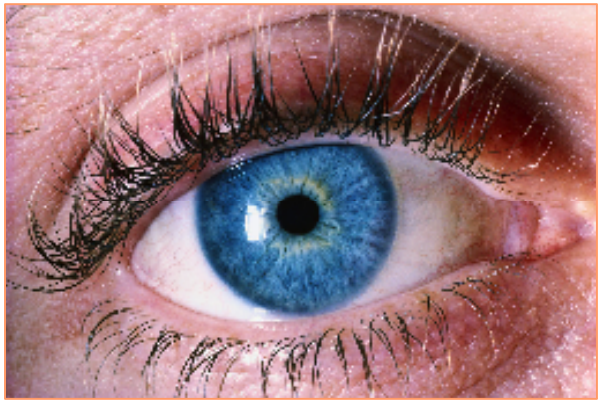
Inside Clinical Trials®

What is a clinical trial?

A clinical trial is a research study of a drug or a medical device in people to answer specific health questions. Conducting clinical trials is the safest and fastest way to develop new drugs and new methods of treatment that fight diseases.

There are two separate phases in the process of developing a new drug: *pre-clinical* and *clinical* phase

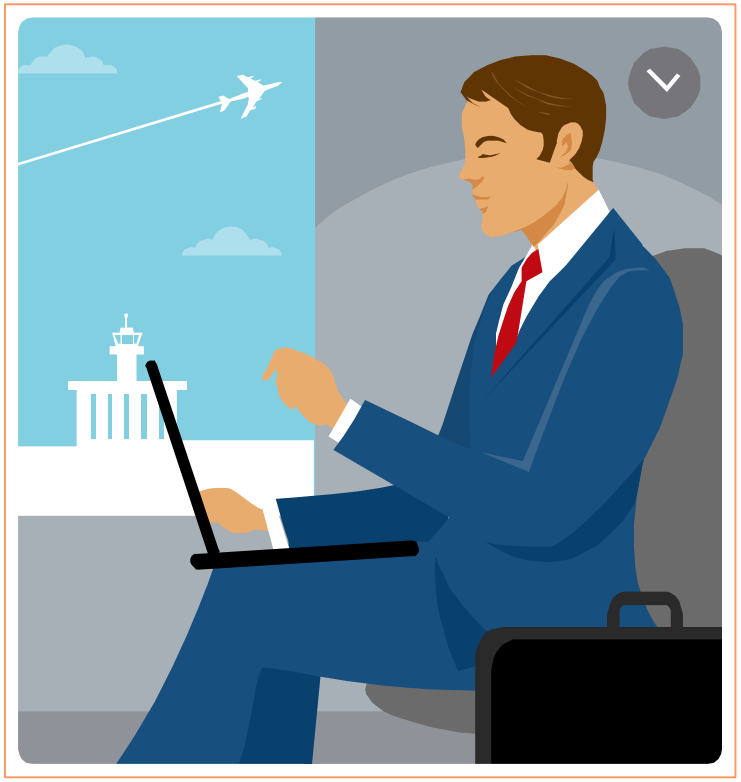


The *pre-clinical* phase is usually performed in pharmaceutical and pharmacological laboratories by researchers from different fields and takes up about four years to be completed.

The *clinical* phase of the drug development process includes applying the potential drug on humans, while investigating the possible adverse effects on organs and systems. It is usually developed for about six years.

Who is conducting the trials?

The Sponsor



The sponsor of a clinical trial is usually a pharmaceutical company or a research organization that has succeeded in the development of a new drug for a certain disease and is willing to prove its effectiveness in people. The sponsor determines the locations of the trials – medical centres, clinics, doctors' offices and/or hospitals.

The Investigator

The investigator is a doctor who is responsible for organizing and conducting the clinical trial, for taking care of the participants (both patients and healthy volunteers), as well as for all administrative activities that take place during and after the end of the trial.

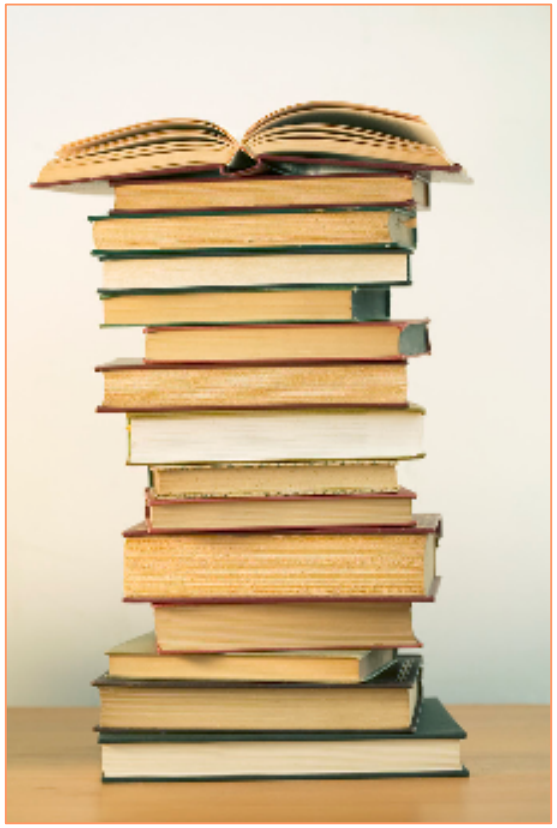
The investigator guarantees compliance to the requirements of Good Clinical Practice .

The Monitor

The monitor represents the connection between the sponsor and the investigator. This is the party that executes control over the study centre at any time. It is important for the participants in clinical trials to know that their health and safety are being cared for and observed by other specialists, who keep a close eye on investigators' actions and are able to prevent any possible mistakes and discrepancies in the conducting of the clinical trial.

How is a trial conducted?

The Protocol of a clinical trial



The plan (also called “the protocol”) of the clinical trial is an unique document describing all details about how it should be conducted. The sponsor of the study appoints a team of specialists to prepare it: physicians, scientists, statisticians, IT specialists, people responsible for the quality of data, etc.

Following the protocol in detail is a fundamental duty of each member of the research team conducting a clinical trial and this is declared in writing by the principal investigator.

Inclusion/Exclusion criteria

The Inclusion/Exclusion criteria are a part of the study protocol that specifies who may participate in the clinical trial. They point out the age group that will be targeted in the study, as well as other factors such as demographic data, disease history, concomitant treatments and all other relevant information. These criteria ensure the safety of the participants' and attempt to reduce the probability of wrong or misleading data to be collected during the trial.

Assessment of risks and benefits

Potential risks

The potential risks when participating in a clinical trial are due to the fact that the tested drugs are new and doctors do not always know what the adverse effects might be.

There may be unpleasant, serious, or life-threatening side effects resulting from the treatment. Some side effects might be temporary, some – permanent. The new treatment may not be as effective for the participant, as it was expected, or may require more time and attention than a standard treatment.

All known or expected risks should be well explained to you by the investigator.

Potential benefits

A clinical trial that is well designed and conducted will ensure that eligible participants have:

- Access to the best therapy available;
- Access to care and treatment by leading specialists in the particular medical field;
- Early and comprehensive diagnostics, which might result in detecting a certain new pathology unknown so far;
- Chances of effective impact on the disease;
- Improved quality of life and decreased unwanted (and sometimes life threatening) side effects;
- Regular and detailed observation by medical specialists;
- Contribution to medical research.

How are study participants protected?

Informed Consent Form

- If you are interested in participating in a clinical trail, you will be given a complete written information about it. This is known as Informed Consent Form. It describes the purpose of the research study, its duration and procedures, the possible risks, discomforts and benefits, the insurance against any possible injury during the participation, as well as compensations for travel expenses, and emergency contacts.
- You must sign the Informed consent form before you are enrolled to participate in the study, showing that you understand it.
- The Informed Consent is not a contract and you can leave the study at any time, for any reason.

Institutional Review Boards (IRBs)

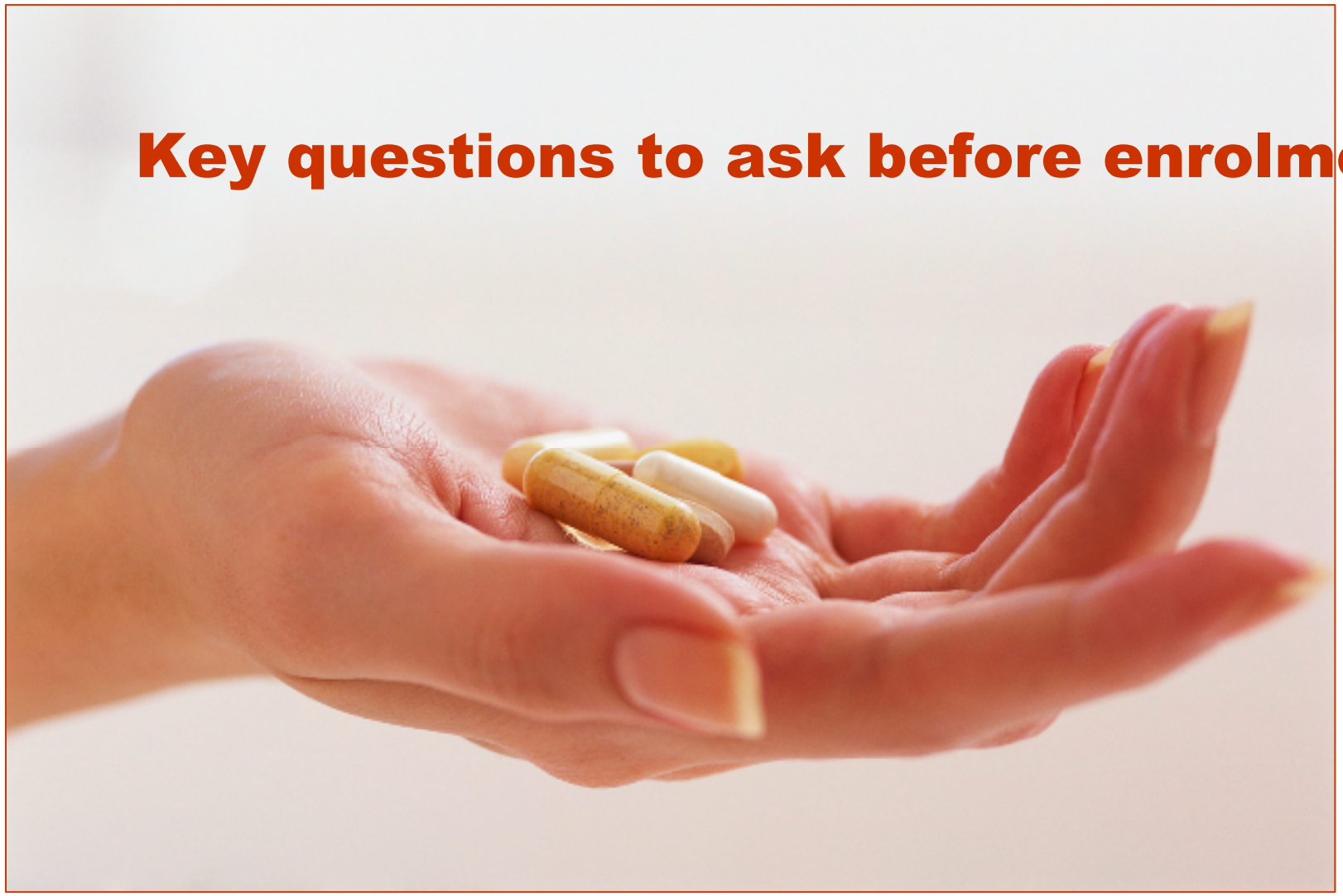
- Doctors, scientists and people from the local community serve on IRBs to review and approve the conducting of clinical trials in their hospitals or research institutions.

- The main task of each IRB is to make sure that the potential risks to the study participants do not outweigh the expected benefits and that the selection and enrollment process is fair and well executed.

Inspections by Regulatory Authorities (FDA, EMEA, Health Canada)

The Regulatory Authorities inspect the research sites that have conducted clinical studies, their records and archives. An inspection aims to check whether the rights of the study participants are protected, as well as whether the study is conducted in compliance with the applicable regulations. Such inspections are also done in response to complaints.

Key questions to ask before enrolment



1. What are the alternative treatment choices? How do they compare to the studied drug therapy?

2. Will I be hospitalized? How much time do the tests and exams take? What are the potential risks and side effects?

3. What will be the benefits? What will happen at the end of the study?

Points to remember

- Ask questions (you may also take a friend with you to support and help you during the discussion).

- Sign Informed Consent Form.

- You can leave the trial at any time.

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