This outreach brochure is deliberately brief and cannot replace specific information about the study in which a patient would like to participate.

For more information, consult your doctor.

EUCROF
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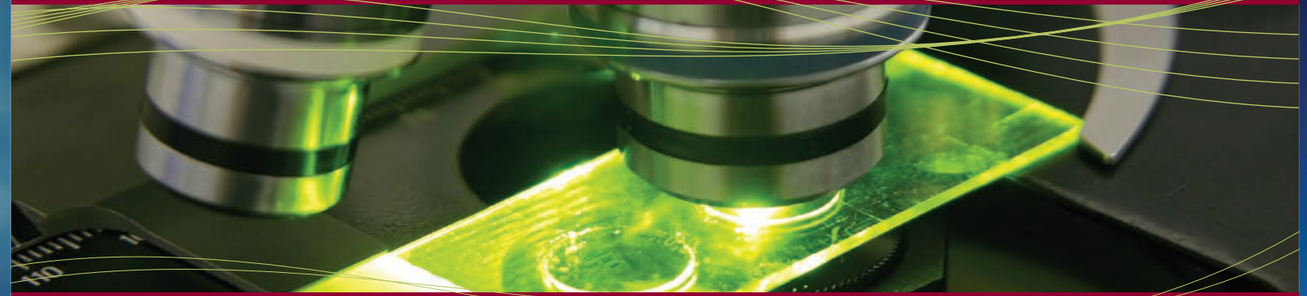
## Inclusion and exclusion criteria

The criteria that need to be checked before you are allowed to participate in a study (the inclusion and exclusion criteria) 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 inclusion criteria or you meet one or more exclusion criteria. These criteria can be very strict because the Sponsor wants to make sure the effects of the new drug are not influenced by any other factors.



## How can I participate?

The European Union keeps an updated list of all ongoing clinical trials open to public consultation (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 in a clinical trial, your doctor will explain the purpose of the trial and the intended benefits you may get. Your doctor will also point out that these benefits cannot be guaranteed because of the research stage the new drug is still in. In addition, all known risks will also be explained.

As mentioned before, all inclusion and exclusion criteria set forward in the study protocol will also be checked to ensure that you are eligible to participate. If you turn out to be eligible, you will then receive an Informed Consent Form which not only describes the most important aspects of the study and the study drug(s), but also your rights, such as the right to end your participation in the trial at any moment. Only once you have signed this form, are you entitled to participate in the study.

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# CLINICAL STUDY

## Patient information

## Clinical Study Process

Every new drug follows the same development process. The potential new drug is first tested in laboratories, then in animals and finally, when it is thought to be safe, in humans. The testing of potential new drugs in humans (clinical studies) follows 4 phases. In phase I, the potential new drug is usually administered in healthy volunteers to study general effects. When no major adverse reactions are observed, the potential new drug is tested in patients, first in small groups (phase II), and later in larger populations in randomised trials to assess the efficacy and long-term safety of the drug (phase III). If the drug receives approval, the safety is further monitored (pharmacovigilance) in phase IV studies (Post-Authorisation Studies).

## How can I benefit?

First of all, as a patient participating in a clinical study, you might benefit from the most up-to-date healthcare and a novel treatment for your disease, whose efficacy and safety are being assessed. Your well-being throughout the conduct of the study is not only focused on by your doctor and his/her follow-up of your progress, but also by independent organisations ensuring the safety of the study.

While participating in a study, your doctor might carry out more tests than what he/she would normally do. These additional monitoring procedures 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 retain your freedom 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 in a clinical trial, you contribute to the scientific progress in the treatment of the disease.

## What about placebo?

The effect of the potential new drug can be compared to an existing therapy or in some cases, to an inactive substance (called placebo). As a participant in a study, you will not know if you receive the new drug or a placebo. However, your doctor will ensure that, if needed, you will receive the appropriate treatment, even if that means that 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 or medical device (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 participate in the trial. Other parties include service providers ensuring the proper conduct of the trial in all participating centres and countries (e.g. Contract Research Organisations; Central Laboratories; Contract Manufacturing Organisations).

Before a clinical study can start, permission needs to be obtained from the country's regulatory bodies as well as from the ethical committee(s). Both authorities will ensure that all patients' rights are strictly respected and that the treatment is in line with all accepted standards. These authorities 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 described.