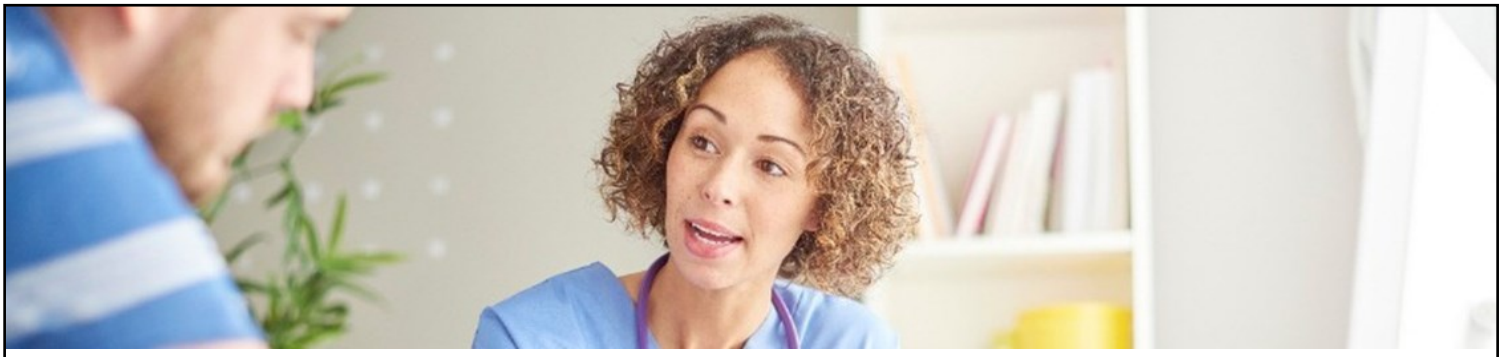

Your Q & A Guide to taking part in a cancer trial

If you've been invited to join a clinical trial

You'll have some questions

Here are some answers

Just ask Your Doctor!

cancer trials ireland

Together, we're finding answers to cancer.

If you've been invited to take part in a cancer trial, you'll have some questions. This brochure provides you with some answers. If you have more questions, ***Just Ask Your Doctor!*** or talk to the cancer research team in your hospital.

Q: What is a clinical trial?

A: A clinical trial is a research study in humans with the aim of answering specific questions about a new medical treatment (vaccines, new therapies or new ways of using known treatments). Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective. Clinical trials are conducted in phases. The trials at each phase have a different purpose and each phase looks at different areas (e.g. toxicity, dose finding etc).

Q: Is clinical research the same thing?

A: Clinical trials are generally research programmes for drug development, other types of clinical research may include medical device investigations, blood sampling, questionnaires and evaluating health care provision.

Q: Who is allowed to set up a clinical trial?

A: Clinical trials are designed by groups of medical and other specialists and conducted by a person called an investigator who is generally a doctor who specialises in the disease being studied. The trial design is usually based on a thorough analysis of existing research, and a realisation that certain questions about treatment or symptom control need to be answered. The trial design is discussed with medical staff, nurses, patients, statistical experts and support staff, as well as representatives from drug companies, to draw up the best possible trial design. The design for the study is known as the 'protocol'.

Q: What is informed consent?

A: Except in exceptional circumstances you cannot be entered into a trial without signing a form saying that you have given your informed consent. Informed consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. If you sign this form, you confirm that you believe you have been given all the important facts about a trial, you understand them and that you have decided to take part in the trial of your own free will. An informed consent is not a contract and you may withdraw from the study at any time.

Phases 1 — 4

Cancer trials are divided into different stages, called phases. The earliest phase trials may look at whether a drug is safe or the side effects it causes. A later phase trial aims to test whether a new treatment is better than existing treatments.

Phase 1 trials (sometimes called early treatment trials) aim to test the safety of various doses of a new drug. This includes looking at the side effects of a drug – for example, does it make people feel bad, raise their blood pressure etc? Phase 1 trials involve only a small number of people, who are usually healthy volunteers. In exceptional cases, for instance in cancer or HIV, patients who are at a very advanced stage of the disease may participate.

Phase 2 trials test the new drug in a larger group of people who are ill, to see whether it has any effects suggesting that it might help them. As in phase 1, the number of participants is limited. Phase 2 trials mainly look at safety and the right dose.

Treatments only move into a **Phase 3** clinical trial if phases 1 and 2 suggest that a substance might actually be useful and safe in ways that patients would regard as important. Phase 3 trials test new drugs in larger groups of people who are ill.

Phase 3 trials compare the new drugs with whatever treatments are currently in use, or occasionally with a placebo. These trials look at how well the new treatment works in practice, and at any side effects. They usually last longer than phase 2 trials – typically a year or more. Often several thousand patients in different countries will be involved in a phase 3 trial. A large number of participants is necessary because investigators have to be able to detect moderate but important differences between treatments.

Post marketing surveillance concerns the last and 4th phase of a clinical trial. After a medicine has been launched, Health Authorities often ask companies to provide additional data, collected from the actual use of the medicine in thousands of patients.

Phase 4 studies are designed to provide broader experience in evaluating the safety and effectiveness of the new medicine in larger numbers of patients, subgroups of patients, and to compare and/or combine it with other available treatments.

Q: What does 'bias' mean?

A: When prejudices lead to incorrect conclusions about the effects of treatment, this is bias. It's really important to avoid bias in health research, as it can distort the results and could lead to unsafe or inefficient treatments being licensed for use, or useful treatments being overlooked. Investigators try to avoid bias by using randomisation and by blinding those administering the drugs and assessing the results of treatments.

Q: What are 'randomised' trials?

A: Most clinical trials are randomised trials. If you take part in a randomised trial, a computer, not a doctor, will decide which treatment to give you. This decision will be random. It will be due to chance alone, and not based on your doctor's decision. Randomisation is the best way of ensuring that people in the different parts of a trial are broadly similar. By comparing similar groups of people, investigators can be sure that their trial is checking the difference between the treatments being studied, and not the differences between the people taking part. Randomisation is important because investigators need to ensure that clinical trials are not biased. It is quite easy for people to be biased without realising it.

Q: What does 'blinding' mean?

A: Blinding means that whoever is assessing the effects of treatment will not know if they are studying patients on the treatment or patients on a placebo. This helps to prevent bias. Sometimes patients will assess the effects of treatment, sometimes doctors will, and sometimes third parties will. Some or all of these people may be kept unaware of which treatment has been received. If you are part of a 'single blind' trial you will not know which treatment you are receiving. If you take part in a 'double-blind' trial, neither you nor your doctor will know which treatment you are receiving. The aim is to make sure that nobody's expectations affect the results of the trial.

Q: What is an 'open label' trial?

A: In an open label trial, both you and your doctor will know which treatment you are receiving. In other words, this is the opposite of a double-blind trial.

Q: What is a 'placebo'?

A: A placebo is a treatment that does not contain any active substance. It allows investigators to test for the 'placebo effect'. This is a psychological response where people feel better even though they do not take a medicine with an active ingredient. By comparing people's responses to the placebo and to the treatment being tested, the benefit of the treatment can be described.

Q: What are 'inclusion criteria'?

A: Inclusion criteria help investigators decide who can join a trial. For example, some trials only include people of a certain age, or at a particular stage in their illness. You may have to have a medical examination before a trial (e.g. a blood test) to assess whether you are suitable to take part.

Q: What are 'exclusion criteria'?

A: Exclusion criteria determine who won't be able to join a trial – for example, many trials exclude women who are pregnant to avoid any possible danger for the baby. Trials may also exclude people who are already taking a drug that may interact with the treatment being studied.

Q: Can I withdraw from a trial?

A: You can change your mind and leave a clinical trial at any time before the study starts, during the study, or during the follow-up period. Participating in research is always voluntary. Even if you decide to participate, you can always withdraw from the study at any time without affecting your relationship with your doctor.

Q: Will taking part in a clinical trial adversely affect the care I receive from my doctor?

A: Absolutely not, in fact you will find that it is exactly the opposite that will happen. As described above, you may have to go and see your doctor more often than before, which will therefore give you more opportunities to ask him or her about the state of your condition, the treatment(s) you are given and your general well-being.

Q: Will I find out the results?

A: It may be some time before the results of a trial become available. Some large trials involve thousands of people and can run for five years or even longer before every participant has been assessed. There may be years between when you take part and when the trial finishes.

At the end of the trial, the study sponsor (e.g. the company) should make the results available to everyone who took part. If not, you can always ask the investigator to tell you about the conclusions.

The results should provide more information about the possible risks and benefits of the different treatments that have been tested. They may help you and others like you to make more informed decisions about your healthcare. Some investigators will also work with patient groups to ensure that the results of trials reach other patients. Investigators have a responsibility to publicise the results of their trial even if the results show that a new treatment doesn't work. They might do this at a conference, in a medical journal or in the press.

Q: What is the Declaration of Helsinki?

A: In order to ensure compliance with ethical standards, the majority of clinical trial protocols are developed in line with the "Declaration of Helsinki ", a set of ethical standards for research involving human beings, human material or identifiable data, devised by the World Medical Association.

Q: If the treatment works, will I be able to carry on getting it after the trial has ended?

A: It should be remembered that in most trials the different treatments are allocated randomly to the patients who enrol and neither you nor your doctor can choose which one you receive.

Furthermore, most trials are also conducted 'blind' and neither you nor your doctor will know which of the treatments you are receiving until the end of the trial. If, at the end of the trial one treatment is found to be better than another, the opportunity to move onto the better treatment may be discussed with you, if it was not the treatment that you were receiving during the trial.

Q: How can I find out more

1. **Ask**

   Just Ask Your Doctor!

2. **Visit**

   cancertrials.ie

3. **Call**

   Irish Cancer Society Cancer Nurseline

   Freephone 1800 200 700

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