

# WHAT ARE CANCER CLINICAL TRIALS ALL ABOUT ?



A Booklet for Patients with Cancer

## Acknowledgement

EORTC is grateful to the 'Fondation Cancer' for their support in producing this booklet



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# What are Cancer Clinical Trials all about ?

## Foreword

*Research studies conducted with patients are called clinical trials or clinical studies. As a patient with cancer, you may be asked to participate in a clinical trial. This booklet is written for you, your family and friends, to explain what clinical trials are and to help you understand how clinical trials (or studies) are designed and carried out. Clinical trials test new treatments for cancer. Clinical trials may involve several types of treatments such as new drugs, new approaches to surgery or radiation therapy, innovative methods such as gene therapy or vaccines as well as new combinations of treatments.*

*The time when cancer is diagnosed or when treatment options are being made is very difficult. Your doctor will talk to you about your disease and that will help you make adequate decisions. It is often hard to remember or understand complex medical explanations. The information in this booklet is meant to complement what your doctors tell you. It provides answers to questions most often asked about clinical trials.*

*There is a glossary of words that relate to clinical trials and cancer care. More information on many cancer-related topics is available from your doctor, from the European Organisation for Research and Treatment of Cancer (EORTC) and also from several cancer leagues in most European countries.*

# What is a Clinical Trial?

In the field of management of cancer, scientists and doctors are constantly looking to develop innovative, more effective and less toxic treatments to improve patients survival and quality of life. Cancer clinical trials are studies conducted with patients and are generally designed to confirm the safety and effectiveness of a new promising treatment. Before any new treatment is made available for testing in patients, it must be thoroughly tested in a laboratory on cell cultures and on animals.

Only when these preclinical (and animal) studies suggest that the treatment is safe, it is then tested in clinical trials with patients.

In cancer research, some clinical trials are aimed at discovering new drugs while others evaluate and optimize different therapeutic approaches including surgery, radiation therapy and combinations of drugs already on the market.

The purpose of the trial may be to test different doses of the treatment, how often it should be taken, and whether it is best to take it for example as tablet or injection. The trial design will be different depending on whether the drug is in an early, intermediate or late stage of development.

The trial may also evaluate optimal ways (and extension) of surgery and or radiation therapy used alone or in combination. However, with any new treatments there may be risks as well as benefits. That is why clinical trials are closely monitored and usually conducted in hospitals or through the outpatient department.

At the end of the clinical trials, which often involve several hundred patients, careful evaluation and analysis of all data are conducted by experts and the results are submitted to review by other experts as well as regulatory authorities for approval when intended for registration.



If a new compound is well tolerated and works in large numbers of patients, the tested drug is granted a licence, making it available for all patients. Once the treatment is available, doctors may wish to combine it with other treatments including surgery and/or radiation therapy.

Clinical trials are also needed in this situation to determine if these combinations are more effective.

Standard treatments, the ones now being used as reference or state-of-the-art-treatment, are often the basis for building new, hopefully better treatments. Many new regimens are designed on the basis of what has worked in the past. Only patients who wish to take part in a clinical trial may be asked to enter a trial. Learn as much as you can about the trial, before you make your decision.

### *Why are clinical trials important?*

Advances in science and medicine are the results of new ideas and approaches developed through research. Innovative cancer treatments must prove to be safe and effective in scientific studies with a certain number of patients before they can be made widely available. Scientific progress in a laboratory does not necessarily mean medical progress unless high-quality clinical trials have been performed in patients. Clinical trials provide the evidence needed to convince medical doctors to change their practices and adopt better treatments for all patients.

Through clinical trials, researchers and doctors learn which new approaches are the most effective treatments.

If you take part in a clinical study, you will also be helping to advance medical science and thereby improving prospects for patients in the future.

### **Cancer Clinical Trials Include Research in Different Phases**

After successful pre-clinical studies, a new treatment is evaluated through a series of clinical trials, methodologically built, to test safety and efficacy. Some clinical trials test one research treatment in one group of patients. Other trials compare two or more treatments in separate groups of patients who are similar in certain ways, such as the extent of their disease. In this way, the groups are alike and the results can be validly compared.

One of the groups may receive standard (the most accepted or the best available one) treatment so the new treatment can be directly compared to it. The group receiving the standard treatment is called the "control group". For example, one group of patients (the control group) may receive the usual surgical treatment for a certain type of cancer, while another patient group with the same type of cancer may receive surgery plus radiation therapy to see if this improves disease control.

Sometimes, no standard treatment yet exists for certain cancer patients. In drug studies for such cases, one group of patients might receive a new drug and the control group, none.

But no patient is placed in a control group without treatment if there is any known treatment that would benefit that patient. The control group is followed as carefully and as often as the "treatment" group.

One of the ways to prevent the bias of a patient or doctor from influencing study results is randomisation. If a patient agrees to participate, this means she/he is selected at random (often by a computer) to be in one group or another. This is important because if the doctor or the patient chooses the treatment, he or she may unintentionally bias the results of the study.

Researchers do not know which treatment is best. From what is known at the time, any one of the treatments chosen could be of equal benefit to the patient.



Clinical trials are carried out in different steps called phases, each designed to find out certain information.

Patients may be eligible for studies in different phases depending on their general condition and the type and stage of their cancer. Each new phase of a clinical trial depends on and builds on information from an earlier phase. More patients take part in the later phases of studies than in the earlier ones.

- **In a Phase I study**, a new research treatment is given to a small number of patients. The researchers must find the best way to give a new treatment and how much of it can be safely given. They watch carefully for any harmful side effects. The research treatment has been well tested in laboratory and animal studies but no one knows how patients will react. For this reason, Phase I studies may involve significant risks. They are only offered to patients whose cancer has spread and who would not be helped by other cancer treatments. Phase I treatments may produce anti-cancer effects, and some patients have been helped by these treatments. The number of patients entered in a Phase I study is usually limited to a few dozen.
- **Phase II studies** determine the activity of a new treatment on various types of cancer. There are about 40-80 patients entered in a Phase II study. If a treatment has shown activity against some types of cancer in Phase II, it moves to Phase III.
- **Phase III studies** aim to compare a new treatment with standard treatment to see which is more effective. These Phase III studies usually require a large number (several hundred or thousands) of patients to provide significant clinical and statistical data. If a new drug has been found to be effective in a large clinical trial, it may also be tested together with other effective drugs, or with surgery and/or radiation therapy.



## How is the Research Conducted and How are Patients Protected?

### *The Protocol*

To protect patients and to produce sound research results, treatments are carried out according to strict scientific and ethical principles. The treatment plan is described in a document called "the protocol". The protocol outlines what will be done in the study and why. It indicates how many patients will be entered in the study and when relevant medical tests will be performed. The protocol must be followed by every doctor taking part in the research.

### *Ethical and Legal protection*

The ethical and legal codes that govern medical practice in the participating countries apply to all clinical trials. In Europe, clinical research is conducted in accordance with international standards for ethics: the Declaration of Helsinki, the Guidelines for Good Clinical Practice approved by the International Conference on Harmonisation. These safeguards include regular review of the protocol (the study plans) and the progress of each study by researchers at other places. Patients' safety is reviewed on an on-going basis in all studies.

Before being conducted, all clinical trials must first be approved by an Institutional Review Board (IRB) also called an Ethical Review Committee, whose mission is to ensure patient protection, safety and integrity. IRB are usually made up of scientists, doctors, clergy and other as lay persons according to national laws. An IRB reviews a study to see that it is well designed with safeguards for patients and that the risks are reasonable in relation to the potential benefits.



### *Informed consent*

Patients learn about the details of a clinical trial from their doctor, but are also given more information during the process of informed consent. This is an important process that ensures that the patient understands and makes their own decision to enrol.

The patient indicates their intent by signing the informed consent form. However, the process of informed consent goes on throughout the trial when the patient may be told of new findings from the clinical trial or informed of new risks.

During the informed consent process, you will learn that a patient may leave a trial at any time, even after the trial is underway, although it is always wise to discuss it with your doctor. You can consider other possible treatments if needed with your doctors and nurses. During the course of a study, if it is clear that a treatment is not in your best interest, you will be removed from the study and you can choose other options with your doctor. Also when there is firm evidence that one method is better than others in a study, the trial is stopped and all patients in the trial are given the benefit of the new information.

### *Confidentiality*

According to international standards and national regulations practice, all data collected on your health for the purpose of research will be kept confidential. Your identity will never be disclosed. Therefore, your privileged relationship with your treating doctor will not be affected by the fact that you are participating in a clinical trial. Confidentiality issues are a subject that you may also discuss with your doctor when you are prepared to take part in a clinical study.

### *Announcing the results*

At the end of the clinical trial, doctors and specialists in biostatistics analyse the results and report them to scientific meetings, and to medical journals. Final publications of trial results are reviewed by experts and by various government agencies for approval of new treatments if appropriate. This helps to speed up the process of bringing better treatments to all patients with cancer.

## Are There Risks or Side Effects in Clinical Trials?

Yes. Treatments used in clinical trials can cause side effects and other health risks depending on the type of treatment and the patient's condition. Side effects vary from patient to patient. Standard treatments, as well as treatments in clinical trials, can cause side effects. New and better ways of helping patients with side effects are being found and used in all cancer treatments, including clinical trials.

Most side effects are temporary and will gradually go away once treatment is stopped. For example, some anti-cancer drugs, whether standard or experimental, cause hair loss and nausea and some do not. They can also affect the bone marrow, which produces blood cells.

During treatment, the number of blood cells, called the blood count, may fall too low. Since this could lead to possible infection or other problems, patients have their blood count checked often. Fortunately, bone marrow has a great ability to replace blood cells, so that the blood count can usually return to normal.

Some side effects of cancer treatment (whether or not in a clinical trial) can be permanent and serious, even life-threatening. Also, certain side effects may not appear until later, after the treatment itself is over.

These 'late' effects may include damage to a major organ such as the heart, lungs or kidneys, sterility or a second cancer. Doctors are concerned and trying to prevent late complications of treatments since many patients with cancer are now living longer, largely because of better treatments.



As a patient, there are a number of things to consider in deciding about your treatment. Cancer is a life-threatening disease, which causes symptoms of its own that are not related to treatment. In each case, the unavoidable risks of the cancer itself, and your condition, should be weighed against the potential risks and benefits of a new research treatment.

During the clinical trial, you will have to report all side effects to your doctor who will be able to help you.

#### ***Why do cancer treatments have side effects ?***

Adverse reactions also called 'adverse effect' differ from one patient to another.

Any medical treatment can carry the potential for side effects in some patients. Cancer treatment is particularly powerful, because it is designed to destroy dividing cancer cells. Such treatments can also affect healthy dividing cells and this can cause side effects. Some forms of surgery or radiation are also used to destroy cancer cells. The challenge to doctors has been to develop treatments to limit the cancer and maintain as far as possible the patient's quality of life.



## Supporting the Patient During Treatment

Cancer researchers are trying to make cancer treatment more effective and lessen its side effects. Results of such efforts include:

- new anti-cancer drugs with fewer or milder side effects.
- better anti-nausea medicine.
- more effective pain killing drugs.
- some shorter periods of time on anti-cancer drugs for some diseases.
- special ways to protect normal tissues during radiation therapy.
- new methods of surgery that are less extensive and less damaging to the body.
- psychological support programmes and information on ways to cope during difficult times; how patients feel during and after treatment is important.
- assessing quality of life: a new major concern of all health care providers.



## Why Should a Patient be Interested in a Clinical Trial?

### *A chance to participate in new treatment development*

Patients take part in clinical trials for many reasons. They wish for the intense medical and scientific attention to their case, the opportunity to receive the most effective and up-to-date treatments and also the benefit of expert monitoring. Increasingly, patients like taking an active role in a decision that affects their lives. Usually, they hope for benefits for themselves. They may hope for a cure of disease, a longer life expectation to live, a way to feel better. At times, they also want to contribute to a research effort that may help others.

The patients in a clinical trial are among the first to receive new treatments before they are widely available. However, how a treatment will work for a patient in a trial cannot be known ahead of time. Even standard treatments, although effective in many patients, do not carry definite benefits for everyone. The researchers design a trial to see if a promising new treatment will improve upon current treatments.

All patients in clinical trials are carefully monitored during a trial and followed up afterwards. They have the guarantee to become part of a unique network of clinical trials carried out in Europe, sometimes in co-operation with the USA. In this network, doctors and researchers pool their experience to design and monitor clinical studies and share their knowledge about cancer treatment. Patients in clinical trials receive care from a specialised research team.

### *Eligibility*

Before you and your doctor make a decision about your treatment (whether it is in a clinical trial or not), your type of cancer will be diagnosed and 'staged' to establish the extent of the disease.

Staging tells whether the disease has spread and how far. Deciding on treatment depends on many things, including the stage of the disease and your general health.

You would most likely be referred to a trial by your own doctor or by a doctor who knows your case. Some patients find out about trials from other sources.

Each study enrolls patients who have a similar disease. The eligibility guidelines are different from trial to trial and may include age, gender, the type and stage of cancer, and whether the patients have had prior cancer treatment or have other health problems. Using these strict criteria helps produce reliable results and also to exclude patients who might be harmed by a treatment. The similarity in the patients is important for the doctors to know which groups of patients will benefit.

### *What is it like to receive treatment in a clinical trial?*

You will receive your treatment in a cancer centre, hospital, clinic, or a doctor's office. You may have a team of health and research professionals (doctors, nurses, pharmacist and other specialists) to see you during the study. You may have more tests and may visit the doctor more often if you are in a clinical trial. This is to follow your progress, ensure your safety, as well as to collect study data. You will be given a treatment plan to carefully follow and you may be asked to fill out forms to evaluate your general feelings, particularly about pain and other symptoms that affect your quality of life.

Throughout a clinical study, a patient's personal doctor will be kept informed of the patient's progress. Patients are encouraged to maintain contact with their referring doctors.



## What Trials are Available for Your Type of Cancer?

There are many ways to find out what your treatment choices are. Talk with your doctor and get the opinion of cancer specialists (oncologists). You should not be afraid to ask for a second opinion. Helpful treatment information can be obtained from the EORTC network of specialists who have the latest information on clinical trials being offered in Europe for each type and stage of cancer. If you are interested in participating, discuss this issue with your doctor.

## What is Best for You?

This is an important question. You should discuss your options with medical experts – including your own doctor – and with those close to you. They can counsel you about your choices.

Talk to them and ask questions about the problems you are facing. If you understand what is going on, you can help your doctor work with you more effectively. You may want to take a friend or relative along with you when you talk to your doctor about your case.

It may help you and your doctor if you plan what to ask and write questions down ahead of time. No question is foolish. Learn about what is available to you. Each patient is different. You are an individual with personal needs, and your health is important. If you are the parent of a child with cancer, of course, you have great concerns about making the best decision for your child's care.

As you decide about treatment, if it is in a clinical trial or not, remember that you are not alone. There are many people to help you – doctors, nurses, social workers, clergy, your family, friends, and other patients. Although it is YOUR decision, they can help you think about it and decide what is best for you.

## Important Questions to ask Before Entering a Clinical Trial

If you are thinking about taking part in a clinical trial, here are some important questions you should ask:

- What is the aim of the study?
- What does the study involve? What kinds of tests and treatments? (Find out what is done and how it is done.)
- What is likely to happen in my case with, or without, this new treatment?
- What are other choices and their advantages and disadvantages? (Are there standard treatments for my case and how does the study compare with them?)
- How could the study affect my daily life?
- What if I have other medical problems? Will I have to stop my regular medication ?
- How long will the study last? (Will it require an extra time commitment on my part?)
- Will I have to be hospitalised? If so, how often and for how long?
- Will there be any costs? Will any of the treatment be free?
- If I am harmed as a result of the research, what treatment or compensation would I be entitled to?
- What type of long-term follow-up care is part of the study?
- Who has reviewed and approved the study?
- Who is the promotor of the study?



## About the EORTC and its Clinical Trials Programme

The EORTC is a non-profit international research association under Belgian law conducting clinical trials in Europe since 1962. The EORTC's mission is to improve the standard of cancer treatment and to facilitate the passage of experimental discoveries into state-of-the-art-treatment. As a result of such a comprehensive research programme, more patients with cancer are being cured today than ever before, and many others are living longer with improved quality of life.

The EORTC brings together a unique network of about 2500 cancer specialists at more than 300 institutions around Europe to achieve this goal. They are more than 6 500 new patients entered in about 100 different EORTC clinical trials every year.

This unique research network has also developed collaboration with experts from the United States and across the world. These high-quality clinical trials play a key role in progress against cancer. Studies conducted within the framework of the EORTC have led to increased survival for childhood cancers, Hodgkin's disease, leukaemia, melanoma, breast, uterine, prostate, testicular and bladder cancers, lung and larynx cancers, as well as many others including rare tumours such as sarcoma.

Today, major laboratory discoveries are part of a revolution in biology and lead to exciting new approaches against cancer. Clinical trials will continue to be the mandatory link between such laboratory research and patient care. The final goal of the EORTC is to translate the best of that research into findings that directly help all patients with cancer in Europe.

The EORTC applies strict legal procedures before initiating a trial. All EORTC clinical trials must receive approval from both the Ethics Committee relevant to the treating institution and from the EORTC Protocol Review Committee consisting of experts evaluating the scientific merit of the study which guarantees the quality and safety of the trial.

The EORTC also aims to improve the quality of its clinical research and has been a pioneer in quality assurance. Well-thought guidelines on quality assurance and quality control mechanisms are applied to all EORTC studies under the supervision of a Quality Assurance Committee and a Quality Assurance Unit based at the EORTC headquarters.

Furthermore, the EORTC has also established a permanent Independent Data Monitoring Committee to review the status of clinical trials and make recommendations to the investigators concerning safety and efficacy leading to the trial's continuation, modification and/or discontinuation.

The EORTC Central Office does not diagnose cancer or recommend treatment for individual patients. It does provide rapid and easy access to cancer specialists, as well as to the latest information on cancer treatment, the local resources, description of clinical trials that are open to patient entry and names of institutions and doctors involved in these activities.

**Please see the EORTC website for further information on the EORTC's activities : <http://www.eortc.be>**



## Glossary

**Adjuvant chemotherapy** – One or more anti-cancer drugs used in combination with surgery or radiation therapy as part of the treatment of cancer. Adjuvant usually means 'in addition to' initial treatment.

**An adverse event** - Any untoward medical occurrence in a patient or clinical investigation subject and which does not necessarily have a causal relationship with the treatment. An adverse event can therefore be any unfavourable and unintended sign, symptom, or disease temporarily associated with the use of a medicinal product or any treatment (surgery, radiation therapy), whether or not related to the investigational medical product, or treatment strategy.

**Antibody** – A protein produced by a plasma cell in the lymphatic system or bone marrow in response to a specific 'antigen' (see **antigen**) which has stimulated the immune system. The antibody binds to the antigen which has stimulated the immune system. Once bound, the antigen can be destroyed by other cells of the immune system. See **Immune System**.

**Antigen** – A substance, foreign to the body, that stimulates the production of antibodies by the immune system. Antigens include foreign proteins, bacteria, viruses, pollen and other materials.

**Biological therapy** – Use of biologicals (substances produced by our own cells) or biological response modifiers (substances that affect the patient's defence systems) in the treatment of cancer.

**Blood count** – Measurement of the number of red cells, white cells, and platelets in a sample of blood.

**Bone marrow** – The inner, spongy core of bone that produces blood cells.

**Cancer** – A general term for more than 100 diseases characterised by abnormal and uncontrolled growth of cells. The resulting mass, or tumour, can invade and destroy surrounding normal tissues. Cancer cells from the tumour can spread through the blood or lymph to start new cancer growth in other parts of the body.

**Chemotherapy** – Treatment with anti-cancer drugs.

**Clinical trial or Clinical study** – Research studies that involve human subjects. Each study tries to answer scientific questions and to find better ways to prevent and treat cancer.

**Combination chemotherapy** – Use of two or more anti-cancer drugs.

**Combination therapy** – The use of two or more modes of treatment – surgery, radiotherapy, chemotherapy, or immunotherapy – in combination, alternately or together, to achieve optimum results against cancer.

**Control group** – In clinical studies this is a group of patients which receives standard treatment, a treatment or intervention currently being used and considered to be of proven efficacy on the basis of past studies. Results in patients receiving newly developed treatments may then be compared to the control group. In cases where no standard treatment yet exists for a particular condition, the control group receives no treatment but is carefully followed.

No patient is placed in a control group without treatment if there is any beneficial treatment known for that patient.

**Hormone** – Chemical product of the endocrine glands of the body, which, when secreted into body fluids, has a specific effect on other organs.

**ICH** – The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. The Guidelines for Good Clinical Practice is a result of this conference and is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.

**Immune system** – A complex network of organs, cells and specialised substances distributed throughout the body and defending it from organisms which cause infection or disease.

**Immunotherapy** – A form of biological therapy. An experimental method of treating cancer, using substances which stimulate the body's immune defence system.

**Informed consent** – The process in which a patient learns about and understands the purpose and aspects of a clinical trial and then decides voluntarily whether or not to participate. This process includes a document defining how much a patient must know about the potential benefits and risks of therapy before being able to agree to undergo it knowledgeably. Informed consent is required in all studies. If a patient signs an informed consent form and enters a trial, he or she is still free to leave the trial at any time, and can receive other available medical care.

**Interferon** – A protein substance produced by white blood cells and other types of cells that have been exposed to certain viruses. In animal tests, Interferon has shown some activity against tumours. Studies of its usefulness in treating some types of human cancer are underway. One of a number of new agents available as biological therapy.

**Investigational new drug** – A drug allowed to be used in clinical trials but not yet approved for commercial marketing.

**Investigator** – An investigator is the doctor who is an experienced clinical researcher who prepares a protocol or treatment plan and implements it with patients.

**Metastasis** – The transfer of disease from one part of the body to another. In cancer, metastasis is the migration of cancer cells from the original tumour site through the blood and lymph vessels to produce cancer growth in other tissues. Metastasis also is the term used for a secondary cancer growing at a distant site unless it is determined to be a new primary tumour.

**Metastatic cancer** – Cancer that has spread from its original site to one or more additional body sites.

**Monoclonal antibodies** – One of several new substances used in biological therapy. Monoclonal antibodies are antibodies of a single type. They are mass-produced and designed to home in on target cancer cells. Monoclonal antibodies are products of new scientific techniques and may prove useful in both cancer diagnosis and treatment.

**Multimodality therapy** – The combined use of more than one method of treatment, for example, surgery and chemotherapy.

**Oncologist** – A doctor who is a cancer specialist.

**Placebo** – An inactive substance resembling a medication, given for psychological effect or as a control in evaluating a medicine believed to be active. It is usually a tablet, capsule, or injection that contains a harmless substance but appears to be the same as the medicine being tested. A placebo may be compared with a new drug when no one knows if any drug or treatment will be effective.

**Protocol** – The outline or plan for use of an experimental procedure or experimental treatment.

**Radiation therapy, also called radiotherapy** – Treatment using X-rays, cobalt-60, radium, neutrons, or other types of cell-destroying radiation.

**Radiosensitisers** – Drugs being studied to try to boost the effect of radiation therapy.

**Randomised clinical trials** – A study in which patients with similar traits, such as extent of disease, are chosen or selected at random, to be placed in separate groups that are comparing different treatments. Because irrelevant factors or preferences do not influence the distribution of patients, the treatment groups can be considered comparable and results of the different treatments used in different groups can be compared. There is no way at the time for the researchers to know which of the treatments is best. It is the patient's choice to be in a randomised trial or not. See also Clinical trials.

**Regression** – A cancer that is growing smaller or disappearing, is said to be "in regression."

**Remission** – When the signs and symptoms of cancer go away, the disease is said to be "in remission." A remission can be temporary or permanent.

**Risk/benefit ratio** – The relation between the risks and benefits of a given treatment or procedure. Institutional Review Boards (IRBs), located in the hospital or clinic where the study is to take place, determine whether the risks in a study are reasonable with respect to the potential benefits. The patient must also assess the risk/benefit ration to decide if it is reasonable for him or her to take part in a study.

**Side effects** – (see adverse event)

**Single blind** – (see double blind)

**Staging** – Methods used to establish the extent of a patient's disease.

**Standard treatment** – A treatment or other intervention currently being used and considered to be of proved effectiveness on the basis of past studies.

**Study arm** – Patients in clinical trials are assigned to one part or segment of a study – a study 'arm'. One arm receives a different treatment from another.

**Therapeutic** – Pertaining to treatment.

**Treatment group** – The group that receives the new treatment being tested during a study.

