

Module II: The Trial Landscape

Unit: Risks and benefits of trial participation

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Risks and benefits of trial participation

Risks and benefits of trial participation



- Common questions asked by potential trial subjects
 - What is a clinical trial?



A clinical trial is a clinical research study in human volunteers to answer specific health questions.

Carefully conducted clinical trials are the fastest and safest way to find new treatments that work in people and ways to improve health.

Clinical trials determine whether new treatments or new ways of using known therapies are safe and effective under controlled environments.

Risks and benefits of trial participation



- Common questions asked by potential trial subjects
 - What happens during a clinical trial?



Participation in a clinical trial means you will work with a research team in a clinical office setting. Team members include doctors, nurses, study coordinators, and other health care professionals.

As a qualified volunteer for a study you will receive all medical visits and procedures directly related to your participation in the study at no cost. This can include: physical exams, doctor visits, study medications, laboratory tests, EKG's, etc.

Risks and benefits of trial participation



- Common questions asked by potential trial subjects
 - Who participates in clinical research?



Lots of different people like you and I participate in clinical research.

Every study identifies some specific characteristics that the participants should have in order to participate. These characteristics are called eligibility criteria.

Some of these characteristics are things like age, general health, a diagnosis of a particular disease, certain symptoms, etc.

Risks and benefits of trial participation



- Common questions asked by potential trial subjects
 - What are the benefits of participating in a clinical trial?



Clinical trials that are well-designed and well-executed are the best approach for eligible participants to:

Play an active role in their own health care

Gain access to new research treatments

Obtain expert medical care during the trial

Help others by contributing to medical research

Risks and benefits of trial participation



- Common questions asked by potential trial subjects
 - What are the risks of participating in a clinical trial?



There may be unpleasant, serious or even life-threatening side effects to treatment.

The treatment may not be effective for the participant.

The protocol may require more of their time and attention than would a non-protocol treatment, including trips to the study site, more treatments, hospital stays or complex dosage requirements.

Risks and benefits of trial participation



- Common questions asked by potential trial subjects
 - What are side effects and adverse reactions?



Side effects are any undesired actions or effects of drug or treatment.

Negative or adverse effects may include headache, nausea, hair loss, skin irritation, or other physical problems.

Experimental treatments must be evaluated for both immediate and long-term side effects.

Risks and benefits of trial participation



- Common questions asked by potential trial subjects
 - How am I protected during the research clinical trial?



Experienced physicians who have been thoroughly trained monitor you throughout the study.

An Ethics Committee must review and approve the trial before you are asked to participate in the study.

Participating in a clinical trial is completely voluntary and you can leave the study at any time if you change your mind.

Risks and benefits of trial participation



- Common questions asked by potential trial subjects
 - What are my rights as a participant in clinical research?



Once you decide to participate in a clinical trial, you will need to sign an Informed Consent form. This form provides a detailed explanation of the purpose of the trial.

The consent form also lets you know whom to contact more information, and fully explains your rights in a clinical trial, including: the right to confidentiality, the right to medical treatment for any trial-related injury, the right to withdraw from the study without penalty or loss of other medical care

Risks and benefits of trial participation



- Common questions asked by potential trial subjects
 - Can I leave a clinical trial after it has begun?



Yes. You can leave the clinical trial, at any time.

When withdrawing from the trial, you should let the research team know about it, and the reasons for leaving the study.

Risks and benefits of trial participation



- Common questions asked by potential trial subjects
 - How is the safety of the participant protected?



The ethical and legal codes that govern medical practice also apply to clinical trials.

In addition, most clinical research is regulated with built in safeguards to protect the participants.

The trial follows a carefully controlled protocol, a study plan which details what researchers will do in the study.

Risks and benefits of trial participation



- Common questions asked by potential trial subjects
 - What is a study protocol?



A protocol is a study plan on which all clinical trial activities are based.

The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions.

A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study.

Risks and benefits of trial participation



- Common questions asked by potential trial subjects
 - How do I know my personal information will be kept confidential?



The law mandate that your personal information be kept strictly confidential and that you be informed of all parties who will view that information.

These parties typically include your doctor, nurse and/or study coordinator, a representative of the sponsoring organization, and occasionally a representative of the local and overseas Drug Regulatory Authorities.

Risks and benefits of trial participation



- Common questions asked by potential trial subjects
 - What is a placebo?



A placebo is an inactive pill, liquid, or powder that has no treatment value.

In clinical trials, experimental treatments are often compared with placebos to assess the treatment's effectiveness.

In some studies, the participants in the control group will receive a placebo instead of an active drug or treatment.

Risks and benefits of trial participation



- Common questions asked by potential trial subjects
 - What is a control or control group?



A control is the standard by which experimental observations are evaluated.

In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo.

Risks and benefits of trial participation



- Common questions asked by potential trial subjects
 - Does a participant continue to work with a primary health care provider while in a trial?



Yes. Most clinical trials provide short-term treatments related to a designated illness or condition, but do not provide extended or complete primary health care.

In addition, by having the health care provider work with the research team, the participant can ensure that other medications or treatments will not conflict with the protocol.

Risks and benefits of trial participation



- Common questions asked by potential trial subjects
 - Where do the ideas for trials come from?



Ideas for clinical trials usually come from researchers.

After researchers test new therapies or procedures in the laboratory and in animal studies, the treatments with the most promising laboratory results are moved into clinical trials.

During a trial, more and more information is gained about a new treatment, its risks and how well it may or may not work.

Risks and benefits of trial participation



- Common questions asked by potential trial subjects
 - What phases are there in clinical trials?



The trials at each phase have a different purpose and help scientists answer different questions:

In Phase I trials, researchers test a new drug for the first time to evaluate its safety and dosage range.

In Phase II trials, the study drug is given to a larger group of patients to see if it is effective.

In Phase III trials, the study drug or treatment is given to large groups of patients to confirm its effectiveness, monitor side effects, compare it to commonly used treatments.

Risks and benefits of trial participation



- Common questions asked by potential trial subjects
 - Who sponsors clinical trials?



Clinical trials are sponsored or funded by a variety of organizations or individuals such as physicians, medical institutions, foundations, voluntary groups, and pharmaceutical companies.

Trials can take place in a variety of locations, such as hospitals, universities, doctors' offices, or community clinics.

Conclusion

Risks and benefits of trial participation



- Clinical trials are described by means of professional phrases that are not easily understood among trial subjects. For instance:
 - ◆ Side effects
 - ◆ Adverse reactions
 - ◆ Study protocol
 - ◆ Placebo
 - ◆ Control
 - ◆ Trial phases



- For your information there is a dictionary with the most commonly used trial phrases at the home page of this e-learning programme.
