

CANCER INFORMATION FACTSHEET



Cancer and Clinical Trials

This factsheet aims to help you to understand more about clinical trials. It is an agreed view on this topic by medical experts. 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 call the National Cancer Helpline on freefone 1800 200 700.

What is a clinical trial?

A clinical trial is a piece of research that studies new ways of preventing, screening and treating physical problems. Clinical trials happen all the time in all areas of medicine. This factsheet discusses clinical trials in cancer treatments.

Clinical trials look at using new drugs or new combinations of drugs that are already used to treat cancer. They also look at diagnostic techniques, surgical techniques and radiotherapy treatments. The aim of clinical trials is to improve treatments for cancer and give these patients a better quality of life.

Many cancer patients take part in clinical trials. Even

though the words 'research' and 'trial' sometimes scare people, there is no need for fear. Before a drug or treatment is used on patients, it goes through many steps to make sure that it is safe to use. If the early stages of research suggest that a new treatment might be more effective than the current or 'standard' treatment, doctors and researchers compare the new treatment with the standard one. A clinical trial is one of the final stages of this long and careful research process.

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.

National Cancer Helpline: 1800 200 700



Why are clinical trials needed?

The idea for a cancer trial usually comes from looking at research that is already being done. Researchers look at what they already know and then search for gaps and new questions that need to be answered. The researchers then 'design' the trial. This is called a trial protocol.

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

Often thousands of people will be involved in one cancer trial and they can take place over years. 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. Sometimes, even though a large number of people are involved in a trial and it takes years to complete, the improvements in treatment are important but 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.



Are clinical trials safe?

In Ireland, all medicines must complete a clinical trial before they are given a licence. Researchers must register with the Irish Medicines Board and supply their trial protocol and relevant scientific and medical information. The board reviews this application and decides whether or not the trial will be allowed to happen.

The application must also be sent to an approved ethics committee. For new medicines the Department of Health supervises this process. The ethics committee makes sure that the rights and well-being of the patients who are taking part in the trial are looked after.

When the trial application has been approved by the Irish Medicines Board and the ethics committee, the researchers can begin the trial. At any time the Irish Medicines Board can audit the trial to make sure it is being carried out properly, with patient safety in mind.

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. If needed, you can find out from the researchers who are organising the trial which treatment you are receiving.

- **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. This makes sure that the trial is fair and that 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?

As mentioned above, clinical trials are long and careful research processes that can take many years. 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 decide to 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 anything from 100 patients to 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 licenced 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.

How long does a clinical trial take?

Clinical trials can take many years to complete. Even though your treatment as part of the trial is complete, all final results of the whole trial might

not be known. 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 the results are reliable.

Your doctor will discuss the details of your treatment with you, including how long it will take. Once you have finished your treatment, your doctor will monitor your progress and continue to report back to the researchers. Each patient starts their treatment at a different time and must be monitored during and after their treatment.

Results 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 licenced and become the new standard treatment.

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 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, if not better than, the standard treatment.

Trials must be very specific so they need patients to be as similar as possible. For example, a new treatment might be designed for a rare type of lung cancer and would not be suitable for all lung cancer patients. 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 excluded. Not everyone is suitable for a particular trial.

The inclusion and exclusion rules are based on reasons why you might or might not be suitable. These might include your age, gender, cancer type, stage of cancer, whether you have had previous cancer treatment and other medical conditions. Strict rules about how patients will be selected help to make the trial safer by making sure that the right 'type' of patients are receiving the

new treatment and that a fair comparison can be made between similar patients.

What happens if I'm suitable for a trial?

Your doctor will give you all the details about the trial. You will then have a chance to think about your choice and discuss your options with the trial nurse. If you decide to take part in the trial, your doctor and nurse will monitor you very closely. Before you start your treatment you will be asked to read a detailed patient information sheet and sign a consent form. This can involve a lot of paperwork but do not worry as your doctor and nurse will go through it with you. The consent form explains why the trial is being run, what it hopes to achieve, what the possible side-effects and risks are and 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. Remember that taking part in a trial is your choice, so take your time and ask your doctor any questions that you might have. All trials are totally confidential and your personal details will be protected.

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 to withdraw, you will be offered the standard treatment instead.

Weighing up the pros and cons

Deciding what treatment to have can be confusing. Remember that you will only be given a choice if your doctor believes that both treatments could be equally useful for you. There are pros and cons to taking part in a trial. Some of the main ones are listed on the next page. If you have any questions about these, talk to your doctor about them.



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.

Questions to ask your doctor

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.

Pros

- You have the chance to have a promising new treatment.
- If the trial treatment is found to be better than the standard treatment, you will be one of the first patients to receive it.
- You will be closely monitored by a team of doctors and trial nurses.
- You may be helping to improve cancer treatment for future patients.

Cons

- The trial treatment may be as good but not better than the standard treatment.
- 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.
- Health insurance companies might not cover costs linked to a trial so it is important that you contact your health insurance company before you start the trial.

- What does the trial hope to find out?
- 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 in the trial?
- What are the risks of taking part in the trial?
- How many patients are taking part in this trial?
- How long will my treatment take?
- Will the trial cost me any money?
- 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 discontinue the trial treatment?
- When will the trial results be available?

CANCER INFORMATION FACTSHEET

Clinical trials in Ireland

Speak to your doctor or nurse in your hospital and they will let you know about any clinical trials that might be suitable for you. You can also find out about any trials that are available by contacting ICORG, who co-ordinate most cancer clinical trials in Ireland.

Other clinical trials are run between the hospital consultants and pharmaceutical companies. Please see the information on useful organisations below.

Other Useful Websites

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

www.icorg.ie

Irish Medicines Board

www.imb.ie

Health Research Board

www.hrb.ie

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

www.clinicaltrials.ifpma.org



FURTHER INFORMATION

For more information on clinical trials, call the **National Cancer Helpline, freefone:**

1800 200 700

(Monday-Thursday, 9am-7pm; Friday, 9am-5pm)
or

email helpline@irishcancer.ie for confidential advice from our cancer nurse specialists.

Irish Cancer Society

43/45 Northumberland Road, Dublin 4

Tel: (01) 231 0500

Fax: (01) 231 0555

Email: helpline@irishcancer.ie

Website: www.cancer.ie

Published by the Irish Cancer Society.

© Irish Cancer Society, 2011

Next revision due: 2013

All rights reserved. No part of this publication may be reproduced or transmitted, in any form or by any means, electronic or mechanical, including photocopying, recording or any other information storage and retrieval system, without permission in writing from the Irish Cancer Society.



helpline@irishcancer.ie