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Biosciences and innovation

CLINICAL TRIALS: FAQ FOR PATIENTS

1. What is a clinical trial

A **clinical trial** is an experimental study that aims to obtain information on how effective and safe a drug, treatment or medical device is for human use. There are many different studies that must be conducted when developing a drug before it can be marketed and used in normal medical practice. But not all clinical trials serve to develop new drugs. Studies continue to be done even after a drug is on the market to learn more about efficacy or how it affects patient quality of life.

Clinical trials fall under the umbrella of scientific research and, therefore, must follow strict scientific procedures that protect patients and allow them to yield reliable results. Furthermore, they are also the fastest and safest way to find treatments that work, benefit society as a whole and help science advance.

A clinical trial only comes about after a long, careful process of laboratory research has indicated that a drug could be beneficial and safe for patients, whether all patients or specific groups for which it may work best.

Nevertheless, before starting a clinical trial, all the information on the drug or treatment to be studied and the trial procedure must be compiled in a document called a “protocol”, which must be evaluated and approved by independent ethics committees and by the Spanish Agency of Medicines and Medical Devices or other competent authority. The trial only kicks off once it has received this approval. This step safeguards patient safety and wellbeing and ensures that the benefits of the trial outweigh its risks.

Plus, patient participation in clinical trials is always voluntary and candidates are only accepted after having undergone the **informed consent process**.

For safety reasons, clinical trials start with small groups of patients and expand as they start to see the benefits of the drug or treatment.

2. How many phases does a clinical trial have?

We break clinical trials down into phase I, II, III and IV depending on how close a drug is to market.

Phase I serves to show that a new treatment is safe for human use. Phase I trials are normally done on small groups of people (often healthy volunteers) and indicate the right dosage for continued research.

Phase II serves to obtain more information on the safety of the new treatment and demonstrate how effective it is at treating a specific condition. In this phase, the proper therapeutic dose is also established.

Phase III serves to compare the new drug with the standard available treatment. Phase III trials are normally done on a large group of people and, if they show results that are beneficial to patients, the drug gets permission to be marketed.

Phase IV serves to research the effectiveness of a drug for the general population and collect more data regarding safety and quality of life. These trials are done after a drug is available on the market.

3. What is the informed consent process?

Participation in any clinical trial is **always voluntary** and a patient may choose to drop out of a study at any time.

Therefore, before starting a trial, doctors must provide patients with all the information necessary, including the benefits and potential risks of participating, in clear, easy-to-understand language, and answer any questions they may have to the patients' satisfaction.

Finally, if the patient decides to participate, they must sign a document called an **"informed consent form"** with all the key information on the trial. This includes the aim of the trial, its length, the tests and procedures involved, the main contact people and the potential risks and benefits of participation. Informed consent isn't a contract and the patient may withdraw consent and drop out of the study at any time.

The informed consent process is an **ongoing process**. This means that doctors are required to keep patients properly informed throughout their participation in the trial and that patients may continue to ask questions.

4. What rights do participants in clinical trials have?

Participants in a clinical trial have the right to:

- Withdraw consent and drop out of the trial at any time
- Receive new information on the study
- Ask additional questions about any aspect of the study at any time during the study
- Be kept up-to-date on the latest news regarding the trial throughout participation
- Receive the drugs assigned free of charge

5. How can I participate in a clinical trial?

If interested in **participating in a clinical trial** underway, patients must contact their doctor, who will notify them of the most suitable trial for them.

Each clinical trial is different and the individual protocols specify what type of patients may participate. These are called inclusion or participation criteria. The doctors or researchers in charge of the study will indicate whether or not each person is a suitable candidate.

All participants in clinical trials are volunteers and may withdraw consent at any time.

6. What are the benefits and risks of participating in a clinical trial?

The most noteworthy **potential benefits of participating in a clinical trial** include:

- Being among the first to benefit from a new treatment or drug, if it works

- Contributing to medical and scientific knowledge that may help others in the future
- Getting free physical exams and diagnostic tests related to the clinical trial

The **potential risks of participating in a clinical trial** include:

- Possible side effects beyond those previously observed or expected from normal treatment
- The treatment in the clinical trial may not be better than normal treatment
- The new treatment may not work for the participating patient, even though it does work for others.

7. How long does participation in a clinical trial last?

The length of a patient's participation in a clinical trial varies from a few weeks, for a short intervention, to months or even years if the trial is studying survival rates for chronic diseases. This information will also be included in the protocol for each clinical trial.

8. What questions should I ask if I want to participate in a clinical trial?

These are some questions you should ask your doctor before participating in a clinical trial:

- Could this research help me?
- What are the potential benefits and risks?
- What will I have to do if I participate in the research?
- If I change my mind, can I drop out of the trial?
- Will they give me the results when the study is over?
- Who can I ask if I have more questions?

9. What protection do I have from possible harm or injury in a

clinical trial?

All clinical trials are evaluated by an ethics committee and must be approved by healthcare authorities before they can begin in order to ensure that the risks involved are reasonable in relation to the anticipated benefits.

Plus, patients must be informed of any possible risks and benefits and of available alternatives in a clear, exact, precise manner during the **informed consent process** that takes place before a patient is included in a clinical trial. Nevertheless, as all clinical trials entail some risk, every study has an insurance policy that covers participants in the case of harm or injury, in accordance with current law.

During the informed consent process, patients are informed that they must notify the researcher and healthcare personnel if they believe they are having any sort of problem during the trial, whether or not it is related with the treatment.