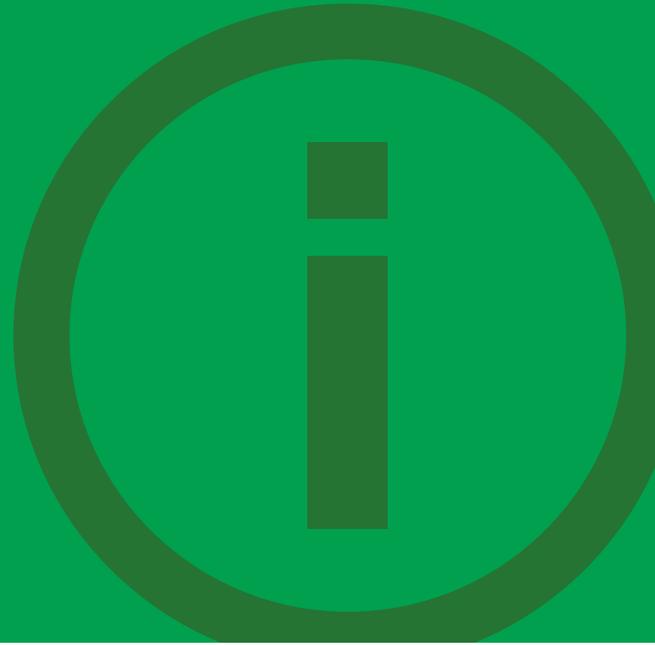


Cancer and Clinical Trials



This factsheet aims to help you to understand more about clinical trials. We hope that it answers some of your questions about clinical trials, including what a trial is, the different types of trials and what to expect if you are taking part in a trial.

If you have any other questions or concerns, please ask your doctor or nurse. You can also call our **Cancer Nurseline** on Freephone **1800 200 700**, email cancernurseline@cancer.ie or visit a Daffodil Centre.

What is a clinical trial?

A clinical trial is a piece of research that studies new ways of preventing, screening and treating physical problems. All the medical treatments that we use today have been tested in clinical trials. This factsheet has information on clinical trials for cancer treatments.

The aim of clinical trials for cancer treatments is to improve treatments for cancer and give patients a better quality of life.

What do clinical trials want to find out?

Clinical trials study the effect of using new drugs or treatments to treat cancer. Or they can look at what happens when existing drugs or treatments are used in new combinations. For example, giving radiotherapy along with chemotherapy. Or combining chemotherapy drugs with newer drugs like biological therapies.

Clinical trials also look at ways of diagnosing cancer, surgical techniques, and treatments like radiotherapy.

Cancer Nurseline 1800 200 700

Clinical trials usually compare a new, promising treatment with the current, standard treatment. If the early stages of research suggest that the new treatment might be more effective than the standard one, a clinical trial can be designed to get evidence about how well the treatment works.

Why are clinical trials needed?

In Ireland, all medicines must go through a clinical trial before they are given a licence.

The treatments we use for cancer now have all been tested in clinical trials. If we did not have clinical trials we could not develop new and more effective treatments. Many cancers have been cured and many patients live longer because of treatments tested in clinical trials.

If a clinical trial has shown that a treatment is effective, more trials can be carried out to see if there are better ways of using it. For example, using different doses or combining a particular treatment with other treatments.

Are clinical trials safe for patients?

When a drug is being used in a clinical trial it has already been carefully tested to make sure it is safe to use in a clinical trial. A clinical trial is one of the final stages in a long and careful research process. If you are likely to suffer side-effects or other problems, this will be described in the consent form. Your doctor will also discuss any risks with you.

If you decide to take part in the trial, you will receive the best possible care and your doctor and nurse will monitor you very closely.

If over the course of the trial the new treatment is not working as well as the standard treatment you will be moved back on to the standard treatment.

When a drug is being used in a clinical trial it has already been carefully tested to make sure it is safe to use in a clinical trial.

All clinical trials are totally confidential. The information collected on the effects of the treatment will be shared with doctors and researchers, but your personal details will be protected. During the trial you will be identified by a unique patient number. Only the researchers will know your personal details.

Who checks that the clinical trials are carried out safely?

There are lots of laws and regulations that say how clinical trials must be carried out. Every clinical trial involving patients in Ireland must be approved before it is allowed to start. Trials must be approved by the Health Products Regulatory Authority (HPRA) and an ethical committee.

Health Products Regulatory Authority

(HPRA): Researchers have to give the HPRA all the information about the trial – how it will be carried out (this is called the trial protocol) and all the relevant scientific and medical information. The HPRA reviews this application and makes sure that the trial meets Irish, EU and international standards for clinical research. The trial will be approved by the HPRA if it meets all the necessary safety standards and regulations.

Ethics committee: A clinical trial must also be approved by an ethics committee. The ethics committee is usually made up of doctors, nurses, medical staff, lawyers and members of the public. The ethics committee makes sure that the rights and wellbeing of the patients who are taking part in the trial are looked after. For new medicines the Department of Health supervises this process.

Monitoring clinical trials: If the trial application is approved by the HPRA and the ethics committee, the researchers can begin the trial. Once the trial has started it will be monitored regularly to make sure the regulations are being followed and everything is being done correctly. The HPRA can also make an official inspection of the trial at any time to make sure it is being carried out properly, with patient safety in mind.

Every clinical trial is covered by an approved policy of insurance and all doctors involved must have current insurance cover.

What should I do if I want to take part in a clinical trial?

Speak to your doctor if you are interested in taking part in a clinical trial. He or she is the best person to give you information about any trials that might be suitable for you and your cancer. You may be offered a clinical trial as part of your treatment plan/consultation, if there are any trials that are suitable.

Your doctor may arrange for you to talk to a research nurse who is part of the team in charge of the clinical trial. He or she can give you more information about the trial.

How does my doctor decide if I am suitable for a trial or not?

If there is a clinical trial that is suitable for you, your doctor will explain this. Not all trials are suitable for all patients with a particular type of cancer. Trials often need patients who are similar in certain ways. These might include age, gender, cancer type, stage of cancer, whether you have had previous cancer treatment and other medical conditions. For this reason, trials have very strict inclusion and exclusion rules. This means that some people can be included in the trial but some are not suitable and so will not be able to take part.

Having strict rules about how patients are selected helps to make the trial safer. It also means the results will be more reliable by making sure that the patients receiving the new treatment are medically suitable and that a fair comparison can be made between similar patients.

If there is a clinical trial that is suitable for you, your doctor will explain this. Not all trials are suitable for all patients with a particular type of cancer.

Getting more information

It is a good idea to bring somebody with you when you meet your doctor to talk about a clinical trial. The information about clinical trials can be confusing, so do not be afraid to ask any questions. It might help you to write down your questions before you meet your doctor.

Questions to ask your doctor



Hints & tips

- What does the trial hope to find out?
- What is the evidence for the trial?
- Will I have many extra visits in comparison to the standard treatment?
- What is the trial called?
- What treatment will I get?
- What is the difference between the trial treatment and standard treatment?
- What are the side-effects of the trial treatment?
- What are the benefits of taking part?
- What are the risks of taking part?
- How many patients are taking part in this trial?
- How long will my treatment take?
- Will the trial cost me any money?
- Where will I get my treatment? Will I be in the same hospital and have the same doctors?
- What treatment will I have if I do not want to take part in the trial?
- What will happen if I want to stop the trial treatment?
- When will the trial results be available?
- What is expected of me during the trial?

What happens if I'm suitable for a trial?

- **Treatment options:** Your doctor will give you all the details about the trial and your treatment options. For example, you may be offered the standard treatment for your cancer and you may also be offered a trial treatment. Remember you will only be offered a trial treatment if your doctor thinks it is at least as good as the standard treatment.
- **Time to think:** You will have a chance to think about your choice and discuss your options with the trial nurse. Before you start your treatment you will be asked to read a detailed patient information sheet.

After listening to all the information, it's a good idea to take the information home and think about whether or not you want to take part. You could also discuss the trial with a friend or relative. Remember that taking part in a trial is your choice, so take your time and ask your doctor any questions that you might have.

Making a decision

Deciding what treatment to have can be confusing. Usually there are pros and cons to taking part in a trial. If you have any questions about the benefits and any possible disadvantages, talk to your doctor.

Remember that you will only be given a choice if your doctor believes that both treatments could be equally useful for you.

No matter what treatment you have, remember that every patient is different and there is no way of knowing if a treatment is going to work for you before you start it. Your doctors can only give you advice based on what they have learnt from other patients with a disease like yours, so make your decision based on what you feel is best for you.

Making a decision

Hints & tips

It can be hard to make a decision about whether or not to take part in a clinical trial. Here are some things to think about.

Pros ✓

- You have the chance to have a promising or better new treatment.
- You will be closely monitored by a team of doctors and trial nurses.
- You may be helping to improve cancer treatment for future patients.
- Your doctor may find out more about your cancer due to extra tests only available on clinical trials.

Cons ✗

- The trial treatment may be as good as the standard treatment but it might not be better.
- You might have some side-effects after taking the trial treatment.
- You might have to make more visits to the hospital than patients who are on standard treatment.
- If you are on a randomised trial using a new drug you may still only receive the standard treatment.

Talk to your doctor about the benefits and any disadvantages of the trial.

Giving consent

Giving consent means you understand the trial and agree to take part. You cannot be part of a clinical trial if you have not given your permission. If you want to take part you will be asked to read a consent form.

The consent form explains:

- Why the trial is being run
- What it hopes to achieve
- What the possible side-effects and risks are
- Why you have been invited to take part.

It is important that you understand everything about the trial before you agree to take part. This is called informed consent.

If you want to take part you will fill in and sign the consent form. This can involve a lot of paperwork but do not worry as your doctor and nurse will go through it with you. You can still change your mind at any point after you have signed the consent form or started your trial treatment.

Can I stop taking part in a trial?

You can withdraw from the clinical trial at any time. This will not affect the care you receive from your doctors and nurses. If you decide you don't want to be part of the trial any more, you will be offered the standard treatment instead. You can discuss your reasons for wanting to leave a trial with any member of the research team. Sometimes you can still be part of the trial with your follow up.

If you decide you don't want to be part of the trial any more, you will be offered the standard treatment instead.

What happens at the end of a trial?

Each patient starts their treatment at a different time and will be monitored during and after their treatment. Once you have finished your treatment, your doctor will monitor your progress and continue to report back to the researchers.

As part of the clinical trial you may be asked to come back for appointments after you have finished your treatment. It is important that you attend these appointments to help the researchers understand the results of the trial.

The results of clinical trials are published in medical journals. Your doctor can tell you what the final results are once they have been published. If a trial treatment is shown to have better results than the standard treatment, it will be licensed and become the new standard treatment.

What are the different types of clinical trials?

The following terms are used to describe different types of trials. Your doctor or nurse will explain which of these terms is relevant to you.

- Controlled trials
- Blind and double-blind trials
- Randomisation
- Placebo

Controlled trials

Some trials need a trial group of patients and a control group of patients. The trial group receives the new treatment and the control group receives the standard treatment. This allows the researchers to compare the two treatments. If you take part in a trial and are assigned to a control group, your participation is just as important to the results as that of the patients in the trial group.

Blind and double-blind trials

In some trials, your doctor will not tell you what type of treatment you are getting. This is called a blind trial. In this case, you will not know if you are receiving the new treatment or the standard treatment. The reason for this is that the researchers need to know that the reported results are not influenced by what the medical team or patients think might or should happen.

When the medical team do not know what treatment you are getting it is called a double-blind trial. They are then in a better position to give a report that is not influenced in any way. The treatment you are receiving is still recorded by the researchers. If you become unwell or experience unusual side effects or if there is a medical need the doctors can ask the researchers what drug you are on.

Randomisation

Randomisation describes how patients are selected into two groups. One group gets the new treatment(s) and the other group gets the standard treatment(s). A computer randomly selects patients into the two groups.

Your doctor and the research team cannot influence which treatment you receive. It is completely random. This makes sure that the trial is fair and the results are reliable. This is important because the results might influence treatment for patients in the future.

Placebo

Many patients worry that if they take part in a trial they will be given a placebo. A placebo can look like a real drug but it has no effect on your body. Placebos are used when there is no standard treatment to compare the new treatment to. However, placebos are rarely used in cancer clinical trials. If a trial uses placebos, you will be told this before you decide to take part.

What does a trial 'phase' mean?

There are a number of 'phases' in a clinical trial. A new treatment must pass each phase before moving on to the next phase. These phases make sure that the research is always carried out in order and safely. If you take part in a clinical trial, it will probably be a phase 3 or phase 4 trial.

Phase I (Phase 1)

Phase 1 is the first stage during which a new treatment is used on people. Before this, the trial is carried out on cancer cells in a test tube or petri dish in a laboratory. Phase 1 trials involve small numbers of people, usually less than 50 and sometimes as few as 10. The purpose of a phase 1 trial is:

- To find a safe dose for the new treatment
- To decide how the new treatment should be given (e.g. tablets/into a vein)
- To see how the new treatment affects the human body

Phase II (Phase 2)

A phase 2 trial also involves a small number of patients, usually less than 100. The purpose of a phase 2 trial is:

- To find out if the new treatment is particularly useful to certain cancers
- To see how the new treatment affects the human body and what the side-effects are
- To see if the new treatment is suitable for a phase 3 trial

Phase III (Phase 3)

Phase 3 trials involve much larger numbers of patients, often from many different hospitals and in many different countries. A phase 3 trial might need hundreds or thousands of patients. The purpose of a phase 3 trial is:

- To compare the new treatment with the standard treatment
- To provide more information on the side-effects of the treatment

Phase IV (Phase 4)

If a phase 3 trial shows that a new treatment is effective, the treatment is licensed and doctors will begin using it on their patients.

Phase 4 trials study further the effectiveness of the treatment and the side-effects linked to it. Phase 4 trials need thousands of patients.

If you take part in a clinical trial, it will probably be a phase 3 or 4 trial.

How long does a clinical trial take?

Clinical trials can take many years to complete. Often thousands of people will be involved in one cancer trial and trials can take place over a number of years. The same clinical trial can be taking place all over the world at the same time. This is because the researchers want to be sure that a new treatment or new way of giving an existing treatment is better than the standard treatment.

Even though your treatment as part of the trial is complete, the final results of the whole trial might not be known for a long time afterwards. This can be frustrating for patients, doctors and researchers. However, trials must run for long enough to recruit enough patients and then have the results analysed to make sure that they are reliable.

Sometimes, even though a large number of people are involved in a trial and it takes years to complete, the improvements in treatment may be small. However, some trials bring significant changes to cancer treatments. This is why researchers continue to design new trials and patients agree to take part.

Clinical trials in Ireland

You can find out about any trials that are available by talking to your doctor or by contacting ICORG. ICORG is the organisation that co-ordinates many cancer clinical trials in Ireland. Their website has details of cancer (oncology) clinical trials that are taking place.

Useful organisations and websites

Health Products Regulatory Authority (HPRA)

Body overseeing clinical trials with medicinal products conducted in Ireland. Approves and inspects trials and monitors safety, quality and other requirements.

Website: www.hpra.ie

All-Ireland Co-operative Oncology Research Group (ICORG)

Information on clinical trials and details of current trials being held around Ireland.

Website: www.icorg.ie

Health Research Board

Supports and funds health-related research.

Website: www.hrb.ie

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

Sets down rules for IFPMA-member pharmaceutical companies about engaging in medical and biopharmaceutical research and handles complaints.

Website: www.ifpma.org

Daffodil Centres

The Irish Cancer Society's Daffodil Centres are located in thirteen hospitals nationwide. The centres are staffed by cancer nurses and trained volunteers who provide confidential advice, support and information to anyone affected by cancer. For details of your nearest Daffodil Centre, call our Cancer Nurseline on 1800 200 700 or visit www.cancer.ie



For more information on cancer and clinical trials, or for confidential advice from our cancer nurse specialists, call our **Cancer Nurseline on Freephone**

1800 200 700

(Monday–Thursday, 9am–6pm, Friday 9am–5pm) or email cancernurseline@irishcancer.ie
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