This vulgarizing document is deliberately kept short and can never replace the specific information relevant to the clinical study in which a patient would be willing to participate.

For more information, contact your Doctor.

BeCRO
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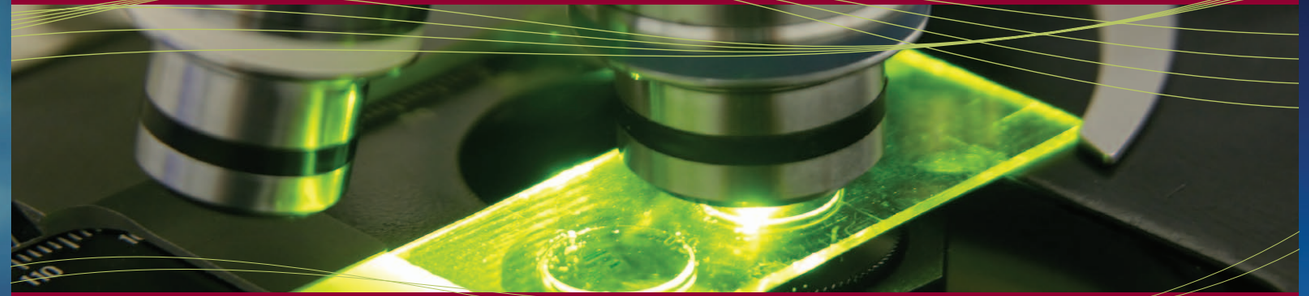
Inclusion and exclusion criteria

The criteria that need to be fulfilled before you are allowed to participate in a study (inclusion criteria such as age and type and phase of disease and exclusion criteria such as concomitant diseases) form an important part of the study protocol. This means that after the initial examinations, your doctor might have to inform you that you cannot participate in the study because you do not meet all the inclusion and exclusion criteria. These criteria can be very stringent because the sponsor wants to make sure the effects of the new drug are not influenced by any other factors.



How can I participate?

Both Belgium and the European Union keep a list of all ongoing trials that can be consulted (https://www.clinicaltrialsregister.eu). However, in most cases, you will hear about a new study through your doctor or your patient association.

If you are interested in participating to a clinical trial, your doctor will explain you the purpose of the trial and the intended benefits you will get. Your doctor will also point out that these benefits cannot be guaranteed as well as the occurrence of adverse reactions because of the research stage the new drug is still in.

As mentioned before, it will also be checked if you fulfill all inclusion and exclusion criteria set forward in the study protocol, making you eligible to participate. If you fulfill these criteria, you will then receive an Informed Consent Form that describes the most important aspects of the study and the study drug, as well as your rights, such as the right to end your participation in the trial at any moment. Once you have signed this form, you are entitled to participate in the study.

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CLINICAL TRIAL

Information for the patient

Development Process of a new drug

Every new drug follows the same development process. The potential new drug is first tested in laboratories, then in different animal species and finally, when it is thought to be safe, in humans.

The testing of potential new drugs in humans follows 4 phases, by means of consecutive clinical studies.

In phase I, the potential new drug is usually administered in healthy volunteers to study general effects (distribution, metabolism and excretion of the product, but also possible adverse reactions).

When no major adverse reactions are observed, the potential new drug is tested in patients (who always participate voluntary), first in small groups (phase II), and later in larger populations to assess the efficacy and long-term safety of the drug (phase III).

If the drug receives a marketing authorisation, the safety is further monitored in phase IV studies, where the objectives are to look for rare adverse reactions or long-term complications.

How can I benefit?

First of all, as a patient participating in a clinical study, you will benefit from the most up to date health care and may have access to a potential novel treatment for your disease, whose efficacy and safety are being assessed.

While participating in a study, your doctor will most likely do more tests than what he/she would normally do and this to monitor closely the effects of the administration of the new drug. These additional treatments and/or tests during the study are at no charge to you.

Moreover, complete confidentiality is guaranteed. Indeed, all data are collected and treated in an encoded way. You also keep your freedom to decide to leave the study at any given point, without this having any effect on the quality of the care given from your doctor.

By participating to a clinical trial, you contribute to the scientific progress in the treatment of your disease.

What about placebo and comparator?

The effect of the potential new drug is most often compared to an existing therapy or in some specific cases, to an inactive substance (called placebo).

In a clinical study patients will therefore receive or the potential new drug or a comparator (existing therapy and/or placebo). As a participant in a study, you will not know if you receive the new drug or a comparator.

However, your doctor will ensure that, if needed, you will receive the appropriate treatment, even if that means you need to stop your participation in the study. Your well-being is the priority; it will always be of higher importance than the results of the study.

Who are the parties involved in a clinical study?

Besides the patient, several other parties are involved in a clinical study. One such party is the company owning the potential new drug (and mostly referred to as the "Sponsor" of the study). Another party is the doctor or investigator who participates in the trial and who will propose his/her patients to enroll in the trial. Other parties include service providers ensuring the proper conduct of the trial in all participating centers and countries (e.g. Contract Research Organizations, Central Laboratories, Contract Manufacturing Organizations).

Before a clinical study can start, an authorisation needs to be obtained from the country's regulatory bodies, and an advice needs to be sought from the ethical committee(s).

Both organizations will ensure that all patient rights are respected and that treatment is in line with all accepted standards. These organizations will review study documents, such as the study protocol and the informed consent in which the entire study conduct is described as well as the investigator brochure in which all available information about the new drug is stated.