NOVARTIS

Patients and Caregivers

Clinical trials cannot be done without the people who choose to participate. Some reasons that people choose to participate in clinical trials are:

- Playing an active role in one's own health care
- To have the possibility of getting access to new research treatments before they are widely available
- Helping others by contributing to medical research

There are also potential risks related to participating:

- The possibility of unpleasant, serious, or even life-threatening side effects
- The treatment may not be effective
- The protocol may require a great deal of time and effort, including trips to the study site, hospital stays, or complex dosage requirements

However, participation in a clinical trial can also help other people get new treatments sooner. Without clinical trials and their participants, the development of these treatments would not be possible. To better understand what it might be like to be in a clinical trial, let's hear from a few people on their perspective towards clinical trials and personal experience when they participated in a clinical trial.

Finding a trial

There are many online resources, such as this website, to help people who are considering participating in finding a suiting study. Also, you can ask your doctor about trials for your condition.

Study entry criteria

Every study has specific criteria for who can take part, called eligibility criteria.

Common eligibility criteria may include:

- Having a certain type or stage of disease
- Having received (or not having received) a certain kind of therapy in the past
- Being in a certain age group
- Medical history
- Current health status

Criteria such as these help to reduce the medical differences among people taking part in the clinical trial so that researchers can be more certain that the results are due to the treatment being tested and not to another reason.

Anyone interested in joining a clinical trial will receive medical tests to confirm their eligibility.

Asking questions to research team

Before agreeing to join a clinical trial, it is important that you ask questions to make sure you understand all aspects of the trial and your role as a participant. You may want to consider taking a friend or relative along with you when you talk to the research team.

It is also recommended that you speak with your primary care doctor or family doctor about your interest in clinical trial participation. It is important that your primary care doctor know what sort of trial you will be participating in and what treatment you will be given, so that they can make sure the trial treatment does not interfere with your standard care. You should ask how the research team will communicate with your primary care doctor during and after the trial.

Below are questions to ask the research team before enrolling in a clinical trial:

- What is the main purpose of this study?
- Does the study involve a placebo or a treatment that is already on the market?
- How will I be assigned a treatment and will I learn my treatment assignment?
- How will the treatment be given to me?
- How long is the study going to last and what will I be asked to do as a participant?
- What has been learned about the study treatment and are any study results published?
- Do I have to pay for any part of the study? Will my insurance cover these costs?
- Is there any reimbursement for travel costs or childcare?
- Will I be able to see my own doctor and can I share the data from the trial with my doctor?
- If the treatment works for me, can I keep using it after the study?
- Can anyone find out whether I'm participating in the clinical trial?
- Will I receive any follow-up care after the study has ended?
- What will happen to my medical care if I stop participating in the study?
- Does the physician/investigator have any financial or special interest in the clinical study?
- What are the credentials and research experience of the physician and study staff?
- When and how will the results of the clinical trial be provided to me?

Clinical trial participants and people who are considering participating usually have even more questions about clinical trials.

Rights and responsibilities

All people who participate in clinical trials have specific rights and responsibilities. The doctors and nurses

involved in the study are required to make sure people know these rights and responsibilities before deciding whether or not to participate in a trial.

All clinical trial participants have the right to:

- Clearly understand the risks, possible benefits, tests that will be done, and other information about the trial that is in the consent form
- Receive a signed and dated copy of the informed consent form
- Ask the doctors and nurses any questions about the trial at any time
- Leave the trial at any time and for any reason
- Ask to receive the results of the trial after it is done

All clinical trial participants have the responsibility to:

- Provide truthful answers to the questions that the doctors and nurses ask
- Follow the rules of the clinical trial that are explained in informed consent

Informed consent

Informed consent is the process of learning about a clinical trial before deciding whether or not to participate. To help someone decide whether or not to participate, the doctors and nurses involved in the trial are required to explain the details of the study.

There is a written document called the “informed consent form”. This is also called the “ICF”. This form includes details about the study including the purpose, risks and potential benefits, duration, required procedures, and important contact information.

If you are considering participating in a trial, you can ask the doctors and nurses any questions about the trial until you feel comfortable about joining. You can also talk with family, friends, or your personal doctor before you choose to participate.

You decide whether or not to sign the form and participate in the trial and no one should pressure or influence your decision in any way. Parents or guardians sign the form and decide whether or not children can participate in a trial.

Informed consent is not a contract and a participant may withdraw from the trial at any time and for any reason.

Study visits

For most studies, you will visit a study clinic or doctor’s office. How often will depend on the type of study and requirements. At each visit, your research team will check in with you and may conduct certain tests. Visits may also be on the phone or at home.

Follow up

To keep a close eye on your health, there may be a follow-up period after the trial where the research team keeps in contact with you.

It is important to note that if at any time a participant wishes to leave the study, that is OK. You inform the research team, whom then will do a final check on your health.

Frequently asked questions

Clinical trial participants and people who are considering participating usually have many questions about clinical trials. This section provides answers to some of the most frequently asked questions.

Review FAQs

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