HIGHTOWER

CLINICAL

A Patient Guide To

CLINICAL RESEARCH

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01 What is a clinical trial?

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

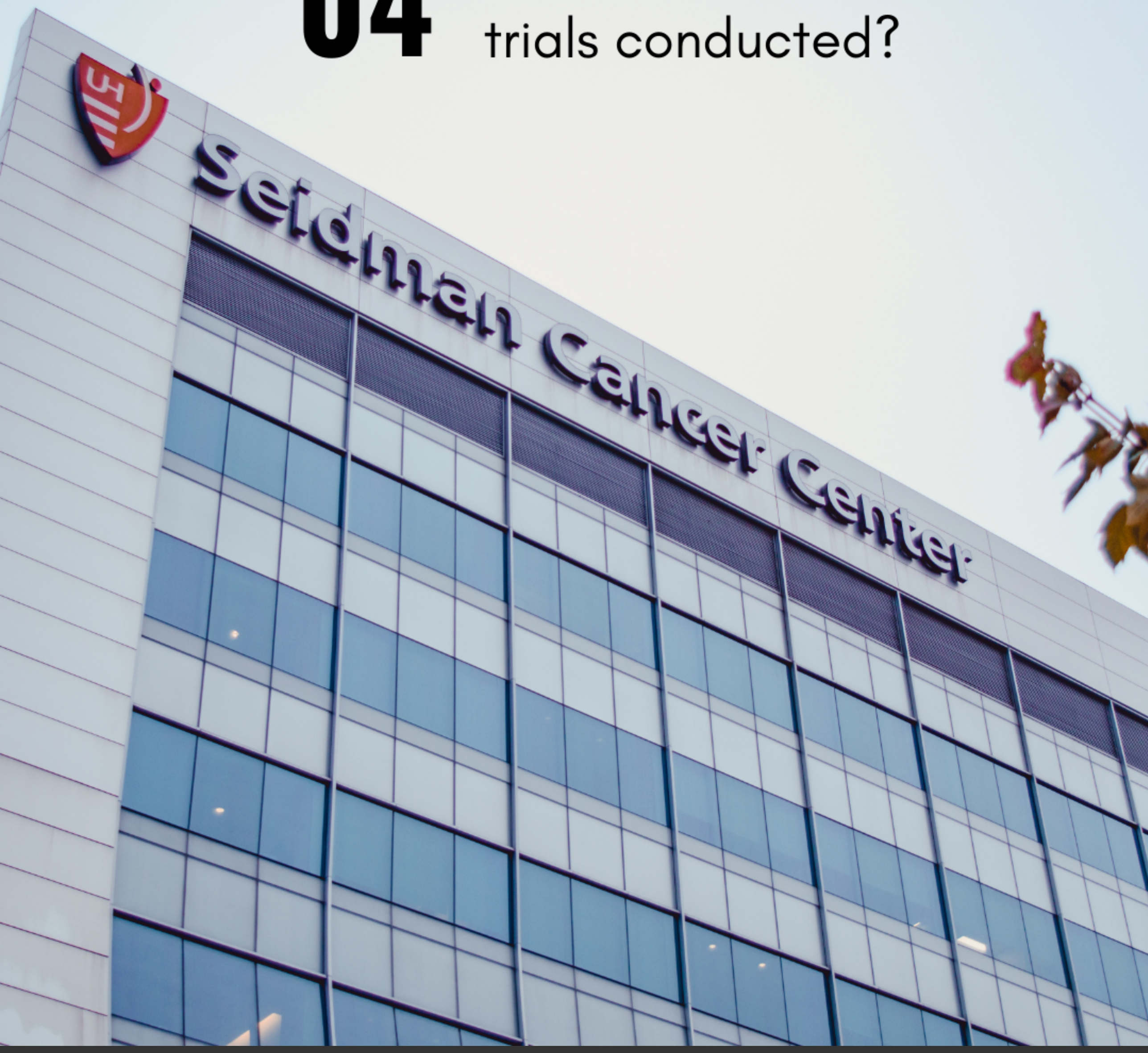
02 Who conducts clinical trials?

Every clinical study is led by a principal investigator, who is often a medical doctor. Clinical studies also have a research team that may include doctors, nurses, social workers, and other health care professionals.

03 Who sponsors clinical trials?

Clinical studies can be sponsored, or funded, by pharmaceutical companies, academic medical centers, voluntary groups, and other organizations, in addition to Federal agencies such as the National Institutes of Health, the U.S. Department of Defense, and the U.S. Department of Veterans Affairs. Doctors, other health care providers, and other individuals can also sponsor clinical research.

04 Where are clinical trials conducted?



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

05 How long do clinical trials last?

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

06 Who can participate in a clinical trial?

Clinical studies have standards outlining who can participate. These standards are called eligibility criteria and are listed in the protocol. Some research studies seek participants who have the illnesses or conditions that will be studied, other studies are looking for healthy participants, and some studies are limited to a predetermined group of people who are asked by researchers to enroll.

07 What determines eligibility?

The factors that allow someone to participate in a clinical study are called inclusion criteria, and the factors that disqualify someone from participating are called exclusion criteria. They are based on characteristics such as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions.

08 How are patients protected?

Patients are protected throughout the process through a number of means including the informed consent process, Institutional Review Board oversight as well as constant monitoring by the research physician and their staff.

09 What is informed consent?

Informed consent is a process used by researchers to provide potential and enrolled participants with information about a clinical study. This information helps people decide whether they want to enroll or continue to participate in the study. The informed consent process is intended to protect participants and should provide enough information for a person to understand the risks of, potential benefits of, and alternatives to the study. In addition to the informed consent document, the process may involve recruitment materials, verbal instructions, question-and-answer sessions, and activities to measure participant understanding. In general, a person must sign an informed consent document before joining a study to show that he or she was given information on the risks, potential benefits, and alternatives and that he or she understands it. Signing the document and providing consent is not a contract. Participants may withdraw from a study at any time, even if the study is not over.

10 What is an IRB?

Each federally supported or conducted clinical study and each study of a drug, biological product, or medical device regulated by FDA must be reviewed, approved, and monitored by an institutional review board (IRB). An IRB is made up of doctors, researchers, and members of the community. Its role is to make sure that the study is ethical and that the rights and welfare of participants are protected. This includes making sure that research risks are minimized and are reasonable in relation to any potential benefits, among other responsibilities. The IRB also reviews the informed consent document.

11 Who else oversees clinical trials?

In addition to being monitored by an IRB, some clinical studies are also monitored by data monitoring committees (also called data safety and monitoring boards).Various Federal agencies, including the Office of Human Subjects Research Protection and FDA, have the authority to determine whether sponsors of certain clinical studies are adequately protecting research participants.

12 Why should you consider a clinical trial?

Clinical trial participants play an active role in their own healthcare. They are closely monitored and cared for by research staff.

Patients can learn about and have access to new treatments before they are publicly available all while gaining insight in to their medical conditions. Research participants may directly benefit from their involvement as well as contribute to future generations knowledge and understanding of disease.

13 What questions should you ask before deciding?

Anyone interested in participating in a clinical study should know as much as possible about the study and feel comfortable asking the research team questions about the study, the related procedures, and any expenses. The following questions may be helpful during such a discussion. Answers to some of these questions are provided in the informed consent document. Many of the questions are specific to clinical trials, but some also apply to observational studies.

What is being studied?

Why do researchers believe the intervention being tested might be effective?
Why might it not be effective? Has it been tested before?

What are the possible interventions that I might receive during the trial?

How will it be determined which interventions I receive (for example, by chance)?

Who will know which intervention I receive during the trial? Will I know? Will members of the research team know?

How do the possible risks, side effects, and benefits of this trial compare with those of my current treatment?

What will I have to do?

What tests and procedures are involved?

How often will I have to visit the hospital or clinic?

Will hospitalization be required?

How long will the study last?

Who will pay for my participation?

Will I be reimbursed for other expenses?

What type of long-term follow-up care is part of this trial?

If I benefit from the intervention, will I be allowed to continue receiving it after the trial ends?

Will results of the study be provided to me?

Who will oversee my medical care while I am participating in the trial?

14 How can you participate?

Ask your doctor if a clinical trial might be right for you. Alternately, you can search for available clinical trials at www.clinicaltrials.gov.