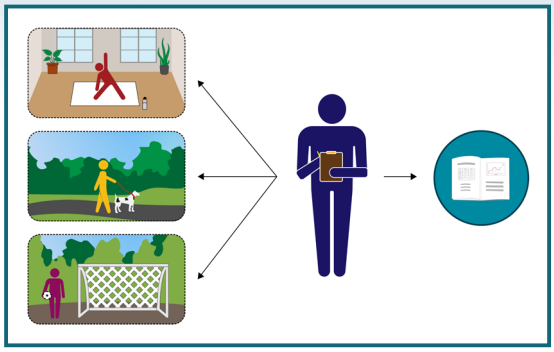
NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

observational study

cdisc

A study that collects health information about study participants without giving a treatment.



Example of *observational study* in a sentence

In an observational study, data will be collected about each participant but no one will be assigned to get a study treatment.

More Info

For example, a study to see whether those who smoke cigarettes report higher rates of lung cancer than those that do not would be an observational study.

Data are collected using methods like surveys and lab tests, as well as from other sources like medical records and historical datasets.

Related Words

natural history study

cohort study

case-control study

empirical study

Other info to think about when joining a study

If you enroll in an observational study this means data will be collected about you but no study treatment will be assigned.

You may want to ask how the research team will collect data from you during your time in the observational study

Other Resources

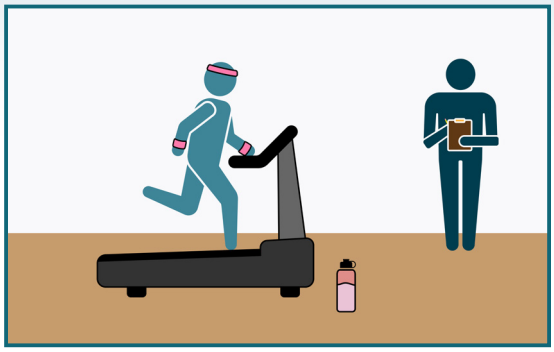
NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

observe

To watch or see how participants are doing in a study.



Example of *observe* in a sentence

Participants may be observed for a few minutes after taking the study treatment to check for any early adverse reactions.

More Info

To observe participants is one way to collect and document data for a study in a planned way.

Related Words

Other info to think about when joining a study

The study consent form or any information the study team gives you about the study you are participating in may mention that you will be observed. This could happen the first time you take an investigational medicine or after you take part in some type of research test.

You can ask how long you will need to be observed if that is something that will happen to you. For example, after getting a vaccine, you may have to be monitored for some time to make sure you have no reactions.

Other Resources

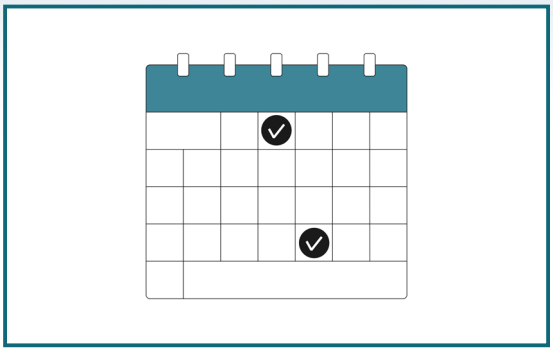
NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

occasionally

Once in a while.



Example of *occasionally* in a sentence

Occasionally there are changes in the study that require participants to re-consent to continue.

More Info

The protocol and consent form will discuss how often certain procedures or possible harms will happen. If the frequency is described as being occasionally, it means an event won't happen that often or predictably.

Related Words

sometimes
rare
infrequent

Other info to think about when joining a study

The word "occasionally" can be used to describe how often an adverse event occurred
in a research study.

You might want to know more about what that frequency could mean if you take a particular study treatment.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

odds ratio

cdisc

The chance of a health event happening in one group compared with the chance of the same event happening in another group.

Example of *odds ratio* in a sentence

An odds ratio is a measure of the link between an exposure and an event.

This graphic represents math and statistics terms in this glossary.

More Info

An odds ratio compares the odds of two different groups. It is used to describe the association of exposure to one variable of interest (e.g. health characteristic, aspect of medical history) to a disease or disorder, compared with the lack of the variable with the disease or disorder. It also looks at the strength of that association.

The odds ratio can also be used to determine whether a specific exposure is a risk factor for a particular outcome. For instance, the ratio of the odds of lung cancer in smokers divided by the odds of lung cancer in non-smokers is 14.

Two events are not related if the odds ratio equals 1, i.e., the odds of event are the same in either the presence or absence of the other event.

If the odds ratio is greater than 1, then two events are positively associated (correlated) i.e. The presence of one event increases the chance of the other one being present.

Related Words

relatedness

relationship

Other info to think about when joining a study

You may see the term "odds ratio" when reading results information of a research study. The results section of a publication will talk about the data and statistics. "Odds Ratio" is a technical math term and will not usually be used in materials designed especially for patients and participants.

If you see this word in a study document for a study you are thinking about joining, enrolled in, or completed, you can ask the researcher or study team any questions you might have.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

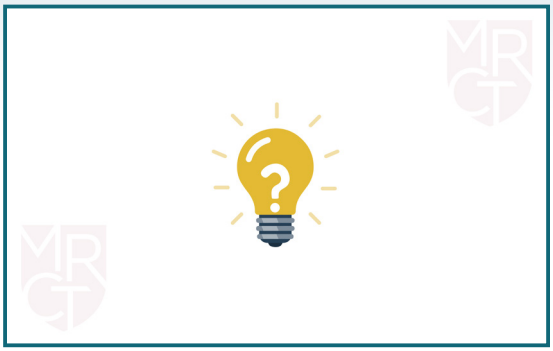
off-label

cdisc

The use of a treatment in a different way or for a condition other than what it is approved for.

Example of *off-label* in a sentence

Doctors can prescribe a medicine or other treatments off-label.



Do you have an idea for an image that could explain this concept? Contact us.

More Info

The "label" in "off-label" refers to the specific, intended use that the medicine or product has been approved for. This approval is given by regulators, health authorities or government agencies. This applies to drugs and devices.

A doctor may prescribe a drug off-label when there is reason to believe that the drug could be helpful when used in a new or different way or for a different condition, as in a different age group, dosage, way to take it, or condition.

Related Words

- off-label use
- unapproved
- unapproved use
- intended use

Other info to think about when joining a study

Some research studies are investigating a treatment that is being given as an "off-label" use.

You can ask the study team what the treatment is approved for and what its intended use is. You may also want to ask why they want to use this treatment off-label and what information they may have that could suggest it would work off-label.

Other Resources

NCI Thesaurus

FDA - Understanding Unapproved Use of Approved Drugs "Off-Label"

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

open-label

cdisc

A type of study where participants and research staff know which treatment participants are being given.

Example of *open-label* in a sentence

When a study treatment is open-label, participants know what they are taking.

More Info

Open-label studies are used in a number of settings, including to learn about the long-term effects of study treatments. Sometimes it is impossible to mask which treatment a person will receive. Sometimes participants who have finished the treatment part of the study keep sharing data so researchers can see how long the effects of treatment last.

Related Words

unblinded

unmasked

Other info to think about when joining a study

Some research studies are investigating a treatment that is being given open-label, without masking what the participant is receiving.

If you are participating in a research study that is testing a study treatment, you can ask the study team whether you will be able to continue taking the treatment as an open-label use.

Other Resources

NCI Thesaurus

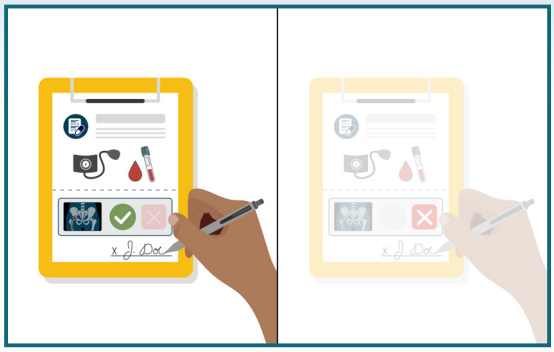
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

opt-in

cdisc

To agree to optional study activities or optional data uses that are not required for the study.



Example of *opt-in* in a sentence

A participant can opt-in and agree to have an extra blood draw that is not required.

More Info

When certain study procedures or activities are optional, and the participant chooses to do them, this is called opt-in.

Sometimes a consent form has multiple parts that participants can choose to opt-in for. For example, a participant might be asked to opt-in for specific study activities, like biobanking samples for future research.

Related Words

opt-out

consent

Other info to think about when joining a study

You might see the term "opt-in" used to describe the choice you have about whether to do certain things in a study or have your data used beyond the original goals of the study.

If you have any questions about what is required to be in a study, and what activities are optional, please ask the study team. You can also ask the study team about what happens if you change your mind.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

opt-out

cdisc

To decline optional study activities or optional data uses that are not required for the study.

Example of *opt-out* in a sentence

Research consent forms sometimes include check boxes that allow a participant to opt-out of a part of the study.

More Info

When certain study procedures or activities are optional, and the participant chooses not to do them, this is called opt-out.

In some cases, a research study may include specific procedures unless a participant decides to opt-out. For example, a study may include the option to collect spinal fluid, but not require it for someone to be in the study. Or a study may plan to videotape a research interview, but the participant can opt out of being recorded.

Opt-out is also used to describe when participants choose not to have their data used beyond the original purpose of a research study.

Related Words

opt-in

consent

Other info to think about when joining a study

You might see the term "opt-out" used to describe the choice you have to not do optional parts in a study or have your data used beyond the original goals of the study.

If you have any questions about what is required to be in a study, and what activities are optional, please ask the study team.

You always have the right to withdraw from a study if you no longer want to be a participant. You should discuss this choice with the study team so that you can leave the study safely

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

outcome (of study)

cdisc

A description of the overall results of the study.

Example of *outcome (of study)* in a sentence

The study outcome describes what the researchers learned from the research.

More Info

The study outcome will report the study results, such as whether or not a study treatment helped participants.

Related Words

result
endpoint
primary endpoint
surrogate
secondary endpoint
clinical endpoint

Other info to think about when joining a study

You might see the word "outcome" when you read about a research study's results and the overall conclusions that researchers came to based on the study data.

If you have any questions about the outcome of the study and what a study's results mean for you, you can ask the study team or discuss with your regular doctor.

Other Resources

NCI Thesaurus

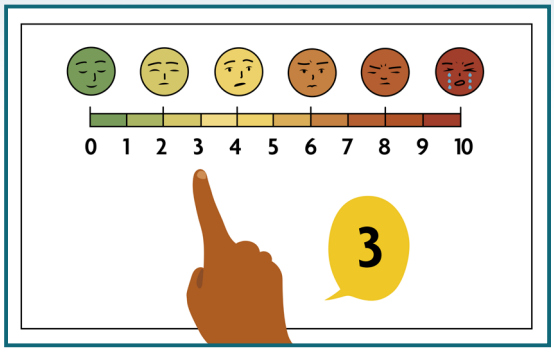
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

outcome measure

cdisc

The way that a study endpoint is measured.



Example of *outcome measure* in a sentence

An outcome measure is used to collect data for the study.

More Info

A study will use one or more outcome measures to collect the data that is needed to answer the research questions. For example, an outcome measure could be a blood test to find out how well the study treatment works to lower cholesterol.

Related Words

questionnaire
assessment
survey
data
endpoint

Other info to think about when joining a study

An outcome measure can be a questionnaire, survey, or any kind of assessment that is done to see any changes over the course of the study. Examples of assessments include blood test, blood pressure reading, MRI, etc.

If you have any questions about the outcome measures being used in a study, feel free to ask the study team.

Other Resources

NCI Thesaurus

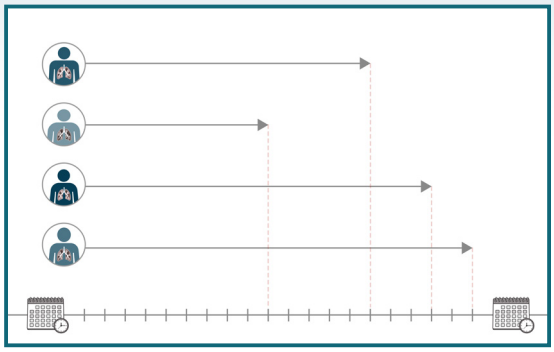
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

overall survival

cdisc

How long people live after a diagnosis or starting a study treatment.



Example of *overall survival* in a sentence

Overall survival is sometimes measured in clinical research studies about study treatments for serious illnesses or conditions to find out how well the study treatment is working for participants.

More Info

Overall survival is a study endpoint that measures how long participants stay alive after a new diagnosis or starting a study treatment. The overall survival is often measured as a rate at the end of a specific time period, such as, the percentage of participants alive at five years.

There are other endpoints that study teams may collect such as quality-of-life or how long participants remain disease-free.

Related Words

progression-free survival

disease-free survival

Other info to think about when joining a study

You may see the term "overall survival" used to describe what the researchers are trying to understand about the study treatment in the research study.

It is important to remember that overall survival is measured at a population level and does not apply directly to any one individual. If you see the term overall survival or overall survival rate, you should ask your study team how that information might apply to you and your health situation.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

p-value (probability value)

cdisc

A number that researchers use to show that a result did not occur by chance.

Example of *p-value (probability value)* in a sentence

The p-value is used in research to show whether a difference in effect between treatments is due to chance.

This graphic represents math and statistics terms in this glossary.

More Info

The p-value is part of the scientific process. It is a number used when analyzing research data and reporting research results.

The p-value shows whether the results could have occurred by chance.

When a p-value is very small, it means that it is less likely to have occurred by chance.

For example, if a study has a p-value of 0.05, this means that if you did the study 100 times, the results would likely be the same 95 times.

It is important to note that even if something has a small p-value and is statistically significant, the result may not make a big difference to patients. For example, a drug may shrink a tumor but not extend a person's life.

Other info to think about when joining a study

You might see the term "p-value" in a publication about research where the study results and statistics are reported.

The article may include a results section that has more information about what the p-value for the study is and what that means for the results.

The p-value could also come up in Plain Language Summaries of a study's results.

If you have any questions about how the p-value is being reported, feel free to talk to the study team.

Related Words

statistically significant

Other Resources

NCI Thesaurus

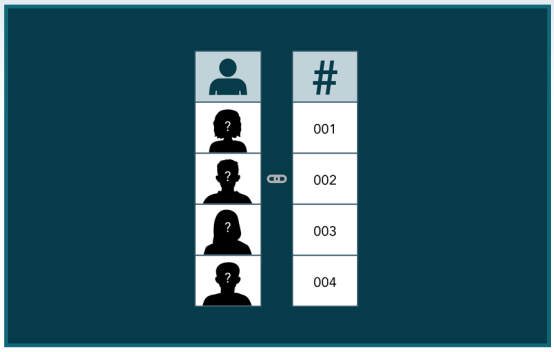
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

participant code

cdisc

A set of numbers, letters, or both that is used to identify a participant instead of their personal information.



Example of *participant code* in a sentence

Using a participant code keeps personal information separate from the rest of the study data.

More Info

When study data are given a participant code, the participant's name, address, medical record number, and other easy to identify personal information are replaced with a unique code number.

This special participant code helps in the data analysis process by allowing various data points to be linked. The participant code can also protect a person's identity by storing the personal information apart from other study data.

Related Words

pseudonymized
participant ID number
study code
trial participant
identification code
deidentified
code

Other info to think about when joining a study

You may see the word "participant code" used to describe how your personal details will be kept separate from your other study data.

When data have a participant code, it is much harder to know which person provided that data. Only study staff who have permission can use the participant code to link the study data back to you.

You can always ask the study team about how your data will be protected.

Other Resources

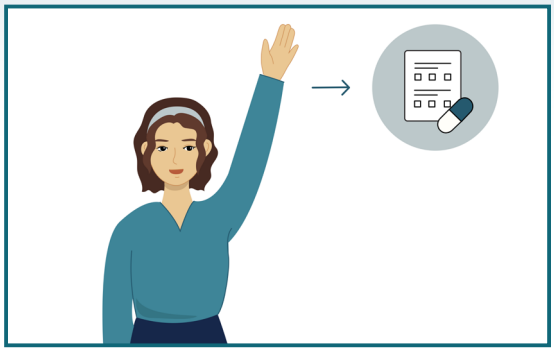
NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

participate

To take part in a study.



Example of *participate* in a sentence

By signing the consent form, a person agrees to participate in the study.

More Info

To participate in a study is voluntary.

Before agreeing to participate in a study, a person should know what the study procedures will be.

A person can always withdraw from a study if they decide that they no longer want to participate.

Before doing so, the participant should have a conversation with the study team.

Related Words

join

be a part of

volunteer

Other info to think about when joining a study

Your doctor may ask you if you want to participate in a study. Additionally, during the consent process, a person from the study team will make sure you want to participate in the study before joining.

You could ask about the benefits and risks if you participate in the study. It will also be important for you to know what the study procedures are when you participate in this study.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Patient Reported Outcomes (PROs)

The information that patients share about their own health or well-being to answer questions in a study.

Example of *Patient Reported Outcomes (PROs)* in a sentence

Patient Reported Outcomes are a way to hear directly from patients about their health or study experience.

More Info

Measures to collect Patient Reported Outcomes (PROs) includes how a participant feels during the study, such as mood, sleepiness, amount of pain, and adverse events. Participants can explain how the disease or the study treatment is affecting their ability to do things like exercising, sleeping, going to work, etc.

PROs might be collected with surveys, questionnaires, diaries, or interviews.

PROs are important because they allow patients to report directly how they feel, and not as observed by the doctor, researcher, or someone else.

PROs can often measure what is important to participants. Analyzing the data allows researchers to draw some conclusions about the outcome.

Related Words

Patient Reported Outcome Measure (PROM)

Other info to think about when joining a study

A study you decide to participate in may involve collecting patient reported outcomes (PROs). This may be listed in the consent form as something you need to do if you enroll in a study.

You may wish to ask how PROs will be collected because it could be from surveys, interviews, diary entries or another way not mentioned here. You may also want to clarify how much detail they want when you provide these answers.

Most PROs are not reviewed in real time so participants should not expect to hear back from the study staff about what was entered.

Other Resources

NCI Thesaurus

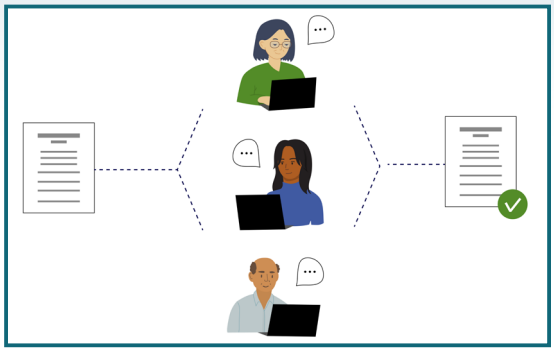
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

peer review

cdisc

Evaluation by independent experts.



Example of *peer review* in a sentence

Medical journal articles and grant applications often go through a peer review process.

More Info

Peer review involves a critical assessment of the ethics, methods, conduct, analysis, and reporting of research by other experts in the field. Peer review is done by people who are independent and not involved in the research study conduct.

A peer review process helps maintain rigor, independence, validity, standards and integrity of research studies.

A peer review process asks "Does the content we are reviewing meet the expected quality and standard?

Related Words

Other info to think about when joining a study

You could hear about scientific journal articles going through a "peer review" process before they can be published. Many scientific journals that report research results include a peer review step to make sure the information is shared publicly.

Other Resources

NCI Thesaurus

NIH - Peer Reviewed Literature

If you know of other resources we should link to to help explain this word, please contact us.

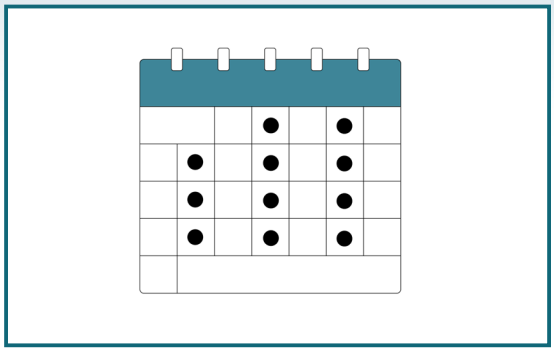
Clinical Research Glossary

periodically

At regular or expected times.

Example of *periodically* in a sentence

The study staff checks in with participants periodically to see how they are feeling.



More Info

When something happens periodically, it usually means that it happens on a schedule and is expected.

Related Words

scheduled
repeatedly
regularly

Other info to think about when joining a study

The word "periodically" could be used to describe how the study is monitored or how often some sort of event could happen.

If something in the study materials is described as "periodically," you may want to ask the study team what that timing will mean for you as a participant in the study.

Other Resources

NCI Thesaurus

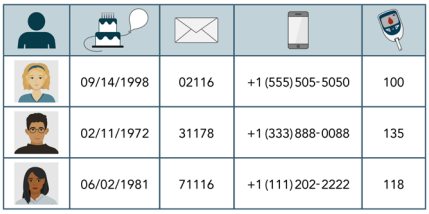
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

personal data

cdisc

Any information that is related to a person, including information that can identify them.



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	02/11/1972	31178	+1 (333) 888-0088	135
	06/02/1981	71116	+1 (111) 202-2222	118

Example of *personal data* in a sentence

A research study will often collect personal data from participants to answer the study question.

More Info

Personal data includes information that can be used by itself or with other data to identify a person. Examples of personal data are name, geographical location, ID numbers, or other information that make a person identifiable.

Researchers use a few different ways to protect participants' personal data, like creating a participant code and storing personal data separately from study data.

Related Words

- participant ID
- Personally Identifiable Information (PII)
- Protected Health Information (PHI)
- coded data
- HIPAA
- data

Other info to think about when joining a study

You might see or hear the term "personal data" in many different contexts.

In clinical research, you might see the term in the consent form or hear about it during conversations about the study and what information will be collected about you during the study.

There are laws in place in clinical research to protect how personal data is used.

You can ask the study team about what personal data will be needed in the study, how that data will be used, and whether any data will be stored for future research.

Other Resources

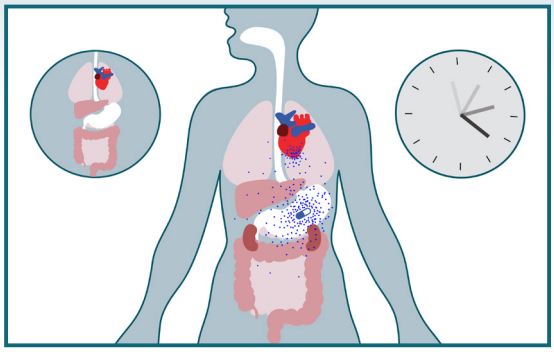
NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Pharmacodynamic (PD) study

cdisc

A study that measures the effects of a drug on the human body.



Example of *Pharmacodynamic (PD) study* in a sentence

During a pharmacodynamic study a participant will have their blood and other body fluids collected a few times over a few hours to see how the dose of the study treatment affects their body.

More Info

A pharmacodynamic (PD) study is the study of the effects of the drug on the human body. A PD study helps researchers learn whether the study treatment is having the desired effect on the body, and how the dose of the drug affects the response. For example, a PD study could try to find out if a drug for cancer will attach to a cancer cell and lead to the cell's death.

Related Words

Pharmacokinetic (PK) study

Other info to think about when joining a study

You might see the term "pharmacodynamic study", when researchers want to find out what effect the drug has on participants' bodies and how their bodies react. This is different from a pharmacokinetic study where the effect of the body on the drug is measured. Researchers use this information to design clinical trials, for example, what doses to give to participants. Because of this, pharmacodynamic studies are usually conducted early in the research process to help guide what is the best dosage for humans to take and to also look at safety in general.

If you are considering participating in a pharmacodynamic study you can ask the researchers about what is already known about the drug, and how the study team will be monitoring the safety of the participants.

Other Resources

NCI Thesaurus

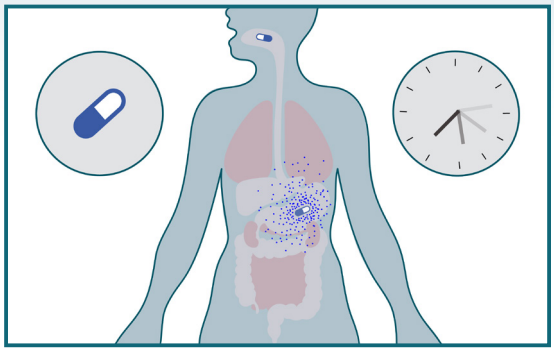
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

Pharmacokinetic (PK) study

cdisc

A study that measures what happens to a drug in a person's body over time.



Example of *Pharmacokinetic (PK) study* in a sentence

A pharmacokinetic study often enrolls healthy volunteers first before other participants.

More Info

A pharmacokinetic study means that a participant will have a blood draw and possibly other body fluids taken a few times over a few hours to see how the study treatment was used by the body.

The PK study is done to find out how a drug is absorbed, moves through, is broken down, and exits the body.

Related Words

Pharmacodynamic (PD) studies

Other info to think about when joining a study

If you enroll in a pharmacokinetic study a drug or medicine will be given to you and then blood samples will be taken several times over several hours to see how the study treatment was processed by your body.

If you have any questions about the drug or medicine being tested or how long the pharmacokinetic study will take, you could discuss them with the study team.

Other Resources

NCI Thesaurus

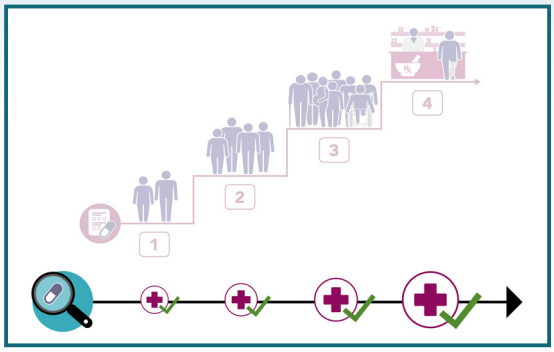
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

pharmacovigilance

cdisc

A process to detect, review, and make decisions about drug safety to protect patients.



Example of *pharmacovigilance* in a sentence

Scientific drug safety monitoring is called pharmacovigilance.

More Info

Pharmacovigilance is the science of monitoring the effects of drugs and vaccines. It involves detecting, understanding, and preventing adverse events and determining whether observed events are caused by the drug or vaccine.

Pharmacovigilance happens during and after a research study, and after a drug is approved.

Related Words

drug safety

Other info to think about when joining a study

The word "pharmacovigilance" is sometimes used in conversations about the risk and safety monitoring of a drug.

If you see this word and have any questions about how it is being used, you should ask the study team.

Other Resources

NCI Thesaurus

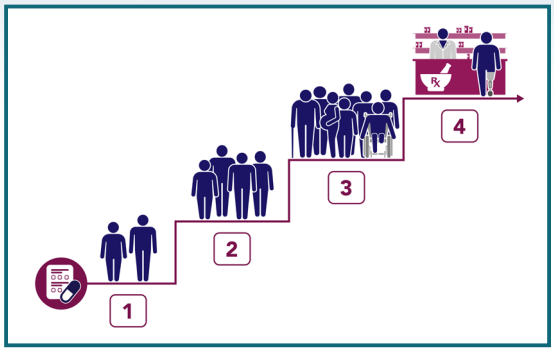
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

phase

cdisc

A step in the overall clinical research process to test a new drug or treatment.



Example of *phase* in a sentence

Research is done in phases to make sure a study treatment is safe and then whether it works before it is approved.

More Info

A phase is a step in the research process. Phases of research studies build on each other and each phase has a separate goal.

Phase 1 studies are usually the first to enroll humans and test for safety.

Phase 2 studies test if the drug, or treatment works.

Phase 3 studies compare the study treatment to the usual, standard treatment.

Phase 4 studies continue to collect data after a study treatment is approved. These are sometimes called post-marketing studies

Related Words

clinical research
clinical trial
preclinical study

Other info to think about when joining a study

You may see the term "phase" when you are reading about clinical trials.

Before you enroll in a clinical trial, you may want to ask about what phase the study is in. You may also want to know more about the information the study team already has about the risks and benefits of the study treatment that is being tested.

Other Resources

NCI Thesaurus

FDA - The Drug Development Process, Step 3: Clinical Research

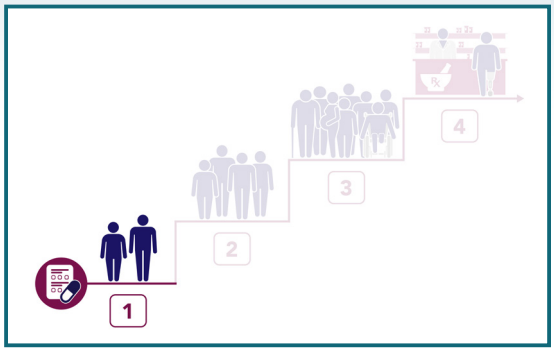
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

phase 1 (study)

cdisc

The first step in clinical research that gives a new study treatment to a very small group of people, to learn about its safety and effects on the body.



Example of *phase 1 (study)* in a sentence

A phase 1 study may be researching a study treatment that has not yet been used in humans.

More Info

In a phase 1 study, researchers try to find out how the study treatment interacts with the rest of the body and how the body processes the new study treatment. Phase I studies can also establish how, how much, and how often a study treatment should be given.

In some phase 1 studies, the participants are healthy volunteers.

In cancer research, phase 1 studies include patients with the disease.

Most phase 1 studies will enroll 20–100 participants.

Related Words

phase
phase 2
phase 3
phase 4
Pharmacodynamic (PD) study
Pharmacokinetic (PK) study
clinical trial

Other info to think about when joining a study

The term "phase 1" may be in the protocol or consent form and the study team may use the term when they are talking to you.

You can ask the study team if this new study treatment has been used in human studies before, what information they already have about its safety, and what will happen if there is a safety issue that occurs.

You can ask to learn more about how they plan to monitor you during a phase 1 study.

Other Resources

FDA—Drug Development Process—Step 3: Clinical Research

NCI Thesaurus

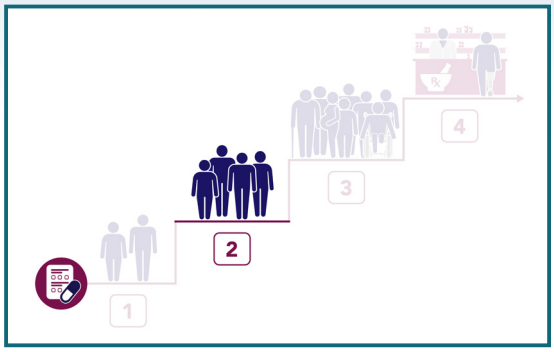
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

phase 2 (study)

cdisc

A step in clinical research that gives a study treatment to a small group of participants who have a disease or condition, to look at the study treatment's safety, and its effect on the disease or condition.



Example of *phase 2 (study)* in a sentence

A phase 2 study can provide researchers with more safety information about the new study treatment.

More Info

Phase 2 studies help researchers determine if the study treatment is safe and has enough of an effect to move on to even larger research studies.

A phase 2 study usually includes participants with the disease, condition, or symptom for which the new study treatment was intended.

Phase 2 studies will usually have more participants than a phase 1 study and may also last longer, but the number and duration depend on the disease or condition. For example, research related to a rare disease may enroll fewer participants.

Early (phase 2a) studies often assess dosage, frequency, and signs of drug activity. Later (phase 2b) studies focus on dose response and early signs of response.

Related Words

phase
phase 1
phase 3
phase 4
clinical trial

Other info to think about when joining a study

You may see the term phase 2 in the protocol or consent form and the study team may use the term when they are talking to you.

You can ask the study team what happened during the earlier (phase 1) studies of this study treatment. For example, were there any effects that the researchers were not expecting? Were there were any adverse reactions or serious concerns? You can also ask the study team who to contact if you have any questions or if you are not feeling well during the study.

If you hear that the research study is a phase 2a or phase 2b study, you can ask the study team to clarify what it means.

Other Resources

American Cancer Society — Phases of Clinical Trials

FDA—Drug Development Process—Step 3: Clinical Research

NCI Thesaurus

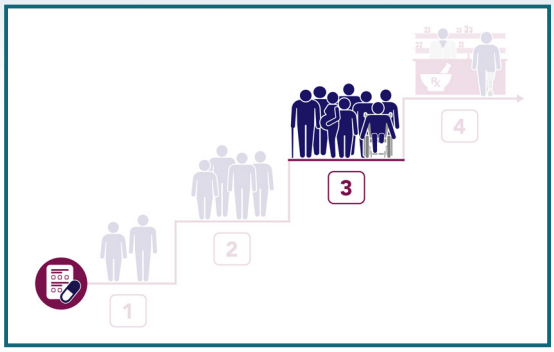
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

phase 3 (study)

cdisc

A step in clinical research that includes a large group of participants who have a disease or condition to find out how well a study treatment works and how safe it is, compared to other treatments or a placebo.



Example of *phase 3 (study)* in a sentence

Some participants in a phase 3 study may receive the new study treatment while other participants receive the standard of care.

More Info

Phase 3 studies follow phase 1 and 2 studies that have met their endpoints. Phase 3 studies enroll even more participants than phase 2 studies and can last a longer time.

In phase 3 studies, participants are usually separated into two or more groups. Some participants will be taking the new study treatment while others could be taking other treatments that are already approved and in use. During a phase 3 study, researchers are comparing the new study treatment to existing treatments or a placebo.

You may also hear about a phase 3b research study. The study team may want to signify if a research study is in a later stage of a phase 3 study.

Other info to think about when joining a study

You may see the term phase 3 in the protocol or consent form about a research study you are interested in joining. The study team may also talk about you joining a phase 3 study when they are talking to you.

You may want to ask the study team what is the standard of care they are using as a comparison in the research study you are thinking about joining.

If the study includes a placebo you may want to learn more about the reason the study is using a placebo and why there is no other treatment comparator.

You can also ask about what happened in previous phase 1 and phase 2 studies that was researching the new study treatment and if there are any articles available about the studies.

If you hear that the research study is a phase 3b study, you can ask the study team to clarify what it means.

Related Words

phase
phase 1
phase 2
phase 4
clinical trial

Other Resources

American Cancer Society — Phases of Clinical Trials

FDA—Drug Development Process—Step 3: Clinical Research

NCI Thesaurus

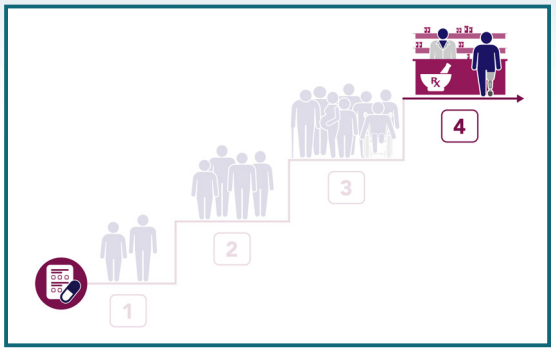
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

phase 4 (study)

cdisc

Clinical research that is done using an approved and available treatment to collect more information.



Example of *phase 4 (study)* in a sentence

Data from phase 4 studies is used to monitor long-term safety, rare side effects, and benefits in large diverse populations, over a long time.

More Info

Phase 4 studies can be used to observe whether an approved treatment has any long-term or rare side effects that were not observed during earlier, smaller, and shorter-term studies.

In addition, phase 4 studies are designed to learn more about how effective the treatments are over time.

All post-marketing surveillance (PMS) studies are considered phase 4 studies.

Related Words

post-marketing approval study

phase

phase 1

phase 2

phase 3

Real World Data (RWD)

Other info to think about when joining a study

You may see the term phase 4 in the protocol or consent form and the study team may use the term when they are talking to you.

You could ask the study team if there are specific things they are looking for during this phase 4 study, how long it will last, and how you and the study team will keep in touch during this time.

Other Resources

American Cancer Society — Phases of Clinical Trials

FDA—Drug Development Process—Step 3: Clinical Research

NCI Thesaurus

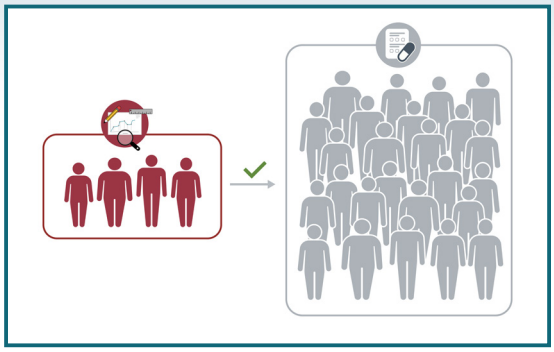
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

pilot study

cdisc

A small study that is done to test a process before starting a larger study.



Example of *pilot study* in a sentence

A pilot study is a way to detect and fix problems in the study process or to test a specific idea.

More Info

A pilot study is done first and enrolls fewer participants to find out the best ways to conduct a larger study.

Related Words

proof of concept
proof of principle
exploratory
first-in-human

Other info to think about when joining a study

A "pilot study" may test whether an intervention works well enough to continue studying it. Other times, a pilot study could be testing how the study treatment works in the body or the safety and participant experience of a product. You may want to ask if other studies have been done and their results, and about the risks and safety of the study treatment.

Other Resources

NCI Thesaurus

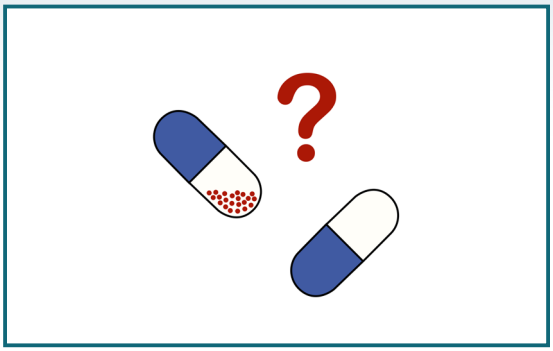
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

placebo

cdisc

Something that looks like the treatment being studied, but doesn't contain any medicine



Example of *placebo* in a sentence

Using a placebo in a research study keeps the participant and study doctor from knowing who is receiving the active treatment.

More Info

A placebo is made to look, taste and smell like the active treatment being studied. Depending on the study, a placebo can also refer to a device or sham surgery. A placebo helps the researcher see whether the active study treatment really works. Using a placebo reduces bias.

Using a placebo in a research study is accepted when the risk of not treating a condition is small or when there is no effective standard of care to compare to.

Related Words

- sham substance
- sham surgery
- control group
- sugar pill

Other info to think about when joining a study

When describing the plan of the study, the study team or consent form will say whether or not a placebo is being used in the study. When a placebo is included in a study, the participants will usually be assigned the placebo through "randomization." This means that whether or not you get the placebo will happen by chance, like flipping a coin.

You should feel free to ask if there is a chance you could be taking a placebo in the study. You can also ask if you will find out if you are on the placebo at the end of the study. It may also be important for you to ask how they will notify your regular doctors if you are on the placebo or taking an active study treatment if there is a medical need to know.

Other Resources

NCI Thesaurus

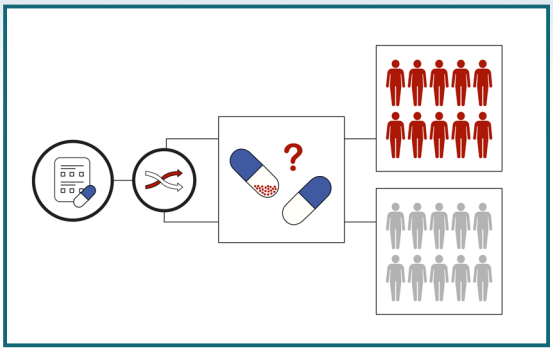
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

placebo-controlled study

cdisc

A study with two or more groups where one group is given a placebo.



Example of *placebo-controlled study* in a sentence

Placebo-controlled trials are done to show how the study treatment performs compared to those not receiving the study treatment.

More Info

A placebo-controlled study compares an active treatment to something that made to look, taste and smell like the active treatment. Using a placebo helps the researcher see whether the active study treatment really works.

Placebo-controlled trials are usually only done when the risk of not offering an active treatment for a condition is small or when there is no effective standard of care to use as the comparison.

Related Words

Other info to think about when joining a study

You will see the term "placebo-controlled study" if the research is using a placebo as a control group.

If you are considering joining a study that has a placebo, you can ask how the researchers decide who gets the placebo. You can also ask if the study team will tell you what you were taking at the end of the study. You can also ask how the researchers will notify your own doctor about what you are taking in the study if there is a medical reason to know.

Other Resources

NCI Thesaurus

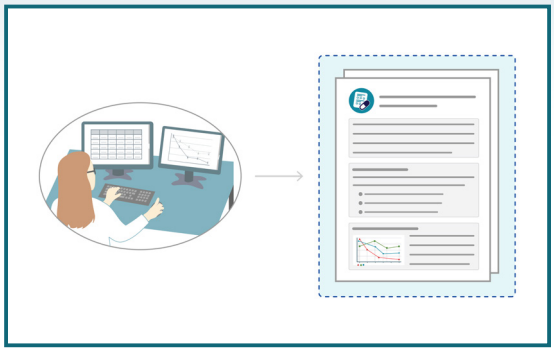
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

Plain Language Summary (PLS)—study results

cdisc

The results of a research study that are written to be easily understood.



Example of *Plain Language Summary (PLS)—study results* in a sentence

A Plain Language Summary may be provided after all the participants have completed the study and the results have been finalized.

More Info

There are different types of Plain Language Summaries (PLS) about research. Most often, the term "PLS" refers to the reporting of study results. Outside of the United States (US), PLS are known as "lay summaries."

PLS of study results can help everyone better understand the findings of a research study. PLS are shorter than articles that are published in medical journals and use language that is less complex.

Certain countries and regions require PLS of study results. For example, countries in the European Union (EU) and European Economic Area require them. In the EU, PLS of study results are published on a public-facing portal.

In the US, PLS of study results are a best practice, and some researchers offer them to participants after the study.

Sponsors sometimes make PLS available on their own company or research center website. Some sponsors may also place their PLS on a centralized website like www.trialsummaries.com.

Other types of PLS can describe the protocol in simpler language or the journal article where the study results are published.

Other info to think about when joining a study

If you are a participant in a study, or considering joining a study, you can ask the study team if they plan to share a Plain Language Summary of the results after the study is over, and how you can access it. This lets the study team know that you and other participants are interested in getting results.

Besides summary results, you can also ask if you and your regular doctors outside the study will be able to get any personal-level data and results that the researchers collect during the study.

Related Words

lay summary

Other Resources

NCI Thesaurus

Trial Summaries – Citeline

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

Plain Language Summary of Publication (PLSP)

cdisc

A scientific article that is written to be easily understood.

Example of *Plain Language Summary of Publication (PLSP)* in a sentence

Some journals require Plain Language Summaries of Publications so that people who are not experts can understand the information.

More Info

A Plain Language Summary of a Publication (PLSP) is its own separate version of a more technical scientific article. Such an article is written for everyone to understand study findings more easily.

Even though PLSPs are not required at this time, they can be a helpful source of information about the overall research study for a wider audience that includes participants, policymakers, and primary care physicians.

Related Words

Plain Language Study (PLS)

abstract

Other info to think about when joining a study

Plain Language Summaries of Publications are not currently required, but you can still ask your study team how results and overall study findings will be shared with you and other participants after the study. This can include asking them if any articles about this research study will also include Plain Language Summaries.

Your questions about the results let the study team know that providing clear communication of the study's findings is important to participants and the larger community.

Other Resources

NCI Thesaurus

Plain Language Summaries

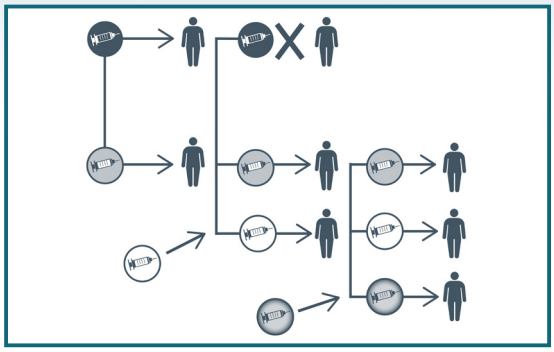
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

platform trial

cdisc

A research study that tests and compares two or more study treatments for a disease or condition, with study treatment groups being added or removed during the study period.



Example of *platform trial* in a sentence

A platform trial is an efficient way to compare many study treatments at the same time.

More Info

A platform trial is a type of randomized controlled trial (RCT). It is sometimes called a Master Protocol. This is because a platform trial uses Master Protocol to test the different study treatments in the same way, using the same design.

A platform trial is done to compare multiple treatments or interventions by comparing them against each other and a control.

This is a way to do research more efficiently with fewer participants to find an answer. As a platform trial progresses, the research team may add new study treatments to compare and remove ones that are not working or have too many adverse events.

Related Words

master protocol
umbrella trial
basket trial

Other info to think about when joining a study

You may hear about platform trials when you are learning about different types of study designs.

If you are unsure about what it means for a research study to be a platform trial, you should ask a member of the study team to clarify any of your questions.

Other Resources

NCI Thesaurus

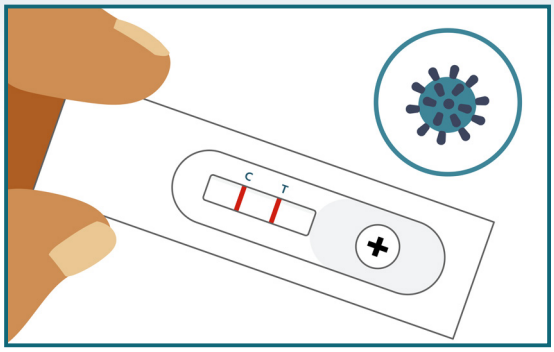
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

positive test result

cdisc

A test result that shows a person has what was tested for.



Example of *positive test result* in a sentence

A positive COVID test means that the person most likely has COVID.

More Info

A positive test result for a disease, condition, genetic marker, or biomarker means that a person is likely to have or to have had the condition.

A "false positive" means that the test incorrectly found someone to be positive when they are actually negative. Tests try to reduce the number of false positives.

Related Words

sensitivity

specificity

false positive

Other info to think about when joining a study

You may see the term "positive test result" in the context of study screening or a study procedure. You may want to ask if you will get the test result and if yes, how long it will take for the results to be ready. If you have any questions about the test result you should discuss with the study team.

Other Resources

NCI Thesaurus

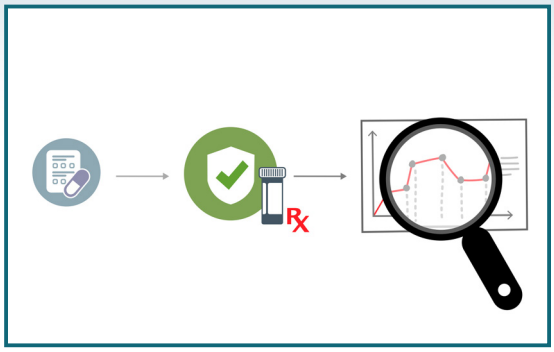
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

post-market surveillance

cdisc

Continuing to collect and analyze information about the risks and benefits of medicine and devices after they have been approved for patient use.



Example of *post-market surveillance* in a sentence

Post-market surveillance means that the risks and benefits of medicines and devices are being reviewed after the product has been approved for use.

More Info

Post-market surveillance happens after a drug or device has received approval by a government health authority.

It can be done by safety reporting, regular monitoring, or a research study.

Related Words

pharmacovigilance
monitoring
phase 4 studies
post-marketing studies

Other info to think about when joining a study

All prescribed and marketed drugs and devices are monitored for safety, termed "post-market surveillance." If you have questions about their safety, you should speak with a member of your usual healthcare team. You may also want to ask how you will be notified if any issues are identified in a drug or device you are using.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

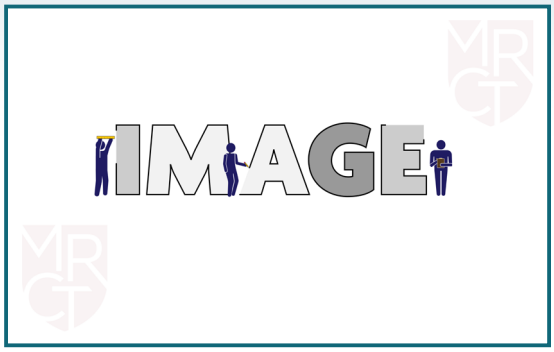
post-trial access

cdisc

When participants can still receive a study treatment after their participation has ended.

Example of *post-trial access* in a sentence

Participants should find out if they will have post-trial access to the study treatment.



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More Info

Post-trial access applies to drugs and devices.

Whether and how participants will be able to receive a study treatment usually comes up when the treatment has not yet been approved/certified and there are few or no alternatives.

Related Words

continued access

Other info to think about when joining a study

You might see the term "post-trial access" while reading a research consent form. It could be helpful to know whether or not you will be able to still take the study treatment after your time in the study is over.

If you are confused about what is being offered post-trial, be sure to ask the study team. If there is no mention of post-trial access, you should still ask the study team if there are plans to give you the investigational product after your participation in the study has ended.

Other Resources

NCI Thesaurus

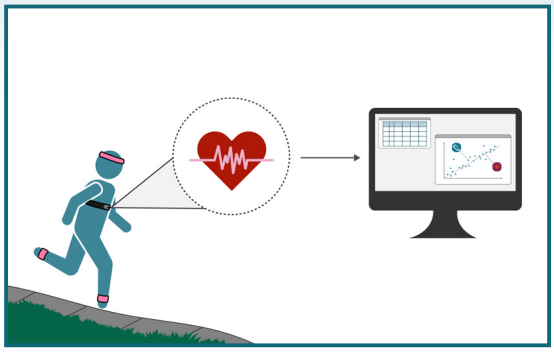
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

pragmatic study

cdisc

A type of research that tests a study treatment in real-world settings.



Example of *pragmatic study* in a sentence

Pragmatic studies enroll participants to assess a treatment in a real-world, routine healthcare setting.

More Info

Pragmatic studies are used to assess the effectiveness of study treatments as they are used in routine healthcare.

Eligibility criteria and study procedures are often broader in pragmatic studies and are designed to be conducted in real-world conditions.

Related Words

embedded trials
pragmatic clinical trial (PCT)
Real World Data (RWD)
real-world evidence
real-world settings

Other info to think about when joining a study

Pragmatic studies offer some flexibility, but still include instructions on how to take the study treatment, a list of study visits you will be asked to attend, and questionnaires you may have to answer.

You should feel free to ask the study team any questions you have about what your study participation will involve.

You can also ask the study team what other research has already been conducted on this study treatment and what past results have found.

Other Resources

EUPATI — Types of Experimental Studies

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

preclinical study

cdisc

A study to test a treatment in the lab or in animals before testing it in people.

Example of *preclinical study* in a sentence

A preclinical study is done to make sure the study treatment is safe enough to give to people.

More Info

If a study treatment has gone through preclinical studies, it means there was lab or animal testing before it was found to be safe enough to give to humans in a clinical trial.

Related Words

Other info to think about when joining a study

Most studies involving investigational products are designed based on data from other studies, including preclinical studies.

If you are thinking about joining a clinical trial, you can ask about the results of the preclinical studies and why the research team thinks this investigational product can be used in humans.

Other Resources

NCI Thesaurus

FDA - The Drug Development Process Step 2: Preclinical Research

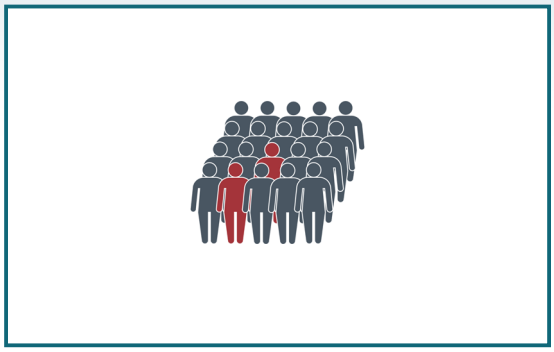
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

prevalence

cdisc

Number of known cases or events in a group.



Example of *prevalence* in a sentence

The prevalence tells us how many people in a population have a specific disease or condition.

More Info

Measuring the prevalence of a health issue is a way to understand how many people are affected in a given time period. It measures how common the condition or disease is, regardless of when the person developed the condition or disease.

For example, in 2021, the prevalence of diabetes in the US was 11.6% of the population, and 14.7% of all adults (i.e., people aged 18 and older).

Related Words

frequency

rate

see also incidence

Other info to think about when joining a study

The term "prevalence" is used to describe how many people are known to have a particular disease or condition.

You may want to ask the study team what the prevalence of adverse events in past studies was.

Other Resources

NCI Thesaurus

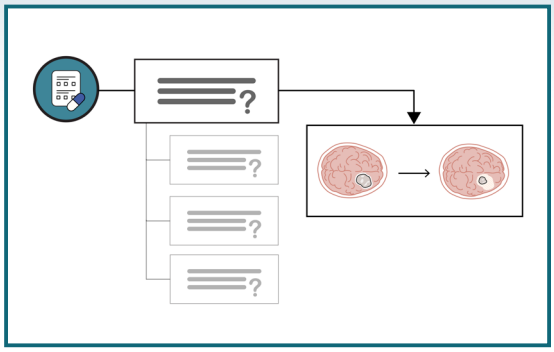
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

primary endpoint

cdisc

A study measure that is used to answer the main research question.



Example of *primary endpoint* in a sentence

The primary endpoint is the main purpose of the study.

More Info

A primary endpoint is how the main research question will be answered. A study is designed to assess the primary endpoint. A study may also have secondary endpoints.

Related Words

primary aim

outcome

outcome measure

Other info to think about when joining a study

You may see the concept of the "primary endpoint" written about in the consent form or hear about it from the study team. Additionally, if you visit a research study registry (like www.clinicaltrials.gov) you may see studies describe primary and secondary endpoints. The primary endpoint is the main thing the study is measuring.

If you are enrolling in a study and have any questions about what the main goal of the study is, please ask the study team.

After a research study is done and publications are released, you may also read about different types of endpoints.

Other Resources

NCI Thesaurus

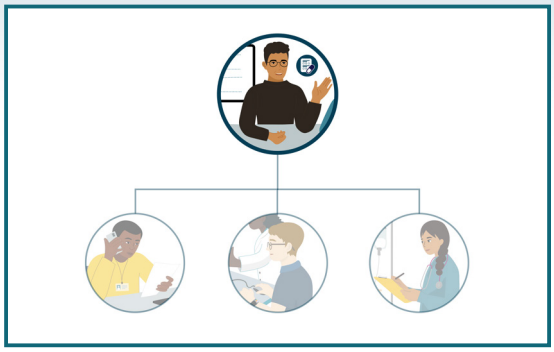
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

principal investigator

cdisc

The main researcher who oversees a research study and makes sure it is done as planned.



Example of *principal investigator* in a sentence

The principal investigator is responsible for all parts of the research study.

More Info

The principal investigator (PI) oversees all the steps and actions that happen in the research study. The PI leads the research team and makes sure the study is done as written in the protocol.

The PI could be at a single site, overseeing all of the other staff at that location. The PI could also be overseeing the research study at many different sites.

There can be other researchers working on the study called investigators, co-investigators, or study doctors. In the US, the FDA refers to the PI as a clinical investigator.

Related Words

investigator

clinical investigator

study doctor

Other info to think about when joining a study

You will most likely see the word "principal investigator" on official study documents like the consent form and the study protocol.

The principal investigator is fully responsible for all parts of the research study. You can ask for the principal investigator's contact information so you can reach them if you have any questions or concerns about the study.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

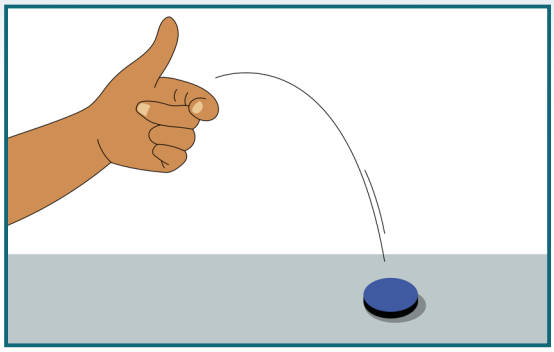
probability

cdisc

The likelihood or chance that something might happen.

Example of *probability* in a sentence

The informed consent process should include information about the probability of adverse events.



More Info

Probability is also used to describe the likelihood of a risk factor or exposure leading to a condition or disease, for example, what the probability of developing lung cancer is after smoking cigarettes.

Related Words

chance
likelihood
odds
possibility

Other info to think about when joining a study

You may see the term "probability" used to describe the chance that you will be assigned into one group or another in the study (randomization). You may also see this term when discussing how likely a risk or adverse event might happen.

When you see this term, it might be helpful to ask what the probability means for you as a participant in the study or if you are taking a particular treatment. For example: What is the probability that you will get one study treatment over another? What is the probability of a particular risk happening to you?

Other Resources

NCI Thesaurus

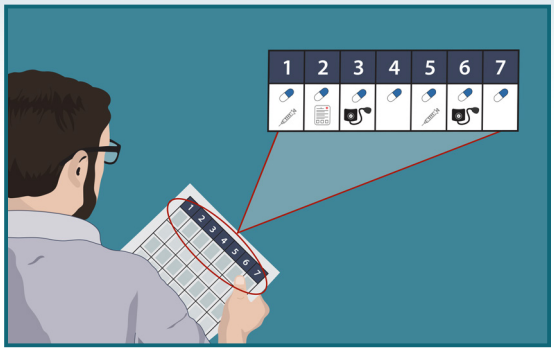
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

procedures (for participants)

cdisc

The activities that participants will be asked to do during the research study.



Example of *procedures (for participants)* in a sentence

The procedures listed in the consent form include all of the activities that participants will do while they are in the study.

More Info

Study procedures are all the ways that the researchers collect data and samples from participants.

Common procedures include interviews, surveys, blood draws, Xrays and scans, and taking a study treatment.

The procedures that impact participants will all be listed in the consent form (for example, study visits, blood draws, filling out questionnaires, etc.). Other study procedures that the study team has to do are listed in the protocol (for example, data collection and entry).

Related Words

schedule of activities

schedule of assessments

Other info to think about when joining a study

The consent form will list the "procedures required for a study." The procedures describes how many visits there are and what study activities will happen at each visit. The study team should review these with you and answer any questions you have.

Other Resources

NCI Thesaurus

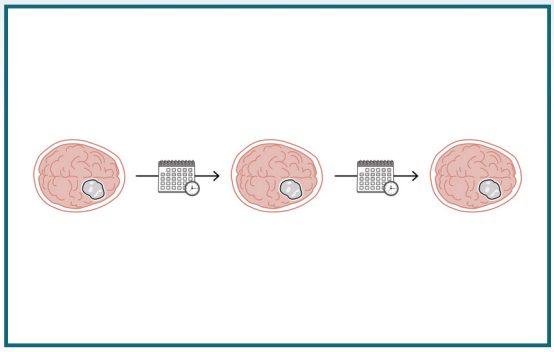
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

progression-free survival

cdisc

The length of time without an illness getting worse.



Example of *progression-free survival* in a sentence

Some studies look at progression-free survival to see if a drug keeps a disease or condition from getting worse.

More Info

Progression-free survival is often used to assess the treatment of diseases that are slow-growing and difficult to cure. Progression-free survival can be measured at an individual or population level.

Whether a disease is getting worse is measured via procedures such as scans, test results, biomarkers, self-report, etc.

Related Words

disease-free survival

Other info to think about when joining a study

Depending on the kind of study you are considering or reading about, you may see or hear references to "progression-free survival" during the informed consent process or other informational study materials.

"Progression-free survival" may be used to explain the purpose of a study or explain the reason for particular procedures and tests. For example, a study could be collecting data on how long a person lives without the illness getting worse.

If you have any questions about what it means for a study to look at progression-free survival, you should ask the study team."

Other Resources

NCI Thesaurus

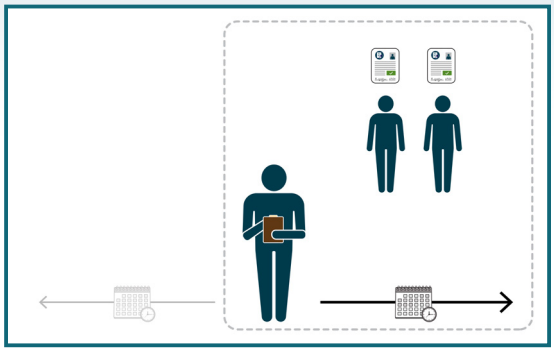
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

prospective study

cdisc

Research that uses new data collected from participants.



Example of *prospective study* in a sentence

Prospective studies actively collect new data from participants.

More Info

A prospective study collects new data over time.

For example, a lung cancer study might compare two treatments to see if one works better than the other to shrink a tumor.

Related Words

forward-looking study

real time study

Other info to think about when joining a study

The word "prospective" is often used to describe the timing of when a study's data are being collected. A prospective study collects data moving forward. It can be helpful to confirm the schedule with the study team.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

protocol

cdisc

A complete description of the research plan and procedures.

Example of *protocol* in a sentence

The protocol is like a recipe to make sure the research study is done in the same way by all of the study team members.

More Info

A protocol is shared among study team members and approved by an institutional review board (IRB) to ensure that the study procedures are conducted consistently. Participants do not usually get to review the complete protocol but its content will be discussed during the informed consent conversation and at study visits.

Related Words

study protocol
research protocol
consent form
informed consent

Other info to think about when joining a study

You may learn about the term "protocol" from the study team or in the consent form.

The protocol could be discussed when the study team talks about the instructions they have to follow to run the study.

Although the protocol is not always shared directly with participants, may the study protocol on trial registration sites like www.clinicaltrials.gov.

Feel free to ask the study team any questions you have about the study protocol.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

proxy

cdisc

A person who is legally allowed to make research decisions for someone else.

Example of *proxy* in a sentence

A proxy has legal permission to choose whether someone who cannot give informed consent on their own should be in a study.

More Info

A proxy can be a legal guardian or legally authorized representative (LAR).

A proxy can make decisions based on the wishes or best interests of the potential participant.

A proxy is permitted to sign a consent form on behalf of the study participant.

Related Words

guardian

legally authorized representative

Other info to think about when joining a study

You may see or hear the word "proxy" used in cases when participants who are legally not able to make research decisions for themselves are being recruited into a study. For example, a proxy might be needed in a situation where someone has a head injury or is so sick that they are not able to talk or sign the consent form.

If you are a proxy for someone else, feel free to ask the study team any questions you have about the research study.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

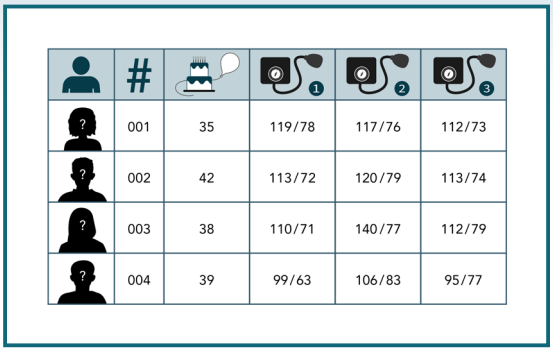
pseudonymized

cdisc

Replace personal details with a code so that data are protected.

Example of *pseudonymized* in a sentence

To *pseudonymize* data means that all direct identifiers such as name, birthdate, or address have been replaced with a code.



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	001	35	119/78	117/76	112/73
	002	42	113/72	120/79	113/74
	003	38	110/71	140/77	112/79
	004	39	99/63	106/83	95/77

More Info

Researchers pseudonymize data to mask the identify of a specific participant. This also protects participants' personal information from anyone who does not have a research-related reason to know.

When data are pseudonymized, identifiable information is replaced with a code to protect their identity. For example, a person's name might be changed to a code like 14252.

In some cases, researchers keep the code linking back to the participant for returning results or seeking additional information, but they do not share that code.

Related Words

anonymize

coded

Other info to think about when joining a study

You may see the word "pseudonymize" used in the consent form to describe how data collected in the study will be protected. Researchers are required to make sure that no personally identifiable information is ever released outside of the study to people who should not have access. If you have any questions about how your data will be protected, please feel free to ask the study team.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

purpose

What the study is testing.

Example of *purpose* in a sentence

The purpose of research is to answer a scientific question.

This graphic represents concepts related to what a study is designed to find out.

More Info

The consent form always includes a description of the purpose of the study.

The purpose is also described in the protocol.

Related Words

- study purpose
- objective
- aim
- goal
- rationale
- hypothesis
- intention

Other info to think about when joining a study

If you are a proxy for someone else, you should consider what would be in their best interest and what they would do if they were able to make the decision on their own.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Quality of Life (QOL)

cdisc

How someone feels and functions day to day.

Example of *Quality of Life (QOL)* in a sentence

The goal of measuring participant Quality of Life is to understand how they feel and their mental, physical, and social well-being.

More Info

Quality of Life (QOL) questions look at how someone feels about their life in the context of their culture and values, QOL is also measured in relation to their own goals, expectations, standards, and concerns.

Quality of Life is often based on the person's ability to do or enjoy daily living activities.

For example, if a person used to take daily walks but no longer is able to, this person's Quality of Life might be impacted negatively.

Related Words

assessment of daily living

Patient Reported Outcome (PRO)

Quality Adjusted Life Year (QALY)

Other info to think about when joining a study

The study team may collect information about your Quality of Life during the study. They may want to compare your Quality of Life before the study and your Quality of Life after you start the study treatment.

Quality of Life may be something you write down yourself using study surveys. This information could also be collected through interviews.

You could ask the study team to list out specific things that you may want to consider when thinking about your own Quality of Life.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

questionnaire

cdisc

A list of questions for study participants to answer as part of the study.

Example of *questionnaire* in a sentence

A questionnaire is one way researchers can collect data.

More Info

A questionnaire could be used to find out if a person is eligible to take part in the study, to see how someone is feeling, or to measure the effects of an intervention.

A questionnaire could be online or on paper.

Related Words

survey
data
assessment

Other info to think about when joining a study

A questionnaire or multiple questionnaires may need to be completed over the course of your participation in the study. This may be something you do by yourself or someone on the research team may do it with you.

As with any study procedure, you can ask what the purpose of the questionnaire is and if it has to be completed all at once.

Other Resources

NCI Thesaurus

Closer - Data Collection Tools

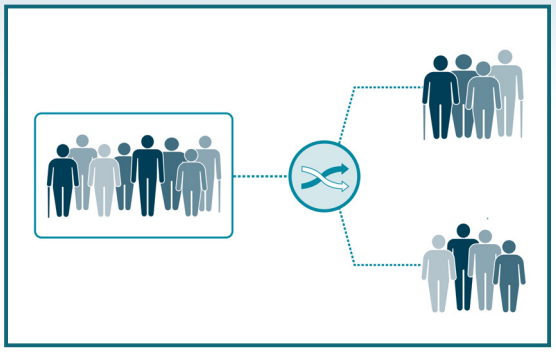
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

randomization

cdisc

A way to use chance to place study participants into different study treatment groups.



Example of *randomization* in a sentence

Study randomization is often done using a computer program to decide which group a participant is put into.

More Info

Randomization helps make sure the study groups are similar so they can be compared against each other at the end of the study. This is a way to avoid bias.

Every participant has a chance to be put into one of the study groups. No one can choose which group a participant is placed in, because it is done by a computer program.

Related Words

- random assignment
- randomize
- randomly assigned
- blinded
- study arm
- bias

Other info to think about when joining a study

Randomization is a common way that is used for participants to be assigned to different treatment groups. You might see the term "randomization" in the consent form or other study materials. Randomization means that you can't chooses which study treatment you will get. The study treatment is chosen by chance, like pulling names out of a hat.

If you are unsure, you should ask if randomization will happen in your study. You can also ask for more information about how the randomization will be completed.

Other Resources

NCI Thesaurus

HHS - Explaining Randomization in Clinical Trials

National Cancer Institute - Randomization and Bias in Cancer Clinical Trials

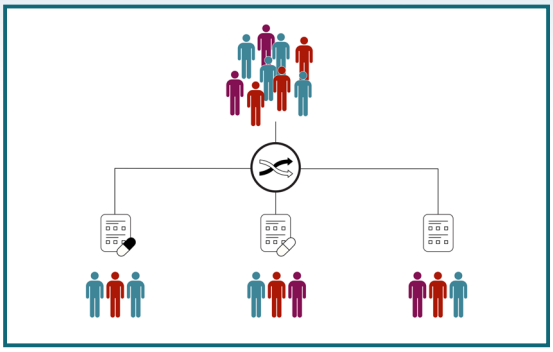
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

randomized controlled trial

cdisc

Research that uses chance to assign participants into study groups.



Example of *randomized controlled trial* in a sentence

A randomized controlled trial is used to compare two or more groups.

More Info

In a randomized controlled trial (RCT), the researchers use a computer program to randomly assign which study treatment each participant receives. The computer program sometimes also randomly chooses the order of the study treatment, depending on the study.

The process of being randomized is sometimes described like "flipping a coin" or "pulling name out of a hat." Randomization ensures that participants are put into different study groups fairly and without bias.

Related Words

randomization
control
control group
research bias

Other info to think about when joining a study

A randomized controlled trial is considered one of the best study designs to find out how well a study treatment works against one or more comparison groups.

If you are asked to participate in a randomized controlled trial, you may want to find out more about the different study groups, what the control group will be, and how participants will be randomized.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

rationale

The reason why a study, or something in a study, is being done.

Example of *rationale* in a sentence

A well-planned research study includes a clear rationale for why the study is necessary and important.

This graphic represents concepts related to what a study is designed to find out.

More Info

The study rationale explains why the study is important and why the study question must be answered. It can include background information, study details, and relevant justifications.

A study without a strong rationale might not be worth doing.

Related Words

reason
explanation
purpose

Other info to think about when joining a study

You might see the rationale for why a research study is done a certain way being described in the study protocol or consent form.

It can be helpful to learn more about the rationale of the study before agreeing to participate. Feel free to ask the study team questions about the background of the study and why it is being conducted.

Other Resources

NCI Thesaurus

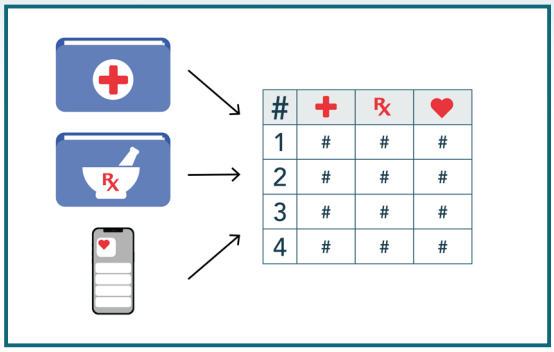
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

Real World Data (RWD)

cdisc

Information from many different sources used for health research purposes.



Example of *Real World Data (RWD)* in a sentence

Real World Data comes from sources like medical records, insurance claims, pharmacies, and wearables such as smart phones or heart monitors set up for that purpose.

More Info

Real World Data are routinely collected and not specifically for research.

Some studies use Real World Data such as health information in electronic medical records or insurance claims to learn more about side effects of medicines.

Related Words

data

Real World Evidence (RWE)

Other info to think about when joining a study

Some research studies use Real World Data. You may see the term "Real World Data" mentioned in a consent form or described in study results.

If a study uses Real World Data, you can also ask how these data are collected and protected.

Other Resources

NCI Thesaurus

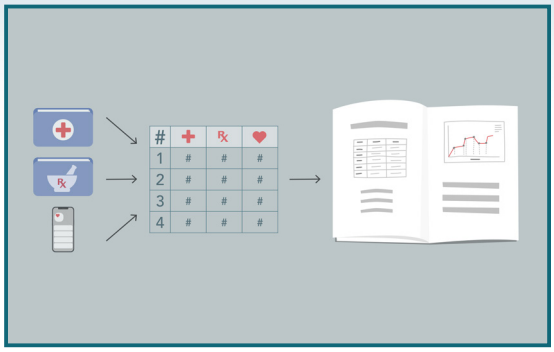
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

Real World Evidence (RWE)

cdisc

Findings from analyzing Real World Data.



Example of *Real World Evidence (RWE)* in a sentence

Real World Evidence comes from analyzing data that are collected from routine sources like medical records and health insurance claims.

More Info

Real World Evidence is often used to understand how medicines work in the real world, not in a clinical trial.

Real World Evidence uses routinely collected Real World Data to answer a study question. For example, Real World Evidence can show whether a drug is effective for a given population or subgroup of people based on the number of doctor's visits they need after taking the drug.

Related Words

Real World Data (RWD)

Other info to think about when joining a study

You may see the term "real world evidence" in research results or study summaries, to describe how the data collected from "real world" sources prove a particular point or supports a certain conclusion. For example, data taken from insurance claims may provide evidence that one kind of treatment reduces hospital readmissions more than a different treatment.

Other Resources

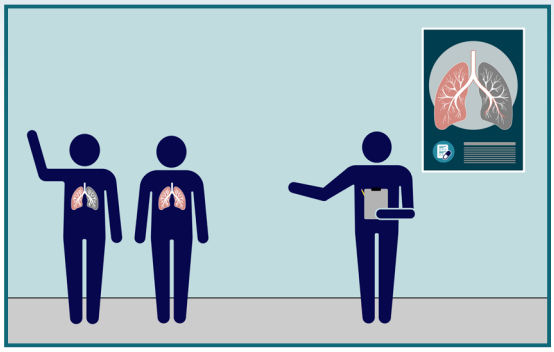
NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

recruiting (status)

cdisc

When a study is open to new participants joining the study.



Example of *recruiting (status)* in a sentence

A study that is recruiting is open to participants being screened and enrolling, if they consent.

More Info

A study that is recruiting follows a process to invite new people to join the study as participants. This is called recruitment.

Recruitment is a focused way to reach out to potential participants to tell them about the research, find out if they match the study criteria, and learn if they are interested in joining the study.

If the participant does want to join the study, the informed consent process can begin.

Related Words

enrolling
enrollment
enroll

Other info to think about when joining a study

You might see or hear the word "recruiting" if you are looking up studies to join or when a study staff member tells you about an open study. If you match the study criteria and choose to enroll in the study, you will next go through the informed consent process.

If you are learning about a study that is recruiting, you should feel free to ask any questions you might have about the research study and what being a participant will mean for you.

You should feel comfortable about the study before you agree to take part.

You can take time to think about whether to join the study. You can ask the study team how long the study will be recruiting and how long you have to decide whether to join.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

registry (study)

cdisc

An organized list of research information.

Example of *registry (study)* in a sentence

A clinical trial registry is a place to search for research studies.

More Info

Organized lists of information are valuable to research so many types of registries exist.

A medicine or research registry has many different types of information for different uses.

One example is a clinical trial registry which can include information about research studies that are planned, enrolling, or completed. Some registries also include research results.

A patient registry might be set up by a hospital or health system to allow their community members to express interest in volunteering for research so they can be contacted for participation when a new study is being offered.

A disease registry, like a cancer registry, is a resource to hold specific information about people with a certain disease. Some disease registries allow those who are registered to indicate they are interested in research. Some disease registries just allow researchers to conduct research using the information in the registry.

Related Words

clinical trial registry
Participant registry
Patient registry
disease registry

Other info to think about when joining a study

Before you consent to join a research-related registry, you may want to find out more about what information about you will be collected, how your information will be used, and how your privacy will be protected.

There are also other types of registries too that don't include any of your personal information.

For example, some studies that are funded with money from the USA government are required to post information about the study and its results on a research registry called www.clinicaltrials.gov. You may see a reference to www.clinicaltrials.gov in the consent form if the study team plans to release the overall study results there.

Other Resources

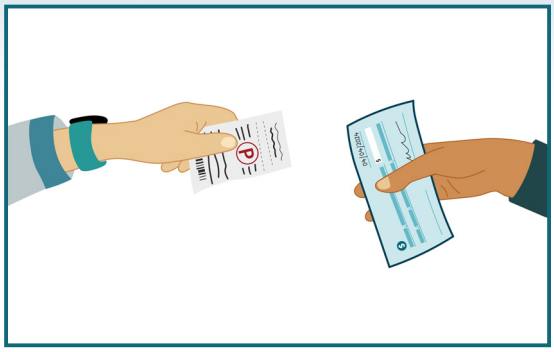
NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

reimburse

Pay money back to participants for their out-of-pocket study costs.



Example of *reimburse* in a sentence

Some studies will reimburse for parking, transportation, and other costs of participation.

More Info

Participants in research should find out whether the study team will reimburse any personal costs that might arise because of being in the study.

Related Words

repay
compensate
refund
remunerate
to pay someone back

Other info to think about when joining a study

When the study team is providing information about what will happen if you participate in the study, they may say if they will reimburse you.

You can ask if the study team will reimburse you for out-of-pocket costs related to participating in the study. For example, if you have to pay for parking at the study site, you can ask if the study team pay you back for that cost. Find out what out-of-pocket costs will be reimbursed can be important when deciding whether or not to join a study.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

relative risk

cdisc

The chance of a harmful event happening in one study group compared with another.

Example of *relative risk* in a sentence

If a relative risk is 1 the chance of an adverse event happening is the same across study groups.

This graphic represents math and statistics terms in this glossary.

More Info

For example, if a study finds that 20% of smokers develop lung cancer and 5% of non-smokers develop lung cancer, then we can calculate the relative risk of lung cancer in smokers versus non-smokers as:

Relative Risk = 20%/ 5% = 4

Thus, in this example, smokers are 4 times more likely to develop lung cancer than non-smokers.

Related Words

risk

absolute risk

Other info to think about when joining a study

You may see the term "relative risk" used in publications about the data and statistics of a research study. The results section of a publication will report the findings which will often include information about how many participants in one arm experienced a health event or problem versus participants in a comparison group. In general, however, "relative risk" is a technical math term and will not usually be used in materials designed especially for patients and participants.

If you see this word in a study document for a study you are considering, enrolled in, or completed, you can ask the researcher or study team any questions you might have.

Other Resources

NCI Thesaurus

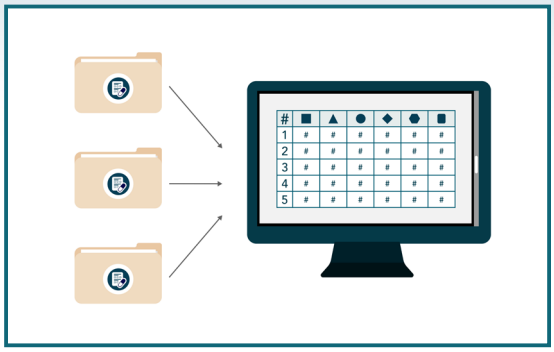
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

repository (research)

cdisc

A collection of participant data and samples stored for future research.



Example of *repository (research)* in a sentence

A research repository is a safe way for data and samples to be stored for future research studies.

More Info

A research repository stores both data and samples that have been collected with the purpose of being used in the future. Like a database, a research repository has strict rules for protecting and accessing the data and samples that are stored in it.

Related Words

database
data bank
biobank
collection of information
sample repository

Other info to think about when joining a study

A research study may collect data and/or samples to store in a repository for future use.

If data or samples will be stored for future use, the informed consent form will ask for your consent. You might want to ask the study team about how your privacy is maintained, how the data and samples are protected, who can use them in the future, and for what purpose. It is unlikely you will be contacted in the future about how they were used.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

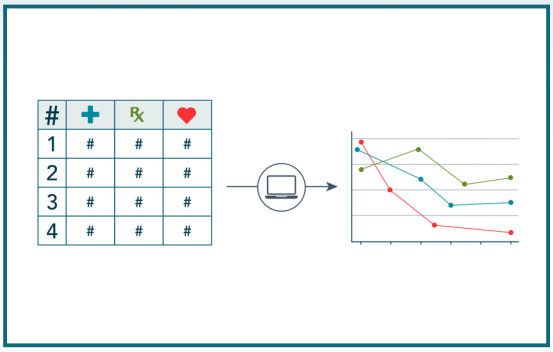
results (study)

cdisc

Findings from the study.

Example of *results (study)* in a sentence

The final results of the study are only available after all data are analyzed.



More Info

Study results are based on the data that were collected, analyzed, and interpreted in the study.

An example of a study result is learning that yoga can decrease low back pain.

Study participants can ask for the research results. Results can be shared in several ways: In a journal article, in a study summary for participants, or in other types of communication.

Related Words

outcome
findings
conclusions
data

Other info to think about when joining a study

The term "results" may appear in publications after the trial is completed and the study team has used the data collected to come out with their findings.

You can ask if and how the study team will share results with you when the study ends. If they will share, you can ask if you will get your individual information or if it will be a summary of the overall findings.

You can also ask if this information will be shared with your regular doctor.

In general, because research studies can take a long time to complete, it may take a while for study results to be finalized and shared. Feel free to ask about when the study team thinks the final study results will be ready.

Other Resources

NCI Thesaurus

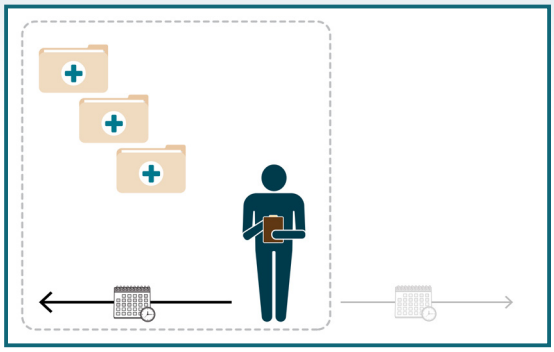
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

retrospective study

cdisc

Research that uses already existing data.



Example of *retrospective study* in a sentence

Retrospective studies use data that were collected in the past.

More Info

A retrospective study looks at the historical data of participants.

For example, a study of people with cancer might use existing medical records to learn more about possible causes and exposures.

A retrospective study may also use stored specimens or tissue samples that were collected in the past.

Related Words

backward-looking study

Other info to think about when joining a study

You may see the term "retrospective study" if you are asked to give informed consent if the study team looks through your past medical records.

You may want to ask them about what information they will be obtaining about you and why, and how your privacy will be protected.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

risk-benefit ratio

cdisc

A comparison of the possible bad and potential good things that could happen if a participant joins a research study.

Example of *risk-benefit ratio* in a sentence

It is important to discuss and understand the risk-benefit ratio of a research study before agreeing to participate.

More Info

People look at the risk-benefit ratio in different ways. Some may be less willing to accept a risk. Others may decide that the possible benefits are greater than the risks.

Feelings about a study's risk-benefit ratio can differ from person-to-person based on their own experiences, life situation, pre-existing conditions, and concerns.

It can be helpful for someone who is thinking about joining a study to discuss the risk-benefit ratio with the study team, trusted friends, and family members.

Related Words

risk benefit assessment
risk benefit profile
therapeutic index

Other info to think about when joining a study

The term "risk-benefit ratio" is sometimes part of consent forms and consent discussions. It is a way to try to describe how the risks and benefits of the study compare. Thinking about the risk-benefit ratio can help you decide whether the study has enough potential benefits to outweigh the risks of being in the study.

You can talk to the study team and other trusted people in your life to work through whether or not to join the study, based on the information that is known about the study treatment.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

risks of a research study

cdisc

The possible harms of being in a research study.

Example of *risks of a research study* in a sentence

Learning about the risks of a research study can help a person decide whether or not to join.

More Info

The risks of a research study depend on the study and study procedures. Both the serious and more common risks are listed in the consent form.

A potential participant should talk about the study risks with the study team and others before deciding whether to participate.

Some risks may not be known when a person signs the consent form. The study team will keep the participant updated if important new risks are identified.

Sometimes there are also risks to other people to consider so these should also be reviewed and understood. For example, if a study shares genetic information that could impact other family members.

The chance of a risk happening is sometimes called "absolute risk." The absolute risk is a number that shows how many people might have a specific event happen. In general, "absolute risk" is a technical math term and will not usually be used in materials designed especially for patients and participants. A related word is "relative risk."

Other info to think about when joining a study

You might see the term "risks of the research study" when the study team gives you a consent form to review and tells you about the study. They will explain the risks that you may experience if you join the study.

Ask questions about any of the risks you don't understand before agreeing to take part in a study. Risk may involve harm to the body but it may also include things like risk of stigma if sensitive information that is collected during the study is accidentally shared or accessed by others without permission.

To learn more about the risks of a research study, you can ask things like:

- How much do the researchers know about the risks of the study treatment – especially if it is new or experimental?
- Does the study treatment have FDA approval or oversight?
- What are the short- or long-term risks, discomforts, or unpleasant side effects? How likely are they to occur, and are any of them severe?
- What are the researchers doing to decrease risks, discomforts, or unpleasant side effects?
- Is there anything a participant could do to minimize their risks during the study?

Related Words

disadvantages
cons
harms
negative impacts
downsides
adverse effects
side effects

Other Resources

NCI Thesaurus

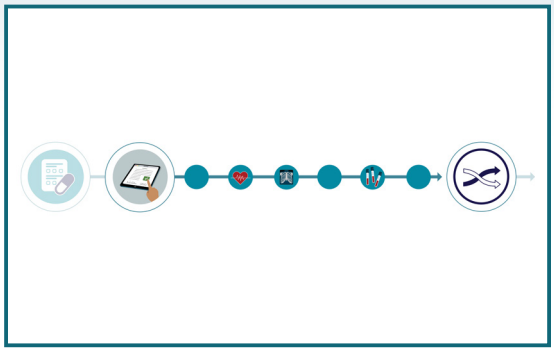
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

run-in period

cdisc

A planned time before randomization at the start of a research study for additional screening and participant preparation.



Example of *run-in period* in a sentence

Some studies have a run-in period, which occurs after informed consent and before randomization or any study drug or treatment is given, for additional screening, wash-out of other medications, or preparation.

More Info

A run-in period in a study can be a time to:

- Conduct more screening activities
- Wean participants off medications that they are taking at home
- Stabilize participants before the study treatment
- Practice study activities to support participants in completing the study.

More screening may be done in the run-in period because the second round of screening could have some increased risks, involve a longer procedure, or cost more.

During the run-in period, a participant could learn they are not able to continue in the study.

A run-in period could last from a few weeks to a few months, depending on the study.

Related Words

screening

wash-out

screening period

Other info to think about when joining a study

You may see the term "run-in period" in materials that talk about the design of a research study. For example, on clinicaltrials.gov, under the sections titled "Design Details" and "Arms and Intervention" there may be information that says if there is a planned run-in period in the study.

If a study you are thinking about joining has a run-in period, you can ask the study team how long the run-in period will last and what will happen during the run-in period.

Other Resources

NCI Thesaurus

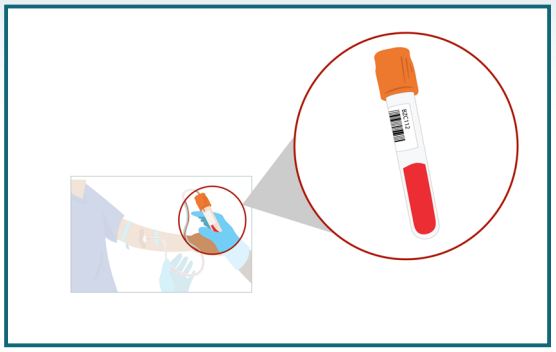
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

sample (study)

cdisc

Body fluids or tissues collected from a participant during a research study.



Example of *sample (study)* in a sentence

A sample is sometimes collected at the start of a study to get baseline data about the participant.

More Info

In clinical research, a sample is something that is collected from participant's body. A sample is sometimes also called a "biospecimen","biosample", or a "research biosample."

A skin biopsy or a piece of tumor can be collected as samples. Blood, urine, saliva, and other fluids can also be collected as samples.

Samples are used to learn more about a disease or condition. Samples can also help in diagnosis and treatment.

Related Words

biosample
biospecimen
biobanking
repository

Other info to think about when joining a study

You might see or hear the term "sample" to describe what could be collected during a research study, such as blood, urine, tissue, or other kinds of biological specimens.

Some things you can ask the study team include:

- if samples will be collected during the study and, if so, what will be collected and how,
- what the samples will be used for and by whom,
- whether the samples will be stored and for how long, and
- what will happen to any test results.

Sometimes samples collected can also be for optional parts of the research study. If you do not want your samples to be used for any optional parts, you can ask the study team how you can opt out.

Other Resources

NCI Thesaurus

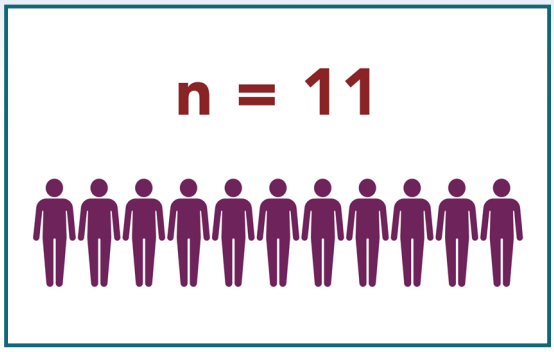
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

sample size

cdisc

The number of participants in a study or study group.



Example of *sample size* in a sentence

A study's sample size should ensure there will be enough participants enrolled to answer the study question.

More Info

The sample size must be able to be reached so that the study question can be answered. A statistician helps to calculate the sample size to ensure it is large enough to answer the study question. Sample size is often reported as n = <insert amount>. For example, a study with 100 participants would have its sample size described at n=100.

Related Words

- population size
- target population size
- statistician
- study population

Other info to think about when joining a study

The study team may tell you about the sample size of the study. You may also read about the sample size of the study in the consent form.

You may want to ask how many people have already enrolled in the study before you agree to join.

Other Resources

NCI Thesaurus

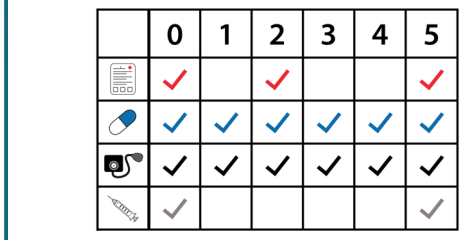
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

schedule of assessments

cdisc

A chart that lists the study activities and when they will happen during a study.



Example of *schedule of assessments* in a sentence

A schedule of assessments can help participants plan for their study visits.

More Info

A schedule of assessments is like a calendar or timeline. The schedule of assessments shows a detailed overview of all the study activities that involve participants and when they will happen.

Study activities can include blood draws, exams, questionnaires, and other medical tests.

Related Words

schedule of activities
timetable
calendar
study schema

Other info to think about when joining a study

If you are thinking about joining a study, you may see a "schedule of assessments" in the consent form. Someone from the study team may also provide more details. The study team will want to know if you can make it to all the study visits and if you understand all the activities you have to do while in the study.

If the schedule seems confusing, it can be helpful to ask the study team to help answer any questions. Additionally, putting all the activities that you need to do to participate in a study (like study visits or surveys) onto your personal calendar can help you plan.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

screen failure

cdisc

When a person cannot join a study because they do not fit its eligibility criteria.

Example of *screen failure* in a sentence

A screen failure happens when study requirements prevent someone from being able to enroll in a research study.

More Info

Most research studies have a list of inclusion and exclusion criteria that need to be checked before a person can enroll as a participant.

A screen failure happens when a patient is screened for a study but cannot be enrolled because they do not meet the eligibility criteria.

Some examples of why screen failures happen include:

- the potential participant is the wrong age
- the potential participant does not have a certain condition or disease
- the potential participant has blood test results outside a specific range.

Related Words

screening
eligibility
inclusion criteria
exclusion criteria

Other info to think about when joining a study

You might see or hear the term 'screen failure' if you go through a research study screening process to see if you are a good fit for the study and match its requirements.

Study teams are careful about who can join for safety reasons and to be sure the study question can be answered.

If you are not able to join one study, you can ask the study team about other options. There could be different studies you may be able to participate in.

Other Resources

NCI Thesaurus

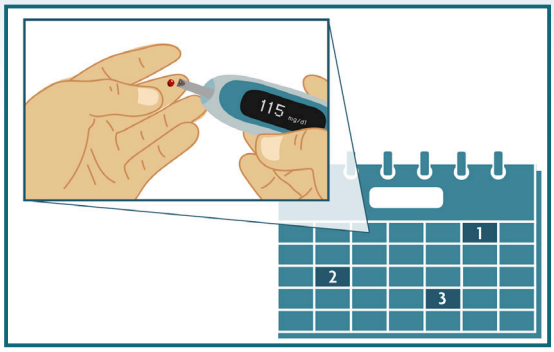
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

screening

cdisc

Tests and questions to find out if a person can join a study.



Example of *screening* in a sentence

Screening is done before a person joins the study to see if they meet the study requirements.

More Info

Researchers review inclusion and exclusion criteria as part of the screening process to make sure the participants are eligible to join a study.

Screening for research often includes an interview, reviewing a person's medical history, a physical examination, and laboratory tests to learn about the potential participant's health.

There is also screening that occurs outside of research like having a yearly breast cancer screening and colonoscopies.

Related Words

- eligibility criteria
- inclusion criteria
- exclusion criteria
- assessment
- study screening
- screen failure
- medical screening
- health screening

Other info to think about when joining a study

"Screening" is a word that is commonly seen in consent forms. There may be some screening questions and medical tests you will complete to see if you meet the study eligibility criteria.

You can ask what kind of screening the study team will have to do before you can join the study.

Other Resources

NCI Thesaurus

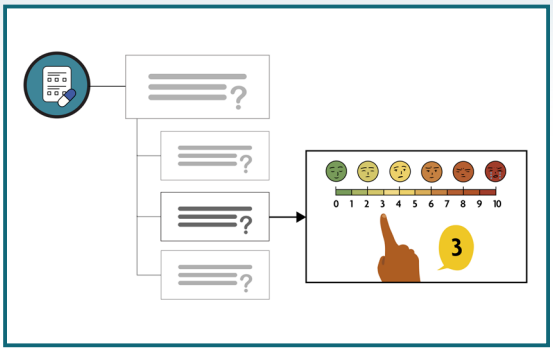
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

secondary endpoint

cdisc

A measure used to answer other important questions in the study that are not the main research question.



Example of *secondary endpoint* in a sentence

A secondary endpoint can provide more information about the effect of the study treatment.

More Info

A secondary endpoint can help guide researchers to answer other questions related to the study treatment.

A secondary endpoint can also be exploratory, for example, looking for information that might be useful for a future study.

Related Words

secondary aim

Other info to think about when joining a study

You may see the concept of the "secondary endpoint" written about in the consent form or hear about it from the study team. Additionally, if you visit www.clinicaltrials.gov you may see references to primary and secondary endpoints.

Secondary endpoints are other aspects that the study is designed to measure. If you are unsure of what it means, please ask the study team for clarification. After the study is done and publications are released, you may also read about different types of endpoints.

Some studies might only have a primary endpoint and you will not see anything about a secondary endpoint. This is normal.

Other Resources

NCI Thesaurus

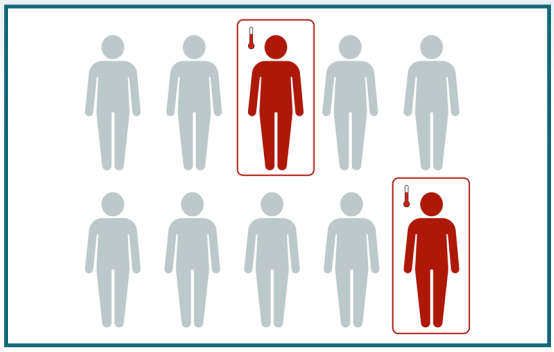
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

sensitivity (medical test)

cdisc

How well a medical test can accurately identify people who have a disease or trait.



Example of *sensitivity (medical test)* in a sentence

The sensitivity of a test refers to how well it detects a disease when the person actually has the disease.

More Info

A medical test that has high sensitivity means it is very good at detecting a disease. If it has low sensitivity it means it is not very good at detecting a disease.

Greater sensitivity leads to a more precise diagnosis.

For example, a COVID test with high sensitivity means the test is able to detect the infection very well.

Related Words

specificity
false negative
true positive
false positive

Other info to think about when joining a study

In clinical research and medicine, the term "sensitivity" is used to describe how well a medical test works to find cases of an illness or condition. A test that works well to identify people with an illness or condition is said to be very sensitive.

You can always ask the study team if you have any questions about the way the term "sensitivity" is being used in the study information.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

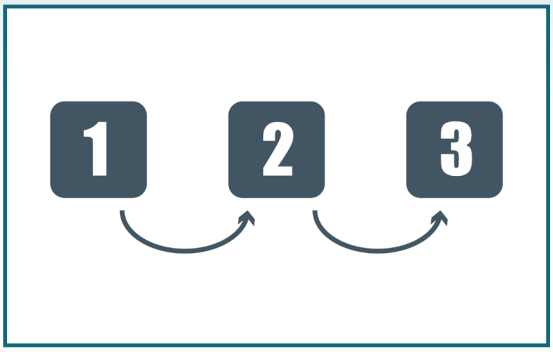
Clinical Research Glossary

sequential

Happening in a specific order.

Example of *sequential* in a sentence

Events that occur one after the other are sequential.



More Info

Research studies have steps and procedures that must be followed in a specific, sequential order.

Related Words

one after the other
successive
consecutive

Other info to think about when joining a study

The word "sequential" can be used to describe the order that study activities are conducted.

If you have any questions about sequential study activities you can ask the study team to better understand.

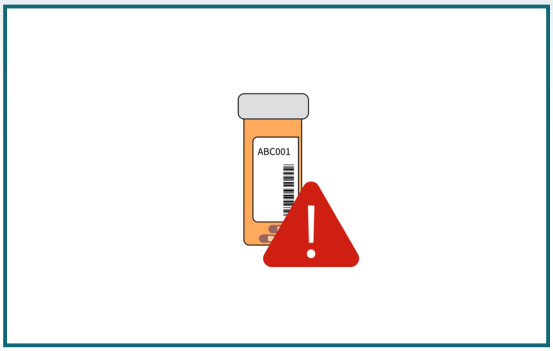
Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Serious Adverse Drug Reaction (SADR) cdisc

A health issue, possibly caused by a medication, that leads to hospital care, lasting medical problems, life-threatening conditions, or death.



Example of *Serious Adverse Drug Reaction (SADR)* in a sentence

A Serious Adverse Drug Reaction is a major health problem that the study team thinks was likely caused by a study treatment

More Info

A Serious Adverse Drug Reaction (SADR) is reasonably likely to be caused by a study treatment and:

- results in death,
- is life-threatening,
- requires a person to stay in the hospital or lengthens their time in the hospital,
- results in ongoing or major disability or incapacity, or
- causes a birth defect.

In a research study, the study sponsor tracks and reports all adverse events and reactions so that there is a record of all the possible risks of the study treatment.

Related Words

Serious Adverse Event (SAE)
adverse event
adverse reaction

Other info to think about when joining a study

You may hear about Serious Adverse Drug Reactions (SADRs) if you are reading the results of what past studies have found.

You could also hear about SADRs if you are learning about the possible risks of being in a study that is testing a drug.

You should feel free to ask the study team about what they know about Serious Adverse Drug Reactions that could happen during the study.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

Serious Adverse Event (SAE)

A health issue that happens during a study and leads to hospital care, lasting medical problems, life-threatening conditions, or death.

Example of *Serious Adverse Event (SAE)* in a sentence

A Serious Adverse Event in a study is usually something very concerning that was not expected.

More Info

Serious Adverse Events (SAEs) are health problems that may result in death, an inpatient hospital stay or longer hospitalization, a life-threatening event, a disability happening, or a birth defect in a baby. An SAE may or may not be related to the study treatment.

There are sometimes new SAEs that could occur that even the study team does not know about yet. The study staff will collect this information from participants to keep track and figure out if it needs to be included in future study informed consent forms.

In contrast to a Serious Adverse Event, an "adverse reaction" is determined to be related to a study treatment.

Related Words

- adverse event
- adverse reaction
- side effect
- dangerous event
- life-threatening event
- unanticipated problem

Other info to think about when joining a study

You may learn about potential Serious Adverse Events during the consent process if they are known. You could also learn about them during or after the research study if they are discovered later.

When you are in a research study, it is important to contact the study team if you have any new health problems whether or not they are serious. This is important for your safety and allows the study team to also monitor the other study participants. You can ask about adverse events, and Serious Adverse Events, before joining or during a study.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

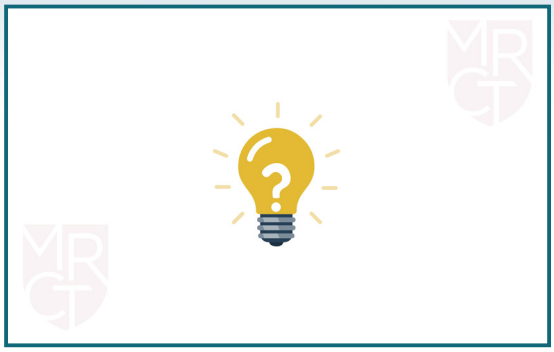
sham (procedure)

cdisc

A medical process that looks and feels like the study treatment, but is not expected to have a health effect on the condition being studied.

Example of *sham (procedure)* in a sentence

A sham procedure in a study keeps the participant and the study team from knowing whether the participant received the active or inactive procedure.



Do you have an idea for an image that could explain this concept? Contact us.

More Info

A sham procedure is sometimes referred to as a fake or pretend procedure. A sham procedure could be done in research studies where it might be difficult keep the participant from knowing whether or not they received the study intervention.

A participant who joins a research study that involves a sham procedure should not be able to tell whether they got the sham or the active treatment.

For example, a study that involves a surgery to insert an implant could include a group that is randomized to receive a sham procedure. That way, all participants go in for surgery but they do not know whether they will receive the implant or not. A sham procedure is done to prevent bias, or the idea that a participant could expect the device to be helping them if they know for sure that they got it.

Related Words

- control group
- placebo
- single-blind study
- double-blind study

Other info to think about when joining a study

You could see the term "sham (procedure)" if you are considering joining a study that is testing an intervention that does not have any other way to keep you from knowing whether you are receiving the active or inactive procedure. If you join a study with a sham procedure, you should not be able to tell if you got the real treatment or the sham.

You should feel free to ask any questions you have about why a sham procedure is being used, what the risks are, and whether there will be an option to get the active treatment in the future.

The study team should discuss any known safety issues with you. For example, if the study involves an implant, you should ask if it contains metal. This is important because doctors need to know if you have metal in your body before you have certain tests, like an MRI.

Other Resources

NCI Thesaurus

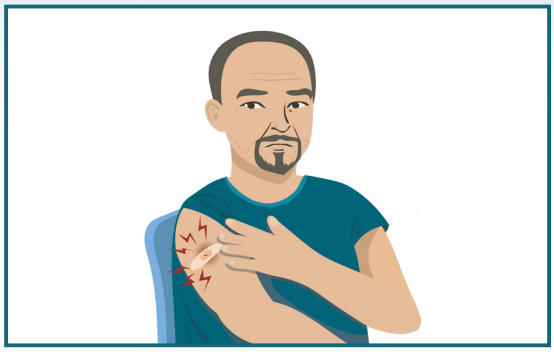
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

side effect

cdisc

A health change that is not the intended effect of the treatment and usually considered a problem.



Example of *side effect* in a sentence

A side effect is not the main effect of the treatment.

More Info

Side effects are things that are known to be a possible effect of a treatment.

For example, a side effect of taking aspirin is excess bleeding. Often times, a side effect is unwanted, but in some cases a side effect could be considered a good thing.

Related Words

health effect

adverse reaction

Other info to think about when joining a study

Known side effects are listed in the consent form. A member of the study team may also tell you about possible side effects.

Ask any questions about the side effects and how likely they are. You can also ask what you should do if you think you are getting a side effect and who you should tell.

Other Resources

NCI Thesaurus

FDA - Finding and Learning about Side Effects (adverse reactions)

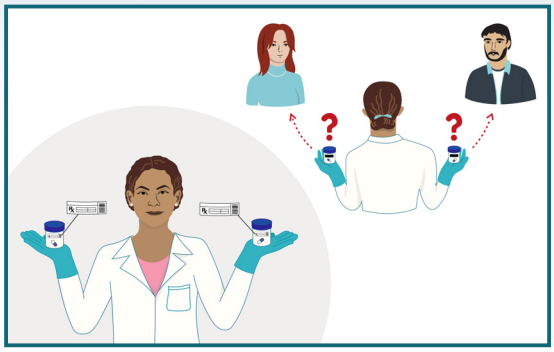
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

single-blind study

cdisc

A study that is set up so that the study treatment each participant receives is not known by the participants but is known by the researchers.



Example of *single-blind study* in a sentence

A participant in a single-blind study will not know which study group they are in, but the study doctor will.

More Info

Some studies are single-blind because participants knowing which treatment they are getting can affect the results of the study, through a concept called bias.

Bias can occur when participants know which study group they are in.

Participants can ask to find out which study treatment they received after the study ends.

Related Words

masked/masking
bias
double-blind study
randomization

Other info to think about when joining a study

The term "single-blind study" refers to how a study was designed. This means that the researcher will know what study treatment each participant received but the participant won't.

You can always ask the researchers why the study is done as a single-blind study. You could also ask if and when you will find out what study treatment you were given.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

specificity (medical test)

cdisc

How well a medical test can accurately identify people who do not have a disease or trait.

Example of *specificity (medical test)* in a sentence

The specificity of a test refers to how well it identifies when an illness is not present.

More Info

A medical test that has high specificity means it is very good at detecting if a person does not have a disease. If it has low specificity it identifies people as having the disease when they actually do not.

Greater specificity allows people who do not have a condition to be identified and screened out so resources can be put toward caring for people who do have the condition.

For example, a COVID test with high specificity means the test correctly identifies when people don't have the infection.

Related Words

sensitivity
true negative
false positive
false negative

Other info to think about when joining a study

In clinical research and medicine, the term "specificity" is used to describe how well a medical test works to show people who do not have an illness or condition. A test that works well to rule out people who do not have an illness or condition is said to be very specific.

You can always ask the study team if you have any questions about the way the term "specificity" is being used in the study information.

Other Resources

NCI Thesaurus

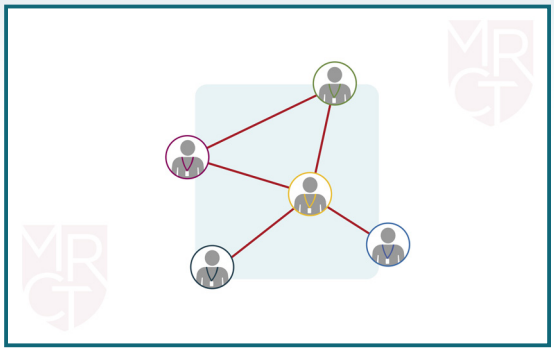
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

sponsor

cdisc

The person or group that has overall responsibility for a research study and may also provide funding for the study.



This graphic represents the groups in a research network that are involved in the conduct of research studies.

Example of *sponsor* in a sentence

The study sponsor is often the drug or device company that makes and studies the product.

More Info

A sponsor in clinical research is a person or group responsible for designing and overseeing a research study.

A sponsor can be a drug or device company, governmental agency, academic institution, person, group, or private organization.

Sometimes the sponsor is an academic researcher who is responsible for the design, conduct, and reporting of the study. This is called being a "Sponsor Investigator."

Related Words

funder

pharmaceutical company

sponsor investigator

Other info to think about when joining a study

The term "sponsor" may be in the consent form or mentioned when the study team discusses who is running the study. The sponsor is the person or group who is responsible for how the study is conducted.

The sponsor could be a drug company or a researcher. You can ask the study team who the sponsor is and if the sponsor of the study is the group that made the investigational product that will be used in the study. You may also ask if the investigators have any financial relationship with the sponsor outside of the study or have been paid by the sponsor for other services besides the study.

In general, any financial relationships between researchers and companies should be described in the consent form and made clear to the study participants.

Other Resources

NCI Thesaurus

Penn State — Investigators, Sponsors, and Sponsor-Investigators

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

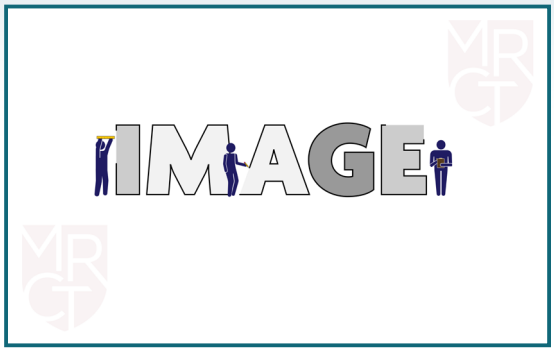
standard of care

cdisc

The usual treatment given to patients for an illness.

Example of *standard of care* in a sentence

Some research studies compare the study treatment to the standard of care for a given condition.



This graphic indicates that a new image is being developed. Check back again soon!

More Info

Depending on the health issue, there could be many types of standard of care that are used by health care providers.

For example, there are different medications used to treat high blood pressure.

Related Words

standard therapy
standard treatment
usual care

Other info to think about when joining a study

The term "standard of care" may come up in the consent form where it may explain that the study is comparing a new study intervention with the existing standard of care.

If you have any questions about the study treatment you are being given or the standard of care, you should feel free to ask the study team.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

statistically significant

cdisc

Results that are very unlikely to have occurred by chance.

Example of *statistically significant* in a sentence

Study results are analyzed to find out if they are statistically significant.

This graphic represents math and statistics terms in this glossary.

More Info

When a result is found to be statistically significant, it means that a study result probably did not happen by chance. It does not necessarily mean that the finding is clinically important.

For example - a study could show a new medicine lowers blood pressure (statistically significant) but the side effects are too great to make it a useful treatment (not clinically meaningful).

Similarly, a statistically significant result in a study may be different than a person's lived experience. For example, a study may show a statistically significant overall decrease in depression scores based on data collected from all participants in the study but an individual participant may still have feelings of depression.

Related Words

clinically meaningful

Other info to think about when joining a study

You might see the term "statistically significant" used in a research article when the authors discuss the results and statistics.

The results section may also provide more information about what it means for the data to be statistically significant.

You may also see this term in Plain Language Summaries of a study's results.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

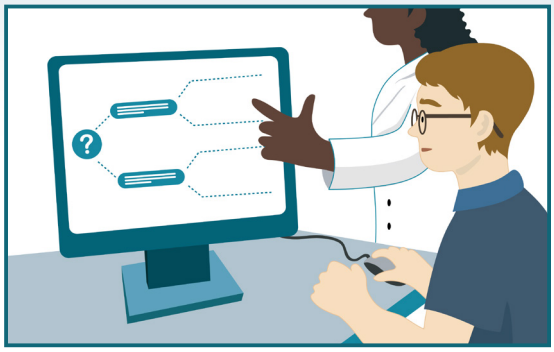
study design

cdisc

The way a study is set up to answer the study question.

Example of *study design* in a sentence

It is very important for researchers to use a study design that will answer the study questions.



More Info

The study design determines how participants will be recruited and enrolled, whether participants will be randomized, what kinds of data will be collected, and how the data will be analyzed.

There are many different types of study design.

Related Words

design
single-blind study
double-blind study
randomization
observational study
clinical trial

Other info to think about when joining a study

Researchers are careful about using the right study design to answer a specific question. You might learn about the study design from the study team or the consent form.

You may be able to find more information about the study you are thinking about joining at www.clinicaltrials.gov. There may be a section called "How is the study designed?"

If there is anything you don't understand about the study design you should ask the study team.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

study doctor

cdisc

A person with relevant health training who makes sure clinical study procedures are done correctly, and participants are safe and cared for.

Example of *study doctor* in a sentence

Research that involves medical tests will often include a study doctor on the study team.

More Info

The study team can have many different staff members.

In some cases, the study doctor may be called an investigator, a clinical investigator, or the Principal Investigator of the study.

Some studies involve medical knowledge or procedures that require a study doctor to ensure that participants are safe and monitored.

Related Words

investigator

clinical investigator

Other info to think about when joining a study

You might hear the term "study doctor" when you are thinking about joining a health-related research study that involves drugs, vaccines, or medical tests or procedures.
This person may be different from your regular healthcare provider.

You can always ask about the roles of different people on the study and why they are involved.

Other Resources

NCI Thesaurus

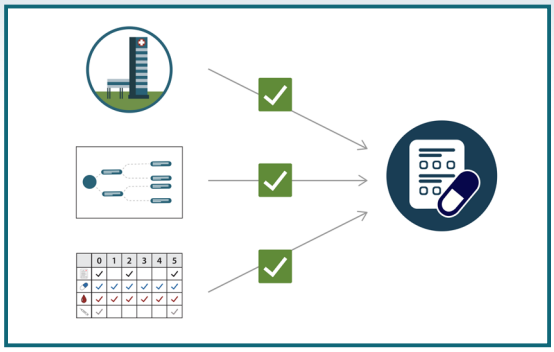
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

study feasibility

cdisc

How likely it is that a study can be completed.



Example of *study feasibility* in a sentence

Research planning involves assessing study feasibility before starting to enroll participants.

More Info

In research, study feasibility means that:

- the study procedures are all necessary and not overly burdensome,
- the number of proposed participants should be possible to enroll in the locations chosen, and
- the study will have enough participants to answer the study question.

Research teams should spend time looking at all the parts of the study to make sure they are "doable."
If a study has low feasibility, it is less likely to generate enough data to answer the study questions.

Low study feasibility is not a failure of participants. Low feasibility reflects a failure of the study planning process.

Related Words

feasible
possible
achievable

Other info to think about when joining a study

Study feasibility is about checking whether a study can be done as proposed. This is not the same as a "feasibility study" which is a study that is done to find out if an intervention is possible.

Feel free to ask questions about how the research team planned the study and how they are ensuring the study will be able to answer the planned research questions.

Other Resources

NCI Thesaurus

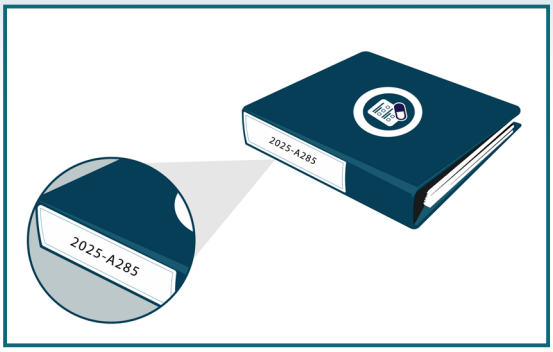
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

study identifier

cdisc

A set of numbers, letters, or both, that is used to identify a study.



Example of *study identifier* in a sentence

Every research study has a study identifier that can be used instead of the study title when looking it up or talking about it.

More Info

There are many different types of study identifiers. A single study could have multiple different unique study identifiers.

For example, a study identifier can be created:

1. by the study sponsor to refer to the study at their company
2. by the research team or study site
3. by the ethics committee or other oversight group for the review process
4. when a study is registered in a clinical trial registry.

Related Words

participant identifier

participant code

Other info to think about when joining a study

If you are thinking about joining a study, you may not hear about the "study identifier" but you will likely see different study numbers or codes, like a protocol number or a registration number. For example, on www.clinicaltrials.gov you would see the a study identifier called the NCT number.

These study identifiers can be helpful as a quick way to refer to a study and make it easier to find in different databases.

Often the research team will just refer to the study by its name, but you can ask the study team if there are other numbers or codes that would be helpful for you to know.

Other Resources

NCI Thesaurus

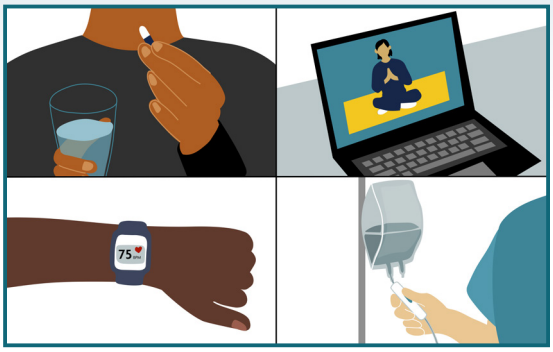
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

study intervention

cdisc

A treatment given to the participants in a study



Example of *study intervention* in a sentence

If a research study includes an intervention, it means participants will test something to see its effects.

More Info

A study intervention can be a treatment of a disease or condition or include ways to change behavior, attitudes, and maintain or improve health. For example, a study might test whether giving participants a step counter leads to weight loss.

Related Words

study treatment
investigational drug
investigational product
investigational device

Other info to think about when joining a study

The study team or the consent form might mention the term "study intervention."

When you are learning about a clinical trial you should be given information about the study intervention which could be something you take (like a medicine) or do (like yoga) during the study to see if it has any effect.

You can always ask for more information about the study intervention the research is testing. You may also want to ask about the background of the study intervention and any prior research that was done that led to the researchers starting a new study.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

study life cycle

cdisc

The steps of a research study from beginning to end.

Example of *study life cycle* in a sentence

The study life cycle refers to all the steps that go into developing and running a research study.

More Info

The steps of the study life cycle include: developing the study protocol and procedures, participant recruitment, screening, and consent, ongoing study procedures, follow-up, end of study procedures, and study close-out.

Related Words

clinical trial life cycle

Other info to think about when joining a study

You might hear about the "study life cycle" when discussing the research process with a study team member. The term "study life cycle" is often used to describe the overall plan for the study.

As a participant, you are part of the study life cycle. If you join a study, your data are important for the study to be completed. Please feel free to ask the study team any questions you might have about the study.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

study monitor

cdisc

A qualified person who checks that a research study is being done safely and is following the study plan correctly.

Example of *study monitor* in a sentence

The study monitor is an independent reviewer who checks that the protocol is being followed as required and that the collected data are accurate.

More Info

The study monitor reviews the progress of a research study, to confirm that it is conducted, recorded, and reported as it needs to be.

The study monitor reviews the study protocol procedures, the study documents, records of data, and other relevant materials.

Study monitors help make sure that the research study is being done as planned, participants are safe, and the data can be trusted.

Related Words

clinical research monitor
auditor
study auditor

Other info to think about when joining a study

You might see the word "study monitor" in the consent form or hear it during conversations with the study team.

The study monitor visits the study site, talks with the research team, and reviews records. They will see your study data as part of their job, but they are trained to keep your information private.

Study monitors do not make changes to your care, but they help make sure the study is safe and fair for everyone.

You can always ask the study team about who has access to your study data and why.

Other Resources

NCI Thesaurus

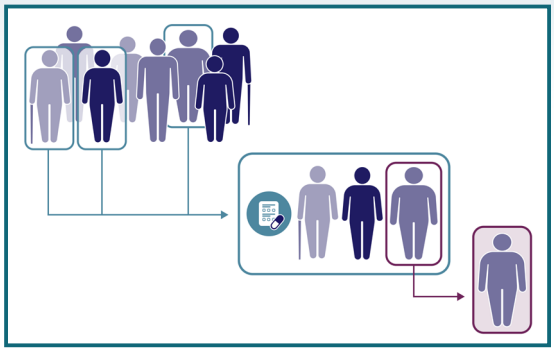
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

study participant

cdisc

A person who joins a research study.



Example of *study participant* in a sentence

A study participant volunteers to join research.

More Info

If you are a study participant in a research study, your data will help answer the research question.

Related Words

- participant
- subject
- research participant
- research subject
- study subject
- healthy volunteer
- data
- clinical trial
- observational study

Other info to think about when joining a study

A person who joins a study is called a "study participant." The consent form will describe the study, and what study participants will be asked to do.

Before you join a study you should understand what participating in the research will involve. Please ask any questions you have about being in the study.

Other Resources

NCI Thesaurus

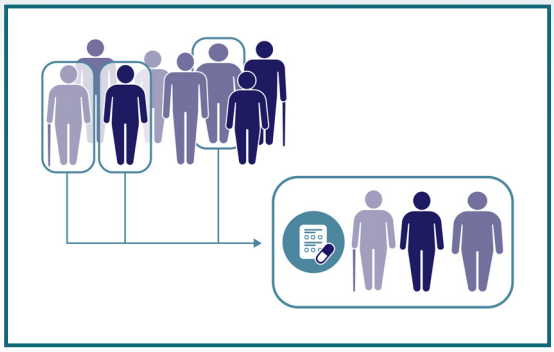
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

study population

cdisc

All the participants in a study.



Example of *study population* in a sentence

A participant is a member of the study population.

More Info

The study population is described in the consent form and the protocol.

Related Words

participant population

participant

Other info to think about when joining a study

You may hear the term "study population" from the study team or read it in the consent form.

There may be information about the number of individuals who are in the study population or what similarities the study population shares. The study population is also discussed in results and journal publications that describe what the study looked at.

If you have any questions about the study population, you should feel free to ask.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

study site

cdisc

An approved location where research study activities take place.

Example of *study site* in a sentence

A study can have multiple study sites where participants can have data or samples collected.

More Info

A study site is where a participant goes to complete some or all of the study activities.

A study site could be at a hospital, doctor's office, laboratory, infusion center, or a temporary but convenient location set up by the study team for this purpose.

Related Words

decentralized clinical trial

multicenter study

Other info to think about when joining a study

You may hear or read about one or more "study sites" during the consent process, and at other points throughout the study.

Before joining a study, you should consider if the study sites are easy for you to travel to. You can always ask the study team if there are study sites that could be better for you to get to, and if there is any reimbursement for your travel or parking fees.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

study statistician

cdisc

A person who uses math to help design a study and interpret the data.

Example of *study statistician* in a sentence

The study statistician reviews and analyzes the data, and reports the results back to the study team.

More Info

Statisticians design studies to decrease bias and make the results as accurate as possible.

Before a study begins, a statistician can help the study team calculate how many participants should be enrolled so the research question can be answered.

A study statistician can analyze study data and present the results using numbers, charts, and graphs. Study statisticians are trained to figure out whether a result happened by chance or not.

Related Words

data
analysis
results

Other info to think about when joining a study

You may hear that a study statistician is part of the research study and will work with the data collected during the study.

It is always fine to ask about who is working on the study and how your data are protected.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

study suspension

cdisc

A decision to pause a study, made by a group that oversees or is responsible for research.

Example of *study suspension* in a sentence

A study suspension can be issued by a sponsor, principal investigator or Institutional Review Board (IRB) due to concerns about the study.

More Info

A study suspension is a formal and mandatory pause or delay of a clinical research study.

A study suspension often occurs due to issues like participant safety concerns, new information that could negatively affect the study's conduct, problems that have occurred, or supply issues.

When a study is suspended, the study is still open. No new participants may be enrolled. How participants currently on the study are treated and cared for is based on their best interests. The study team still tracks issues that arise, like adverse events.

Related Words

clinical hold

Other info to think about when joining a study

If there is a study suspension of a research study you are participating in, you can ask the team what the reason was, what the plans to address the concerns are, and when there will be more information about whether the study will continue.

You should ask any questions you have about what the study suspension means for you and how you will be taken care of during the pause.

Other Resources

eCFR — Title 45

NCI Thesaurus

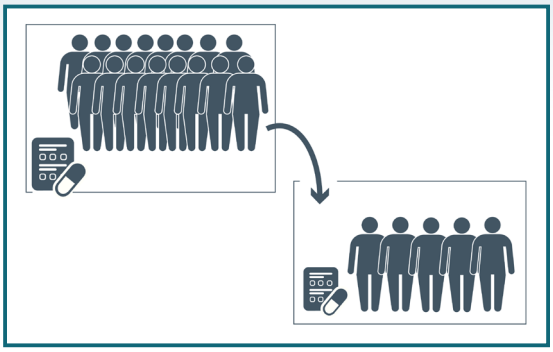
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

substudy

cdisc

A study with a smaller group of participants already enrolled in the main study.



Example of *substudy* in a sentence

A substudy is a study to answer questions related to the main study.

More Info

A substudy asks a separate research question from the main study. It adds to the main study's objectives and uses all or a subset of participants or samples from the main study.

A substudy is sometimes designed at the beginning of the main study. It is also possible that a substudy could happen later after some data have been analyzed.

Related Words

basket trial
cohort trial
umbrella trial
master protocol

Other info to think about when joining a study

When you enroll in a study, there may be additional substudies you can choose to enroll in. For some substudies, you may need to go in for extra study visits or do some extra tests. The study team may want to collect more information from you to answer additional questions that the first study you enrolled in is not looking at. You will be consented for additional substudies.

You may want to ask if there are substudies in the study you join. Additionally, you can ask if you have to join any substudies and ask for more information about how the substudy is different from the first study you are enrolling in. It could also be helpful to ask if you have to do additional tests or go in for more study visits if you join a substudy. This could help you decide if you have the time to join.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

superiority trial

cdisc

A study to test if a study treatment works better than another treatment for the same condition.

Example of *superiority trial* in a sentence

One example of a superiority trial would be to test whether a new medicine is better for treating asthma than an existing one.

More Info

Superiority trials are done to find treatment options that work better than those that are already approved for a specific disease or condition.

Related Words

superiority study
confirmatory trial
equivalence trial
control
non-inferiority trial

Other info to think about when joining a study

If you are thinking about joining a superiority trial, it will be a study that looks at whether one treatment works better than another. You should ask any questions you have about the treatments being tested before you consent.

Other Resources

NCI Thesaurus

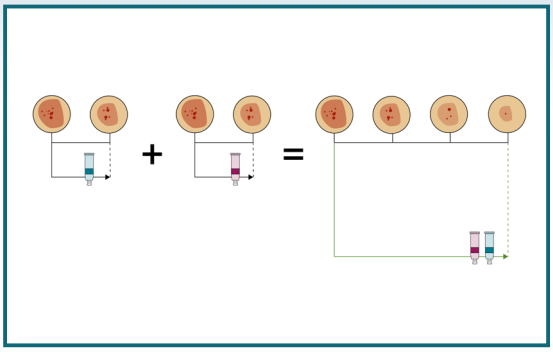
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

synergistic effect

cdisc

When two or more things combined have a greater effect than when their individual effects are added together.



Example of *synergistic effect* in a sentence

A synergistic effect means that the combined effects of two products is stronger than what was expected.

More Info

A combination of medications is synergistic if they work better together than if the individual component effects were added together.

For example, Drug A decreases cancer growth by 10% and Drug B by 20% when each are used alone. One would predict that used together, cancer growth might be decreased by 30% (additive). If Drug (A + B) used together decreases cancer growth by 35% or more, the effect is considered "synergistic."

Related Words

additive effect

Other info to think about when joining a study

The term "synergistic" is sometimes used to describe how two things that are used together actually have a greater effect than just one of them used alone. It's like the two things work in synergy with each other to have more of an effect.

You can ask the study team if you have any questions about the word "synergistic" is being used in study documents or conversations you are having.

Other Resources

NCI Thesaurus

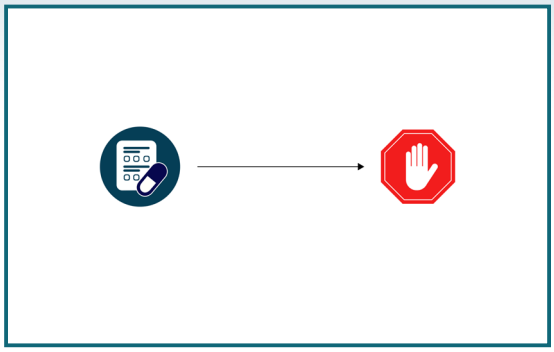
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

termination (of a research study)

cdisc

When research is stopped earlier than planned.



Example of *termination (of a research study)* in a sentence

A research study may be terminated because of early positive or negative results.

More Info

There are different reasons why research may be terminated.

- There could be positive results that make continuing the study unethical since the study question has been answered.
- There could be safety issues or other concerns that cause a research study to be terminated early.
- There could be a lack of enrollment.

Some research studies have planned interim analyses and the results from those analyses could provide information on whether a study should be terminated.

Termination in the clinical research context refers to when all participant activities are stopped.

If a research study has multiple arms, one of the arms could be terminated while the rest of the research study continues.

Research data and samples from terminated research will still be analyzed and reported.

Other info to think about when joining a study

You could see or hear the term "termination" or "terminated" being used to describe a study that has stopped early.

If a study you are in is terminated, you should feel free to ask what the reason for the termination is, and whether there are other studies that might be good for you to consider.

Related Words

withdraw

discontinue

Other Resources

NCI Thesaurus

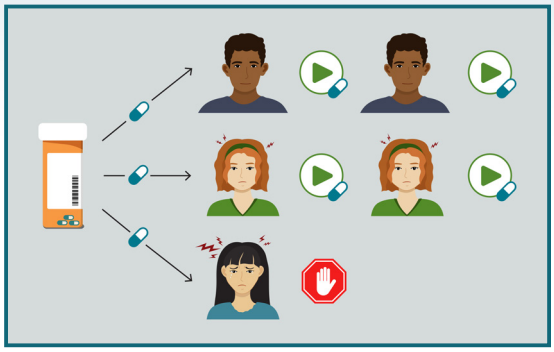
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

tolerability

cdisc

How much a participant or group of participants can accept a study treatment's unwanted effects so they can keep taking it.



Example of *treatment tolerability* in a sentence

Many drug studies look at the tolerability of the study treatment.

More Info

Tolerability is looked at to find out how easy it is for a treatment to be delivered. For example, researchers can learn whether a pill is too big to be swallowed.

Tolerability also tells us about the problems a treatment may cause, and how severe those problems are. If a person has to stop taking a study treatment because of related problems, then tolerability is low.

Related Words

safety

adverse effects

side effects

Other info to think about when joining a study

Someone from the study team may ask you about the tolerability of the study treatment during follow-up visits or on questionnaires.

You may want to clarify what they mean by "tolerability." For some people, nausea might be tolerable while for others it's not, so you should let the study staff know what you are feeling while taking the study treatment. You could also ask the study staff what you should do if you are having trouble taking the study treatment, or wish to stop taking it.

Other Resources

NCI Thesaurus

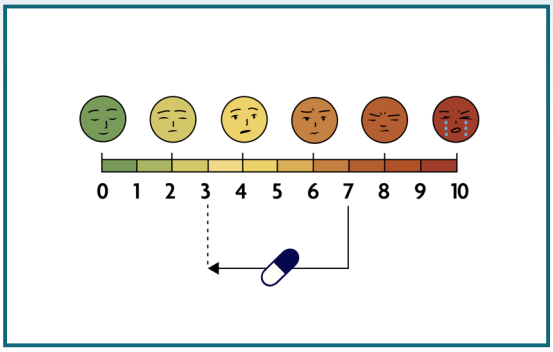
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

treatment effect

cdisc

How much a study treatment changes a condition, symptom, or function.



Example of *treatment effect* in a sentence

Some drug studies collect information from participants to measure the treatment effect.

More Info

The treatment effect shows how much the study intervention changes what the study is measuring when compared to not getting the study treatment or getting something different.

For example, a study might measure whether, and by how much, blood pressure is lowered when participants take a new medicine.

Related Words

study effect

intervention effect

efficacy

Other info to think about when joining a study

For studies that are looking at what a study treatment does, researchers often measure the treatment effect which is connected to the main purpose of the study and the types of data being collected.

You should feel free to ask if you have any questions about how the treatment effect is being measured in the study.

Other Resources

NCI Thesaurus

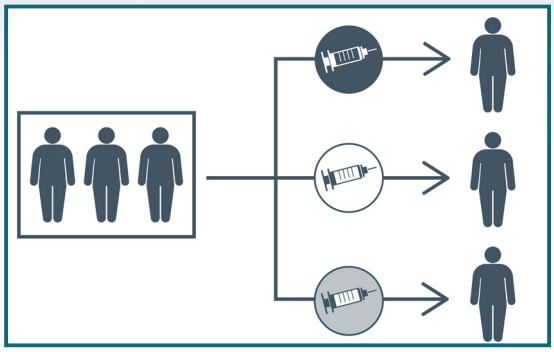
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

umbrella trial

cdisc

A research study that tests and compares two or more study treatments for one disease or condition.



Example of *umbrella trial* in a sentence

In an umbrella trial, multiple study treatments are compared in a single disease or condition.

More Info

An umbrella trial is a type of randomized controlled trial (RCT). It is also a type of Master Protocol Study.

An umbrella trial uses a Master Protocol to compare different study treatments in the same way, using the same design, in a certain disease or condition.

The difference between a basket and an umbrella trial is that a basket trial uses one drug to test against multiple diseases while an umbrella trial studies different drugs in a single disease.

Related Words

adaptive trial

basket trial

master protocol

platform trial

Other info to think about when joining a study

You may hear about umbrella trials when you are learning about different types of study designs.

If you are unsure about what it means for a research study to be an umbrella trial, you should ask a member of the study team to clarify any of your questions.

Other Resources

NCI Thesaurus

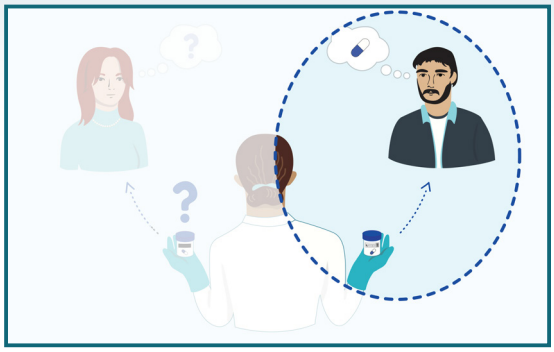
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

unblinding

cdisc

In a blinded study, when a participant or study staff finds out which study arm a participant was in.



Example of *unblinding* in a sentence

Unblinding lets participants and study staff know which study treatment each participant received.

More Info

Unblinding can apply to the study team, participants, sponsor or anyone else involved in the study.

Unblinding can happen at many different points during a study. It could happen because of an emergency, for a scheduled analysis of the data to make sure that the trial should be continued, or at the end of the study to let participants know what study treatment they received.

Sometimes unblinding may not be planned, such as when a study team member accidentally finds out what study group a participant was assigned.

Related Words

unmasking
blinded
single-blinded study
double-blinded study

Other info to think about when joining a study

If you are thinking of joining a study that involves randomization and you will not know which study treatment you will be taking, you can ask the study team if unblinding will happen at the end of the research study.

You can also ask about what the unblinding process will be if there is an urgent reason to find out what study treatment you are taking.

Other Resources

EUPATI — Blinding in Clinical Trials

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

vaccine

A medical substance that helps the body's immune system build protection against an infection or disease.

Example of *vaccine* in a sentence

A vaccine is a way to protect a person from getting a serious illness.

More Info

A vaccine can be given through a needle, or as a liquid, pill, or nasal spray. A vaccine teaches the body's immune system to protect itself from harmful germs. It can help stop a person from getting sick, or from getting as sick as they might have without the vaccine.

A vaccine is usually made from weak or killed forms of a virus or bacterium, its toxins, or surface proteins.

All vaccines involve adding a small piece of a bacterium or virus into a person's body, to help the immune system get stronger by causing an immune response. A vaccine boosts the body's immune system so when it sees the vaccine agent, it destroys it and remembers the agent in case of future exposure.

Related Words

immune response
immune system
vaccination
immunization
antibody

Other info to think about when joining a study

A vaccine is an important way to prevent some illnesses and diseases.

Studies about vaccines are done to make sure the risks and benefits are understood.

If you are thinking about joining a research study that involves a vaccine, feel free to ask any questions you have. You might want to learn more about what past studies have shown and why this new study is recruiting participants.

You may also want to find out more about how the study team will check your safety when you get the vaccine. You should also ask who to contact if you feel unwell after receiving the vaccine.

Other Resources

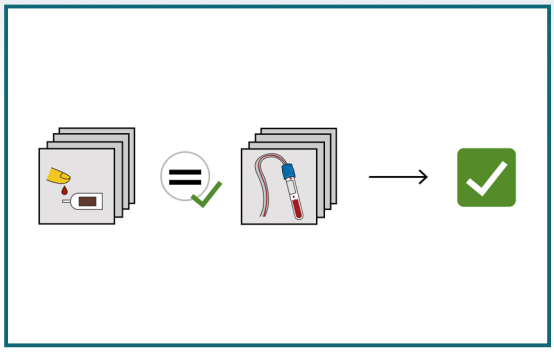
NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

validate

To confirm that a process or test works as planned, or results are true.



Example of *validate* in a sentence

In research, to validate something is to make sure that it works as expected.

More Info

Anything used to measure research data should be valid and precise.

Medical tests and surveys are validated through a process to make sure that they are measure what they intend to measure.

Results can also be validated, which means they go through a process to see if the findings are true.

Related Words

- confirm
- certify
- substantiate
- authenticate
- replicate

Other info to think about when joining a study

You may hear study teams talking about validating the data and information they collect. This could include checking measurements they take from you and comparing them to expected outcomes to see if the equipment is working correctly.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

voluntary participation

cdisc

Choosing to participate in research without feeling pressured.

Example of *voluntary participation* in a sentence

Joining a research study is voluntary.

More Info

Research participation must be voluntary so no one feels pressured to join a study or that they must stay in a study. A participant can withdraw at any time.

Related Words

free will
freely chosen
independent choice
autonomy

Other info to think about when joining a study

Before you join a study, the study team will want to be sure you know that participation is voluntary. The study team may tell you this verbally and it may also be in the consent form they give you to review. You should not feel forced into joining the study.

Other Resources

NCI Thesaurus

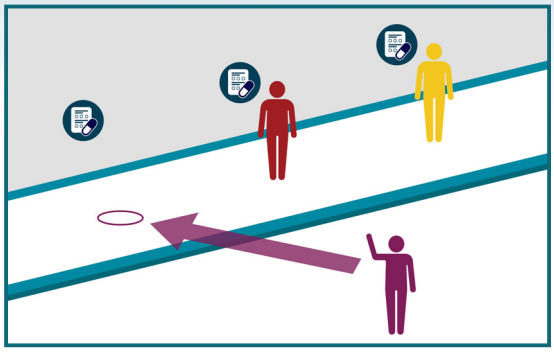
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

volunteer (to)

cdisc

To choose to join a study.



Example of *volunteer (to)* in a sentence

A participant is someone who chooses to volunteer to join a research study.

More Info

Participants might be healthy volunteers or patients, but everyone is free to make their own decision about participation. Even if they volunteer, they are free to leave the study at any time.

Related Words

agree

voluntary participation

Other info to think about when joining a study

Your doctor may ask if you want to volunteer for a study during a visit. You may also see this when reviewing a consent form, letting you know you do not have to join this study if you do not want to.

You may want to ask your doctor about how to volunteer for a study. If you are considering volunteering for a study, you can ask about what the study procedures are and what will happen to participants in the study.

You should not feel pressured to join a research study.

Other Resources

NCI Thesaurus

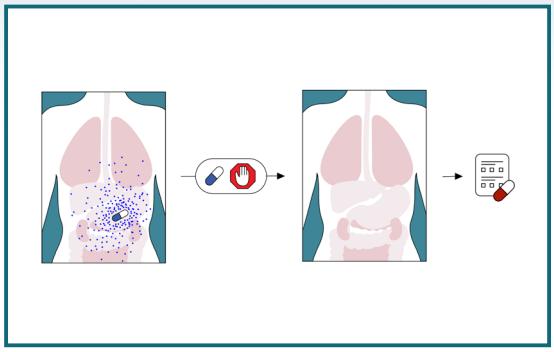
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

wash-out

cdisc

A time before starting a study treatment when a person stops taking other medicines.



Example of *wash-out* in a sentence

A wash-out period removes certain current medications in the body so that they don't interfere with the study treatment.

More Info

In research, a wash-out is a time when medication is stopped so it can be cleared from a person's body before the study intervention is given.

A wash-out period makes sure that the medication and the study intervention don't interact and increases the study's safety. It also helps to show that effects observed in a study are from the study medication and not previous, unrelated medications.

Not every study has a wash-out period. When a study has a wash-out period it is a pre-set time that depends on the protocol and what medicines the person is taking.

Related Words

discontinue

remove

Other info to think about when joining a study

Whether a research study requires a wash-out will be described in the consent form and the study team will discuss this with you.

It will be important for you to ask if you will have to go through a wash-out period and how that might affect you if you have been taking medications regularly before starting the trial. It could be important to discuss this with your regular doctor to let them know you will be stopping your routine medications.

Other Resources

NCI Thesaurus

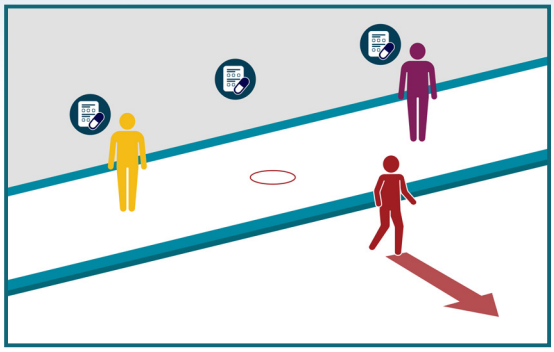
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

withdraw

cdisc

To stop being a participant in a study.



Example of *withdraw* in a sentence

If a participant decides to withdraw from a study, they should discuss with the study team how to do so safely.

More Info

A participant can decide to withdraw from a study or an investigator can decide to withdraw the participant, usually for safety reasons. Reasons to withdraw from the study should be discussed.

Related Words

discontinue

Other info to think about when joining a study

There may be information about how to withdraw from the study that you hear about when going through the consent process.

If you are thinking about stopping your participation in the study, ask the study team how to withdraw safely. You may also ask what may cause an investigator to withdraw you from the study.

If there are incentives for being part of the study, you may not get all of them if you leave the study early.

Other Resources

NCI Thesaurus

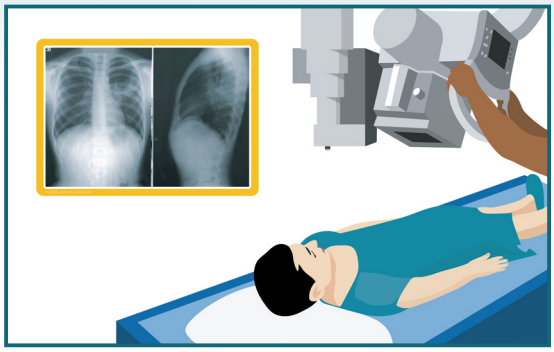
If you know of other resources we should link to to help explain this word, please contact us.

Clinical Research Glossary

X-ray

cdisc

A way of taking pictures of the inside of a person's body using X-ray radiation.



Example of *X-ray* in a sentence

An X-ray uses radiation to create images of bones, organs, and tissues.

More Info

An X-ray creates pictures of the inside of a person's body to view bone fractures and dislocations, certain tumors and other growths, pneumonias, fluid collections, and other problems.

Related Words

imaging study

MRI

CT scan

Other info to think about when joining a study

You may hear the term "X-ray" when the study team is talking about what happens in the research study. The study team could also say they are looking at your X-rays to get data for the study.

If you do need an X-ray for the study, you can get more information about what kind of X-ray the study team will need and what part of the body they will scan. You can also find out if the X-ray results from the research will be put into your medical records for your regular doctor to see.

Other Resources

NCI Thesaurus

If you know of other resources we should link to to help explain this word, please contact us.

Appendix

Appendix A — Glossary Website Links

abstract (research)	https://mrctcenter.org/glossaryterm/abstract-research/
active comparator group (active control group)	https://mrctcenter.org/glossaryterm/active-comparator-group-active-control-group/
additive effect	https://mrctcenter.org/glossaryterm/additive-effect/
adherence	https://mrctcenter.org/glossaryterm/adherence/
adverse event	https://mrctcenter.org/glossaryterm/adverse-event/
adverse reaction	https://mrctcenter.org/glossaryterm/adverse-reaction/
allocation (research)	https://mrctcenter.org/glossaryterm/allocation-research/
analyze	https://mrctcenter.org/glossaryterm/analyze/
anonymize	https://mrctcenter.org/glossaryterm/anonymize/
antagonistic effect	https://mrctcenter.org/glossaryterm/antagonistic-effect/
antibody	https://mrctcenter.org/glossaryterm/antibody/
antigen	https://mrctcenter.org/glossaryterm/antigen/
approval (IRB/ethics)	https://mrctcenter.org/glossaryterm/approval-irb-ethics/
arm	https://mrctcenter.org/glossaryterm/arm/
assent	https://mrctcenter.org/glossaryterm/assent/
assent form	https://mrctcenter.org/glossaryterm/assent-form/
assessment	https://mrctcenter.org/glossaryterm/assessment/
baseline assessment	https://mrctcenter.org/glossaryterm/baseline-assessment/
basket trial	https://mrctcenter.org/glossaryterm/basket-trial/
benefits of a research study	https://mrctcenter.org/glossaryterm/benefits-of-a-research-study/
bias (research)	https://mrctcenter.org/glossaryterm/research-bias/
biobanking (research)	https://mrctcenter.org/glossaryterm/biobanking-research/
biomarker	https://mrctcenter.org/glossaryterm/biomarker/
birth control	https://mrctcenter.org/glossaryterm/birth-control/
blinding	https://mrctcenter.org/glossaryterm/blinding/
blood draw	https://mrctcenter.org/glossaryterm/blood-draw/
case-control study	https://mrctcenter.org/glossaryterm/case-control-study/

clinical benefit	https://mrctcenter.org/glossaryterm/clinical-benefit/
clinical hold	https://mrctcenter.org/glossaryterm/clinical-hold/
clinical research	https://mrctcenter.org/glossaryterm/clinical-research/
Clinical Research Coordinator (CRC)	https://mrctcenter.org/glossaryterm/clinical-research-coordinator-crc/
clinical trial	https://mrctcenter.org/glossaryterm/clinical-trial/
clinician	https://mrctcenter.org/glossaryterm/clinician/
cohort	https://mrctcenter.org/glossaryterm/cohort/
cohort study	https://mrctcenter.org/glossaryterm/cohort-study/
Comparative Effectiveness Research (CER)	https://mrctcenter.org/glossaryterm/comparative-effectiveness-research-cer/
comparator	https://mrctcenter.org/glossaryterm/comparator/
compensation (study)	https://mrctcenter.org/glossaryterm/compensation-study/
compliance	https://mrctcenter.org/glossaryterm/compliance/
Computerized Tomography (CT) scan	https://mrctcenter.org/glossaryterm/computerized-tomography-ct-scan/
concomitant medications	https://mrctcenter.org/glossaryterm/concomitant-medications/
conduct	https://mrctcenter.org/glossaryterm/conduct/
confidence interval	https://mrctcenter.org/glossaryterm/confidence-interval/
confidentiality	https://mrctcenter.org/glossaryterm/confidentiality/
confirmatory clinical trial	https://mrctcenter.org/glossaryterm/confirmatory-clinical-trial/
confounding	https://mrctcenter.org/glossaryterm/confounding/
consent form	https://mrctcenter.org/glossaryterm/consent-form/
Contract Research Organization (CRO)	https://mrctcenter.org/glossaryterm/contract-research-organization-cro/
contraindicated	https://mrctcenter.org/glossaryterm/contraindicated/
control group	https://mrctcenter.org/glossaryterm/control-group/
correlation	https://mrctcenter.org/glossaryterm/correlation/
crossover trial	https://mrctcenter.org/glossaryterm/crossover-trial/
data	https://mrctcenter.org/glossaryterm/data/
database (research)	https://mrctcenter.org/glossaryterm/database-research/
Data Monitoring Committee/Data and Safety Monitoring Board (DMC/DSMB)	https://mrctcenter.org/glossaryterm/data-monitoring-committee-data-and-safety-monitoring
data sharing (research)	https://mrctcenter.org/glossaryterm/data-sharing-research/
decentralized clinical trial	https://mrctcenter.org/glossaryterm/decentralized-clinical-trial/
discontinue (participant)	https://mrctcenter.org/glossaryterm/discontinue-participant/
discontinue (study treatment)	https://mrctcenter.org/glossaryterm/discontinue-study-treatment/
disease progression	https://mrctcenter.org/glossaryterm/disease-progression/
disease-free survival	https://mrctcenter.org/glossaryterm/disease-free-survival/
dissent	https://mrctcenter.org/glossaryterm/dissent/
dose escalation study	https://mrctcenter.org/glossaryterm/dose-escalation-study/
double-blind study	https://mrctcenter.org/glossaryterm/double-blind-study/
drug holiday	https://mrctcenter.org/glossaryterm/drug-holiday/
drug therapy	https://mrctcenter.org/glossaryterm/drug-therapy/
e-consent (form)	https://mrctcenter.org/glossaryterm/e-consent-form/

effectiveness	https://mrctcenter.org/glossaryterm/effectiveness/
efficacy	https://mrctcenter.org/glossaryterm/efficacy/
eligibility criteria	https://mrctcenter.org/glossaryterm/eligibility-criteria/
Emergency Use Authorization (EUA)	https://mrctcenter.org/glossaryterm/emergency-use-authorization-eua/
endpoint	https://mrctcenter.org/glossaryterm/endpoint/
enroll	https://mrctcenter.org/glossaryterm/enroll/
epidemiologist	https://mrctcenter.org/glossaryterm/epidemiologist/
equipoise	https://mrctcenter.org/glossaryterm/equipoise/
equivalence	https://mrctcenter.org/glossaryterm/equivalence/
equivalent (effect)	https://mrctcenter.org/glossaryterm/equivalent-effect/
eSignature	https://mrctcenter.org/glossaryterm/esignature/
evaluate	https://mrctcenter.org/glossaryterm/evaluate/
exclusion criteria	https://mrctcenter.org/glossaryterm/exclusion-criteria/
expanded access	https://mrctcenter.org/glossaryterm/expanded-access/
experimental	https://mrctcenter.org/glossaryterm/experimental/
exploratory research	https://mrctcenter.org/glossaryterm/exploratory-research/
focus group	https://mrctcenter.org/glossaryterm/focus-group/
frequency	https://mrctcenter.org/glossaryterm/frequency/
funder (research)	https://mrctcenter.org/glossaryterm/funder-research/
generalizability	https://mrctcenter.org/glossaryterm/generalizability/
genetic testing	https://mrctcenter.org/glossaryterm/genetic-testing/
hazard ratio	https://mrctcenter.org/glossaryterm/hazard-ratio/
healthy volunteer	https://mrctcenter.org/glossaryterm/healthy-volunteer/
hereditary	https://mrctcenter.org/glossaryterm/hereditary/
human subject	https://mrctcenter.org/glossaryterm/human-subject/
hypothesis	https://mrctcenter.org/glossaryterm/hypothesis/
immune response	https://mrctcenter.org/glossaryterm/immune-response/
incentive	https://mrctcenter.org/glossaryterm/incentive/
incidence	https://mrctcenter.org/glossaryterm/incidence/
inclusion criteria	https://mrctcenter.org/glossaryterm/inclusion-criteria/
informed consent	https://mrctcenter.org/glossaryterm/informed-consent/
infusion	https://mrctcenter.org/glossaryterm/infusion/
Institutional Review Board (IRB)	https://mrctcenter.org/glossaryterm/institutional-review-board-irb/
intermittent	https://mrctcenter.org/glossaryterm/intermittent/
investigational device	https://mrctcenter.org/glossaryterm/investigational-device/
Investigational Device Exemption (IDE)	https://mrctcenter.org/glossaryterm/investigational-device-exemption-ide/
investigational medicine	https://mrctcenter.org/glossaryterm/investigational-medicine/
Investigational New Drug (IND) application	https://mrctcenter.org/glossaryterm/investigational-new-drug-ind-application/
investigational product	https://mrctcenter.org/glossaryterm/investigational-product/
investigator	https://mrctcenter.org/glossaryterm/investigator/
long-term follow-up (research)	https://mrctcenter.org/glossaryterm/long-term-follow-up-research/

longitudinal study	https://mrctcenter.org/glossaryterm/longitudinal-study/
Magnetic Resonance Imaging (MRI)	https://mrctcenter.org/glossaryterm/magnetic-resonance-imaging-mri/
masking (study treatment)	https://mrctcenter.org/glossaryterm/masking-study-treatment/
master protocol	https://mrctcenter.org/glossaryterm/master-protocol/
maximum	https://mrctcenter.org/glossaryterm/maximum/
mean	https://mrctcenter.org/glossaryterm/mean/
median	https://mrctcenter.org/glossaryterm/median/
medical device	https://mrctcenter.org/glossaryterm/medical-device/
methods (research or study)	https://mrctcenter.org/glossaryterm/methods-research-or-study/
minimal	https://mrctcenter.org/glossaryterm/minimal/
minimum	https://mrctcenter.org/glossaryterm/minimum/
minor	https://mrctcenter.org/glossaryterm/minor/
monitor	https://mrctcenter.org/glossaryterm/monitor/
morbidity (rate)	https://mrctcenter.org/glossaryterm/morbidity-rate/
mortality (rate)	https://mrctcenter.org/glossaryterm/mortality-rate/
multicenter trial	https://mrctcenter.org/glossaryterm/multicenter-trial/
n-of-1 study	https://mrctcenter.org/glossaryterm/n-of-1-study/
negative test result	https://mrctcenter.org/glossaryterm/negative-test-result/
negligible	https://mrctcenter.org/glossaryterm/negligible/
non-compliance	https://mrctcenter.org/glossaryterm/non-compliance/
non-inferiority trial	https://mrctcenter.org/glossaryterm/non-inferiority-trial/
objective	https://mrctcenter.org/glossaryterm/objective/
observational study	https://mrctcenter.org/glossaryterm/observational-study/
observe	https://mrctcenter.org/glossaryterm/observe/
occasionally	https://mrctcenter.org/glossaryterm/occasionally/
odds ratio	https://mrctcenter.org/glossaryterm/odds-ratio/
off-label	https://mrctcenter.org/glossaryterm/off-label/
open-label	https://mrctcenter.org/glossaryterm/open-label/
opt-in	https://mrctcenter.org/glossaryterm/opt-in/
opt-out	https://mrctcenter.org/glossaryterm/opt-out/
outcome (of study)	https://mrctcenter.org/glossaryterm/outcome-of-study/
outcome measure	https://mrctcenter.org/glossaryterm/outcome-measure/
overall survival	https://mrctcenter.org/glossaryterm/overall-survival/
p-value (probability value)	https://mrctcenter.org/glossaryterm/p-value-probability-value/
participant code	https://mrctcenter.org/glossaryterm/participant-code/
participate	https://mrctcenter.org/glossaryterm/participate/
Patient Reported Outcomes (PROs)	https://mrctcenter.org/glossaryterm/patient-reported-outcomes-pros/
peer review	https://mrctcenter.org/glossaryterm/peer-review/
periodically	https://mrctcenter.org/glossaryterm/periodically/
personal data	https://mrctcenter.org/glossaryterm/personal-data/

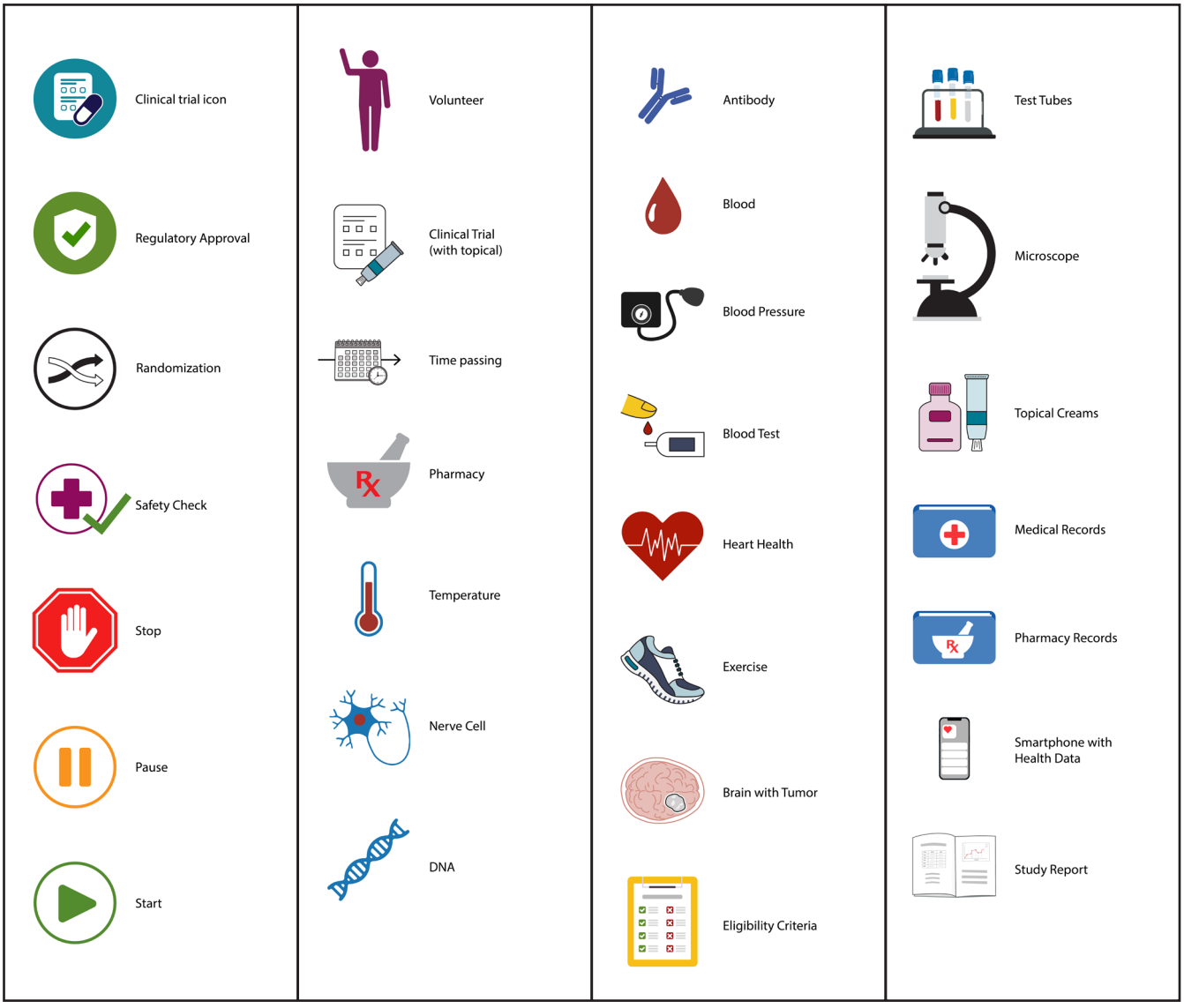
Pharmacodynamic (PD) study	https://mrctcenter.org/glossaryterm/pharmacodynamic-pd-study/
Pharmacokinetic (PK) study	https://mrctcenter.org/glossaryterm/pharmacokinetic-pk-study/
pharmacovigilance	https://mrctcenter.org/glossaryterm/pharmacovigilance/
phase	https://mrctcenter.org/glossaryterm/phase/
phase 1 (study)	https://mrctcenter.org/glossaryterm/phase-1-study/
phase 2 (study)	https://mrctcenter.org/glossaryterm/phase-2-study/
phase 3 (study)	https://mrctcenter.org/glossaryterm/phase-3-study/
phase 4 (study)	https://mrctcenter.org/glossaryterm/phase-4-study/
pilot study	https://mrctcenter.org/glossaryterm/pilot-study/
placebo	https://mrctcenter.org/glossaryterm/placebo/
placebo-controlled study	https://mrctcenter.org/glossaryterm/placebo-controlled-study/
Plain Language Summary (PLS) - study results	https://mrctcenter.org/glossaryterm/plain-language-summary-pls-study-results/
Plain Language Summary of Publication (PLSP)	https://mrctcenter.org/glossaryterm/plain-language-summary-of-publication-plsp/
platform trial	https://mrctcenter.org/glossaryterm/platform-trial/
positive test result	https://mrctcenter.org/glossaryterm/positive-test-result/
post-market surveillance	https://mrctcenter.org/glossaryterm/post-market-surveillance/
post-trial access	https://mrctcenter.org/glossaryterm/post-trial-access/
pragmatic study	https://mrctcenter.org/glossaryterm/pragmatic-study/
preclinical study	https://mrctcenter.org/glossaryterm/preclinical-study/
prevalence	https://mrctcenter.org/glossaryterm/prevalence/
primary endpoint	https://mrctcenter.org/glossaryterm/primary-endpoint/
principal investigator	https://mrctcenter.org/glossaryterm/principal-investigator/
probability	https://mrctcenter.org/glossaryterm/probability/
procedures (for participants)	https://mrctcenter.org/glossaryterm/procedures-for-participants/
progression-free survival	https://mrctcenter.org/glossaryterm/progression-free-survival/
prospective study	https://mrctcenter.org/glossaryterm/prospective-study/
protocol	https://mrctcenter.org/glossaryterm/protocol/
proxy	https://mrctcenter.org/glossaryterm/proxy/
pseudonymized	https://mrctcenter.org/glossaryterm/pseudonymized/
purpose	https://mrctcenter.org/glossaryterm/purpose/
Quality of Life (QOL)	https://mrctcenter.org/glossaryterm/quality-of-life-qol/
questionnaire	https://mrctcenter.org/glossaryterm/questionnaire/
randomization	https://mrctcenter.org/glossaryterm/randomization/
randomized controlled trial	https://mrctcenter.org/glossaryterm/randomized-controlled-trial/
rationale	https://mrctcenter.org/glossaryterm/rationale/
Real World Data (RWD)	https://mrctcenter.org/glossaryterm/real-world-data-rwd/
Real World Evidence (RWE)	https://mrctcenter.org/glossaryterm/real-world-evidence-rwe/
recruiting (status)	https://mrctcenter.org/glossaryterm/registry-study/
registry (study)	https://mrctcenter.org/glossaryterm/recruiting-status/
reimburse	https://mrctcenter.org/glossaryterm/reimburse/
relative risk	https://mrctcenter.org/glossaryterm/relative-risk/

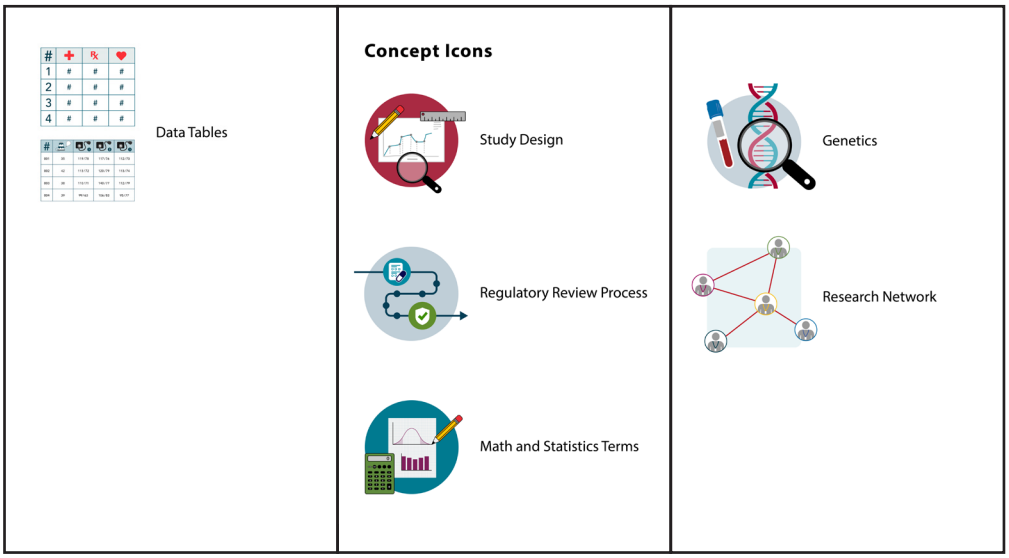
repository (research)	https://mrctcenter.org/glossaryterm/repository-research/
results (study)	https://mrctcenter.org/glossaryterm/results-study/
retrospective study	https://mrctcenter.org/glossaryterm/retrospective-study/
risk-benefit ratio	https://mrctcenter.org/glossaryterm/risk-benefit-ratio/
risks of a research study	https://mrctcenter.org/glossaryterm/risks-of-a-research-study/
run-in period	https://mrctcenter.org/glossaryterm/run-in-period/
sample (study)	https://mrctcenter.org/glossaryterm/sample-study/
sample size	https://mrctcenter.org/glossaryterm/sample-size/
schedule of assessments	https://mrctcenter.org/glossaryterm/schedule-of-assessments/
screen failure	https://mrctcenter.org/glossaryterm/screen-failure/
screening	https://mrctcenter.org/glossaryterm/screening/
secondary endpoint	https://mrctcenter.org/glossaryterm/secondary-endpoint/
sensitivity (medical test)	https://mrctcenter.org/glossaryterm/sensitivity-medical-test/
sequential	https://mrctcenter.org/glossaryterm/sequential/
Serious Adverse Drug Reaction (SADR)	https://mrctcenter.org/glossaryterm/serious-adverse-drug-reaction-sadr/
Serious Adverse Event (SAE)	https://mrctcenter.org/glossaryterm/serious-adverse-event-sae/
sham (procedure)	https://mrctcenter.org/glossaryterm/sham-procedure/
side effect	https://mrctcenter.org/glossaryterm/side-effect/
single-blind study	https://mrctcenter.org/glossaryterm/single-blind-study/
specificity (medical test)	https://mrctcenter.org/glossaryterm/specificity-medical-test/
sponsor	https://mrctcenter.org/glossaryterm/sponsor-3/
standard of care	https://mrctcenter.org/glossaryterm/standard-of-care/
statistically significant	https://mrctcenter.org/glossaryterm/statistically-significant/
study design	https://mrctcenter.org/glossaryterm/study-design/
study doctor	https://mrctcenter.org/glossaryterm/study-doctor/
study feasibility	https://mrctcenter.org/glossaryterm/study-feasibility/
study identifier	https://mrctcenter.org/glossaryterm/study-identifier/
study intervention	https://mrctcenter.org/glossaryterm/study-intervention/
study life cycle	https://mrctcenter.org/glossaryterm/study-life-cycle/
study monitor	https://mrctcenter.org/glossaryterm/study-monitor/
study participant	https://mrctcenter.org/glossaryterm/study-participant/
study population	https://mrctcenter.org/glossaryterm/study-population/
study site	https://mrctcenter.org/glossaryterm/study-site/
study statistician	https://mrctcenter.org/glossaryterm/study-statistician/
study suspension	https://mrctcenter.org/glossaryterm/study-suspension/
substudy	https://mrctcenter.org/glossaryterm/substudy/
superiority trial	https://mrctcenter.org/glossaryterm/superiority-trial/
synergistic effect	https://mrctcenter.org/glossaryterm/synergistic-effect/
termination (of a research study)	https://mrctcenter.org/glossaryterm/termination-of-a-research-study/
tolerability	https://mrctcenter.org/glossaryterm/tolerability/

treatment effect	https://mrctcenter.org/glossaryterm/treatment-effect/
umbrella trial	https://mrctcenter.org/glossaryterm/umbrella-trial/
unblinding	https://mrctcenter.org/glossaryterm/unblinding/
vaccine	https://mrctcenter.org/glossaryterm/vaccine/
validate	https://mrctcenter.org/glossaryterm/validate/
voluntary participation	https://mrctcenter.org/glossaryterm/voluntary-participation/
volunteer (to)	https://mrctcenter.org/glossaryterm/to-volunteer/
wash-out	https://mrctcenter.org/glossaryterm/wash-out/
withdraw	https://mrctcenter.org/glossaryterm/withdraw/
X-ray	https://mrctcenter.org/glossaryterm/x-ray/

Appendix

Appendix B — Icon Legend




Data Tables
Concept Icons
Study Design
Regulatory Review Process
Math and Statistics Terms
Genetics
Research Network

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