Understanding Clinical Trials In Colorectal Cancer (CRC)

Complete Guide for Patients and Carers

EuropaColon

... because life matters

EuropaColon

EuropaColon is a not-for-profit organisation established in 2004. It is committed to preventing deaths from colorectal cancer and improving the quality of life and providing support for those affected by the disease. As the first European umbrella organisation EuropaColon has affiliate and associate member patient organisations in 20 European countries.

EuropaColon Vision and Goals

Reducing Colorectal Cancer Mortality in Europe			
To reduce the number of European citizens affected by colorectal cancer	To identify colorectal cancer at an early stage	To ensure access to best treatment and care for all European patients	To support novel and innovative colorectal cancer research

EuropaColon is working with patients, carers, clinicians, the media, the citizens of Europe, Governments and the European Commission to create an effective and powerful Colorectal Cancer Community.

Note to Readers

Although every effort was taken to ensure that the information in this booklet is accurate, EuropaColon cannot accept any liability in relation to the information provided here. It is not a substitute for professional medical care. Readers are strongly advised to discuss issues raised in this booklet and seek personalised advice from their doctor or health care professional.

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Introduction

In order to understand colorectal cancer, many different types of research are conducted. This includes testing a wide range of health care approaches such as new means of preventing the disease, different drug options, diagnostic procedures, surgery, radiotherapy, educational programmes, physical and psychological therapies. Results from all these trials and research studies increase our knowledge about colorectal cancer and help in the search for better outcomes for patients and families. If you have been diagnosed with colorectal cancer (or you are the carer of someone with colorectal cancer) you might be interested in finding out about a clinical trial or other research in which you or your family member can participate. This booklet aims to answer many different questions regarding clinical trials. It explains what clinical trials are, why and how they are conducted. It provides you with the information to help you decide about participating in a clinical trial but also to help you think about possible questions you may want to ask your doctor or other health care professional before making an informed decision whether to take part in a trial. At the end of this booklet a list of useful links is provided where you can search for potential trials that are currently recruiting.

There is no need to read this booklet from cover to cover – just read the parts that you find useful. Medical and research terms that may be unfamiliar are explained in the glossary at the end of the booklet. You may also like to pass this booklet on to your family and friends for their information.

Clinical Trial Overview

What Are Clinical Trials?

Clinical trials are medical research studies involving people (also called participants). They are the safest way to evaluate new drugs, procedures or methods for preventing, diagnosing or treating diseases. Some trials involve healthy individuals while others involve patients who may be offered the option of taking part in a trial during their care and treatment. However, all clinical trials are carried out to try to answer a specific, defined set of questions about health and illness.

Clinical trials aim to find the best ways to:

1. *Prevent the disease and reduce the number of people who become ill.*
2. *Treat illness to improve survival rates or increase the number of people cured.*
3. *Improve the quality of life for people living with illness, including reducing symptoms or the side effects of treatments, such as chemotherapy.*
4. *Diagnose diseases and health problems.*

Clinical trials cover a wide range of different types of research. They are used to test new medicines or new combinations of existing medicines. They can also be used to test whether giving a treatment in a different way will make it more effective or reduce the side effects. Some trials are designed to try out ways to prevent a particular disease thus they can be used to test and offer suggestions to help people change their behaviour or lifestyle and so improve their health.

The European Prospective Investigation into Cancer and Nutrition (EPIC) was designed to investigate the relationship between diet, nutritional status, lifestyle and environmental factors and the incidence of cancer and other chronic diseases. More than half a million of people from 10 European countries have been recruited to the EPIC study. One of the key findings from the EPIC trial is that the combination of four dietary factors (i.e. fibre, fish, red and processed meats) plays a major role as a cause for colorectal cancer, in addition to alcohol intake, obesity and low physical activity.

Why Are Clinical Trials Important?

Clinical trials are the best way to compare different approaches to preventing and treating colorectal cancer. Evidence gathered from clinical trials is used by health care professionals to determine which treatment option works best for certain groups of patients.

All drugs currently used for the treatment of colorectal cancer were tested in clinical trials in order to obtain licences from the European Medicines Agency (EMA) or national regulatory bodies.

How Are Trials Set Up?

Health professionals work together with a wide range of people, including patients, to decide what questions need to be answered. The first step is to carefully look at the results of any earlier trials to find out what is already known, called a **systematic review**. It provides more accurate answers than individual trials, and also helps to identify important questions that still need to be answered through further research.

Once the specific set of questions is defined, doctors, nurses, patients and researchers work together with statisticians, trial managers and representatives from pharmaceutical companies, if relevant, to design a trial to give the most relevant outcome.

A wide range of national and international protocols and guidelines are established to make sure that people participating and the processes of the trial are safe.

Who Conducts a Clinical Trial?

A clinical trial is guided by a **principal investigator (PI)** usually a medical doctor with valid experience in colorectal oncology research. A **research team**, composed of other doctors, scientists, nurses, psychologists and medical and research professionals, supports the principal investigator

Who Sponsors a Clinical Trial?

A trial can involve many different bodies or companies as sponsors such as public health agencies, not-for-profit organisations and/or a private pharmaceutical or

biotechnology company. If you are thinking about participating in a clinical trial, you might request further explanation of the role of each sponsor before deciding to enroll in a particular trial.

Who Can Take Part in Clinical Trials?

All trials have defined **eligibility criteria** or guidelines about who can take part. The eligibility criteria make sure that trials include people who should benefit from the treatment. This could mean that there may not always be an appropriate or suitable clinical trial for you to take part in.

Inclusion criteria help the researchers decide who can take part in the trial. Some trials only include people of a certain age group, or of one sex, or at a particular

stage of their illness. For example, some colorectal cancer trials include only patients with rectal cancer while other may only include patients with metastatic disease, irrespective of the location of the primary tumor.

Exclusion criteria indicate who cannot take part in the trial, such as people with certain conditions or those already taking particular medicines as these may affect the treatment being tested.

Before you start a trial you may have some extra tests to see if you are eligible or to make sure that you are not likely to be at risk of being harmed by the treatments being tested. For example, if a potential side effect of a new drug is that it increases blood pressure, you may have your blood pressure checked.

How Are Clinical Trial Participants Protected?

After a study design (also called protocol) is finalised, before the recruitment starts, the protocol needs to be approved by an **Ethics Committee (EC)** or an **Institutional Review Board (IRB)**. This independent group of people includes doctors, nurses, other medical staff, members of the public and sometimes patient representatives.

The research ethics committee decides whether:

1. *The potential benefits of a new treatment are likely to outweigh the side effects.*
2. *The information provided to help people decide whether they want to take*
3. *part in a trial is clear and transparent.*
4. *The way people will be asked to take part in a trial is appropriate*
5. *There will be compensation for people in the trial if something goes wrong.*
6. *Travel expenses should be offered to people who take part in the trial.*

Each institution may also have a series of **standard operating procedures (SOP)** concerned with different aspects of a trial. Also, the participating clinics and doctors' offices may also have a policy similar to a **Patient's Bill of Rights**. Before enrolling in a clinical trial you might want to request a copy of these documents and any others specific to your country.

How Are People Asked to Take Part in a Trial?

A clinical trial is often run in a number of different hospitals or health centres; possibly in more than one country. The health professional who asks you to take part in a clinical trial may not be the person who designed and set it up. They should give you

all the information you need to consider participating and should be able to answer your questions.

What Are the Potential Risks?

Clinical trials are carefully designed to avoid any risks and get the most benefits for everyone taking part, whatever treatment they receive.

If you are considering participation in a clinical trial you need to understand that the purpose of most clinical trials is to test a new treatment or practice compared to existing methods. In cancer clinical trials a placebo (a treatment that does not add therapeutic benefits) is not usually given unless it is administered along with a treatment proven to be effective. This may be the case in the co-therapy study, where the existing treatment and placebo are tested against the existing treatment with a new treatment.

It is important to remember that in a clinical trial you may be in the control arm and not given the experimental treatment However, you will then receive the best standard care available and be monitored more frequently and carefully than usual.

In all trials, the treatment may cause **side effects (adverse events)** that cannot be predicted. These may be unpleasant and, very rarely, can be life-threatening. You should be warned about any possible risks and side effects, and why the trial is necessary, so that you can make an informed decision about whether to take part. In any event, as with your current treatment, the trial could be stopped if it is detrimental to your health.

A clinical trial may require different tests and/or suggest a different method of delivering the treatment as compared to the standard practice. This could mean going to your hospital more frequently, so bear this in mind before you agree to take part. Some trials may involve travelling distances across the country. Usually you will be able to claim back any extra costs you have. Prior to making an informed decision to participate in a trial, you should discuss personal time management and leave from work with the research team and your family and also with your employer, if appropriate.

Most people diagnosed with cancer decide to participate in research because they feel that they are taking an active part in their health care. They are also helping others in the future, by helping to identify the best treatments.

What Are Possible Benefits?

By taking part in a clinical trial, participants are observed very closely by doctors and nurses. Research shows many people feel that they receive superior medical care

while taking part in a clinical trial. If a new therapy shows superior benefits to existing methods then the study subjects may be the first to have access to and benefit from the new treatment or practice. Some clinical trials have been halted early because the treatment benefits were so clear that all parties involved felt it necessary to make the treatment available to as many cancer patients as soon as possible.

Participating in a clinical trial for colorectal cancer is one of the ways to contribute to the effort to find better ways of preventing, detecting and treating colorectal cancer.

How Are Trials Designed And Run?

Are There Different Types of Trial?

There are two main types of clinical studies: interventional and observational studies. In an **interventional study** participants are assigned to receive specific interventions according to the research plan or protocol while in an **observational study**, investigators assess health outcomes in groups of participants according to a protocol or research plan, but participants are not assigned to specific interventions.

Regarding what is being tested, **treatment trials** test a new therapy (a drug, surgical procedure or radiation therapy, gene therapy, or a combination of these therapies) to treat cancer. **Diagnostic trials** aim to identify better tests or procedures for diagnosing a particular type of cancer. **Prevention trials** test a new method to lower the risk of a type of cancer occurring. **Screening trials** test ways to diagnose cancer sooner, in the early or even pre-cancerous stages of the disease. **Quality of life (QoL) trials** examine ways to support cancer patients and their families and to improve their comfort and enhance their quality of life.

Clinical trials with humans are begun only after laboratory (in vitro) and animal studies have shown that the new therapy is safe and effective.

There are four different stages (phases) of clinical trials.

Phase I trials are mainly aimed at finding how safe a drug is and to evaluate side effects. They usually involve very small numbers of volunteers. Participants can be healthy volunteers or patients with advanced cancer for whom there is no effective standard treatment. This part of the study investigates the best method to deliver the new treatment and to identify the maximum tolerated dose.

Phase II trials are conducted in a larger group of people to better measure the safety and side effects, and to see if the drug has a positive effect in patients.

Phase III trials aim to study the new treatment's efficacy compared to standard, existing treatments. Because they enroll large number of participants, better evaluation of occurrence and seriousness of any side effects or risks is achieved.

Phase IV trials are carried out after a new drug has been shown to work and has

been licensed for use. This type of study examines how well the drug works when it is used more widely and looks at additional long-term risks and benefits.

There are three terms used to describe trials: **controlled trials**, **blind trials** and **randomised trials**.

Controlled trials are designed to compare different treatments, usually a new treatment with the standard treatment by setting up two groups of people. One group, known as the **trial group** or **intervention group**, is given the new treatment. The other group known as the **control group**, is given the standard treatment. The control group is very important. Comparing the results of the control group with those of the treatment group is the only way researchers can reliably find out whether any improvement seen with the new treatment is really due to that treatment and not just due to chance.

In a **blind trial**, the people taking part are not told which group they are in. This is because if they knew which treatment they were getting, it might influence how they felt or how they reported their symptoms. Some trials are **double blind**, which means that the people taking part and the doctors treating them do not know who is getting the new treatment. This avoids the doctors' hopes and expectations influencing the results of the trial. To prevent people from guessing which treatment they are getting, all the treatments are made to look as similar as possible.

In **randomised trials** the participants are put in the trials treatment groups at random, usually by using a computer programme. This is done so that each group has a similar mix of people of different ages, sex and states of health. If one group does better than the other, it is likely to be because of the treatment, as the two groups are similar in every other way.

Randomised controlled studies are considered as the gold standard for clinical research and testing new treatments, particularly when they are double-blind, placebo-controlled trials.

Why Do Some Trials Need a Lot of People?

Some trials need large numbers of people to prove whether one treatment is better than another. Statisticians give expert guidance to help the researchers make sure a trial includes enough people to give reliable results.

Why Do Trials Sometimes Take Many Years?

There are several reasons why it sometimes takes a long time to get the results of a particular trial. This could be because:

- It takes a long time to recruit enough participants

- The protocol is designed in a way that participants are followed over a long period of time, or
- The protocol is designed in a way that treatment is given over a long period of time.

Participating in a Clinical Trial

Should I Participate in a Clinical Trial?

As with all issues regarding health and medical care, the decision to take part in a clinical trial should be reviewed carefully with your doctor or nurse.

If you have been diagnosed with colorectal cancer (or you are the carer of someone with colorectal cancer) it is important that you learn as much as possible about the disease, the diagnosis and available treatments and new therapies under investigation.

What Is Informed Consent?

Informed Consent is the permission you should give to your health specialist before your enrollment into a clinical trial.

In a clinical trial it is essential that the participants and the research team actively communicate as much as possible so that the study results are reliable. The team member asking you to join a trial should discuss it with you in detail, answer all your questions and give you an information leaflet to read in your own time. You may want to discuss it with your family or friends.

You should feel free to ask any questions you feel important to help you make a decision and also be given enough time to think about the trial and what it will mean to you.

Once you decide to take part in a trial, you will be asked to sign an **Informed Consent Form (IRF)** to confirm that you agree to join the trial and have decided to do so of your own free will. You will be given a copy of the signed form to keep. If English is not your first language, the trial should be explained to you in your preferred language. You should also be given a consent form that has been written in a language of your choice.

However, if you decide not to take part in the trial, your decision will be respected and you do not have to give a reason. You will continue to receive the appropriate medical treatment that any other person would receive.

And remember, even if you give your consent you are free to leave the trial at any time without giving a reason.

What Happens During A Trial?

Once you are enrolled, you will be given specific instructions about the trial. These need to be followed both for your safety and so that the trial results are as reliable as possible. During a trial, tests will be carried out in order to determine how well the treatment is working, as well as what are the side effects and new symptoms you may have.

Researchers will also look at the effects a treatment has on your life as a whole and for that reason you could be given questionnaires to measure your quality of life. For example, you may be asked whether you can continue with your everyday activities whether you feel happy or sad, anxious or depressed etc.

There are also trials assessing how cost effective a treatment is and its effects on other aspects of care. For this reason you may be asked whether you can work during the treatment, about the number of times you visit your hospital, how you travel, etc.

What Happens At The End Of A Trial?

The research team may stay in contact with you for some time after the trial so that they can collect long-term information on how you are doing. You might return to having the standard care and/or check-ups that are appropriate for you, depending on the stage of the cancer and what your cancer specialist recommends.

At the end of a trial the results will be available to everyone who took part. The researchers must publish them, regardless of what they show, and state how the results add to available knowledge. These results will be used to help others make decisions about treatment and health care. In some cases it can take many years before the results are known and published.

Will My Information Be Confidential?

If you agree to take part in a clinical trial, all health data that is collected about you will be kept confidential. The researchers cannot tell anyone that you are taking part in the trial without asking you first.

Once the trial has finished, the results are often presented at medical conferences. No name or any information that can identify you will be used in any reports about the trial.

What Happens If Something Goes Wrong?

Trials performed by pharmaceutical companies are insured so that if a patient is harmed by their drug, compensation is paid. However, it is very rare for patients to

be seriously harmed by trial treatments, although some may cause unpleasant side effects. Ethics committees can refuse to allow a trial if it has no insurance or other compensation arrangement.

Before agreeing to take part in a clinical trial you may want to find out exactly what arrangements there are for compensation.

How Can I Find Specific Trials for Colorectal Cancer?

The first step is to ask your health care provider about any trials. You should also search the Internet. Some trials are listed on the websites of not-for-profit organisations and public health agencies. The World Health Organization (WHO) has established the **International Clinical Trials Registration Platform** (www.who.int/ictrp). The aim of the platform is to standardise the way information on medical trials is made available to the public.

The **EU Clinical Trials Register** website (www.clinicaltrialsregister.eu) provides information on protocols of drugs clinical trials. Through this site, you can learn about Phase II-IV adult clinical trials where the investigator sites are in EU member states and the European Economic Area. This includes information on the trial design, the sponsor, the medicine being investigated, the therapeutic areas, and the status of the trial, i.e., if it is authorised, ongoing or complete. One can search for clinical trials using certain key words, such as colorectal cancer, or the type of colorectal cancer, or a drug name. The advanced search allows for filters such as country, age group, gender, trial phase, trial status, date range, etc. For further information on searching for information on the EU Clinical Trials Register go to: www.clinicaltrialsregister.eu.

The National Cancer Institute, which is part of the United States Department of health and human services, provides a comprehensive online database of cancer clinical trials from around the world (www.cancer.gov/clinicaltrials). The list can be searched according to type of cancer, stage/subtype, type of trial, trial location (country, institution or hospital), type of treatment, drug name, trial phase, or a combination of these and other criteria. The list contains protocols for clinical trials that are accepting patients, including trials for cancer treatment, genetics, diagnosis, supportive and palliative care, screening and prevention, as well as those for trials that are completed or no longer recruiting patients.

Ten Steps to Finding a Clinical Trial (Adapted from the National Cancer Institute)

1. Understand clinical trials (by reading this booklet and other key resources).
2. Talk with your doctor about your options.

3. Know as much about your cancer as possible so that you know if you meet the eligibility criteria of a trial. See the NCI Cancer Details Checklist. (www.cancer.gov)
4. Search for the appropriate clinical trial on https://www.clinicaltrialsregister.eu and www.cancer.gov/clinicaltrials/search.
5. Search other sources for clinical trials, such as research organisations, drug and biotech companies or advocacy groups (see Resources for further trial information at the end of this booklet).
6. Make a list of potential clinical trials, including key factors such as the trial objective, eligibility criteria, the location and the length of the study.
7. Contact the clinical trial team directly or through your doctor.
8. Ask the trial co-ordinator questions about the trial (see the questions below).
9. Before making a final decision, discuss your options with your doctor.
10. If you decide to participate, schedule an appointment with the trial team.

For the full National Cancer Institute How to Find a Cancer Treatment Trial: A 10-Step Guide see: www.cancer.gov

Questions to Ask Before Joining A Trial?

Will my doctor help me evaluate a potentially appropriate clinical trial by reviewing the study protocol with me?

How will participation in a trial affect my current care?

How will my doctor monitor my care if I decide to participate in a trial?

Will my doctor help me evaluate ongoing concerns about my participation?

Will my doctor have any direct contact with the study investigators?

What type of colorectal cancer is the study investigating?

What type of clinical trial is this study?

What is the aim of the study?

What are the requirements for participation?

What are the study treatments?

Where will I undergo treatment in the study?

Who is sponsoring this clinical trial?

How are participants assigned to different treatment groups in the study?

Can I choose to be in a specific group within the study?

How many people will participate in the study?

How long does the study last?

What happens at the end of the trial?

How will the results be presented?

What are the short- and long-term potential benefits?

What are the potential short- and long-term risks?

What are the possible effects of the treatment on my family and social life?

Will the treatment affect my fertility?

Will the treatment affect my ability to work?

What medical tests will be given and how often?

What information will be collected and how often?

What kind of long-term follow-up does the trial involve?

What can I do if I don't feel well during the study?

What happens if I decide to leave the trial early?

Who pays for the cost of my care during the trial?

What are the conditions of patient privacy for this study?

Who will have access to the information gathered in the study?

Will other people have access to that information in the future?

Further Clinical Trial Information

Where Can I Find Further Clinical Trial Information?

Bowel and Cancer Research: www.bowelcancerresearch.org

Cancer Research UK: www.cancerresearchuk.org

EU Clinical Trials Directive: eur-lex.europa.eu

EU Clinical Trials Register: www.clinicaltrialsregister.eu

European Medicines Agency (EMA): www.ema.europa.eu

European Organization for Research and the Treatment of Cancer (EORTC): www.eortc.be

National Cancer Institute, U.S. Department of Health and Human Services: www.cancer.gov

World Health Organization (WHO), International Clinical Trials Registry Platform (ICTRP): www.who.int

Other Helpful Resources

Council for international Organizations of Medical sciences, World health Organization, Geneva. International Ethical Guidelines For Biomedical Research Involving Human Subjects: www.cioms.ch (Translations available)

European Commission, Directorate General for Health & Consumers. Clinical Trials. (Available online: ec.europa.eu)

European Organisation for Research and Treatment of Cancer. Clinical Trials. (Available online: www.eortc.org)

International Conference on Harmonisation. Good Clinical Practice Guideline E6(R1), 1996. (Available online: www.ich.org)

National Institutes of Health. How to Find a Cancer Treatment Trial: A 10-step Guide. (Available online: www.cancer.gov)

National Institutes of Health. NIH Clinical Research Trials and You. (Available online: www.nih.gov)

World Health Organisation, The Importance of Pharmacovigilance – Safety Monitoring of Medicinal Products. (Available online: apps.who.int)

World Medical Association. World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. Adopted by the 18th WMA General Assembly Helsinki, June 1964. Last amended by the 59th WMA General Assembly, Seoul, Korea, October 2008. (Available online: www.wma.net)

Medical and Clinical Trial Terms

Glossary

While reading this booklet or talking to your health specialist, you may come across new terms. Below, you can find the explanation for the most commonly used terms. Active ingredient: The compound in a medicine that has a therapeutic effect on the body.

Adjuvant chemotherapy: An anti-cancer drug given in addition to another type of treatment, such as surgery or radiation therapy.

Adverse event: Any untoward medical occurrence in a patient; it is not necessarily due to treatment.

Baseline: A phase during a study when the participants are not receiving any treatments. This is usually at the beginning of a trial before treatment is started. Bias: Human choices or other factors not related to the treatments being tested that might affect a study's results.

Blinded trial: A trial in which participants do not know which treatment they are getting.

Blood test: A test that examines a sample of blood. It assesses levels of different substances in the blood to help diagnose disease.

Cancer: A disease of the body's cells that starts in the genes. Damaged genes cause cells to behave abnormally, and they may develop into a growth called a tumour. Cohort: A group of individuals sharing a similar characteristic such as age, sex, disease or exposure to a pollutant or drug.

Cohort study: A study to determine risk factors for a disease by tracking a group of healthy people who share a similar characteristic, such as their type of work, and seeing whether they develop the disease in question. A cohort study also has a control group.

Combination therapy: Using two or more treatments at once.

Comparator: A product or placebo used as a reference in a clinical trial.

Control group: A group of participants in a clinical study who receive the standard treatment against which the study medication will be compared.

Control treatment: The treatment that is being compared with the experimental treatment. The control is generally the best standard treatment available. In some cases, a placebo is used.

Controlled trial: A trial in which the product being investigated is compared to a reference treatment.

Crossover: A comparison of at least two treatments in which subjects are switched to the alternative treatment after a specified period of time.

CT scan: A computerised tomography scan. This scan uses x-rays to create a picture of the inside of the body.

Data Monitoring Committee: A group of independent, external experts that assesses a trial's progress, and data on safety and efficacy, if applicable.

DNA: A tiny molecule in every cell of the body that carries instructions for how those cells behave and function. Also called deoxyribonucleic acid.

Double-blind study: When both the study participants and the research team are unaware which medication has been administered in order to reduce bias. **Eligibility criteria:** Requirements that a person must meet in order to be able to participate in a clinical study, such as age, type and stage of cancer, general health and previous treatment.

Epidemiology: The study of health on a population level.

Ethics: The study of responsible conduct and what is fair.

Ethics Committee (EC): At all health care facilities, a designated group of scientists, doctors, consumers and other individuals that reviews and approves the protocol for a clinical trial (see Institutional Review Board).

Experimental group: The group of patients that receive the experimental treatment in a randomised controlled trial. Also called the test group.

Experimental treatment: The new or modified treatment that is being tested in a clinical trial.

Gene: A small part of DNA that causes people to have particular characteristics relating to their physical appearance or health.

Genetic marker: A gene or DNA sequence associated with a particular characteristic. Hypothesis: An explanation or guess based on limited evidence that serves as a starting point for research.

Informed consent: A process required in all clinical trials, whereby a patient is told of the aims and details of a clinical trial in order to be able to voluntarily decide whether or not to participate. It involves the participant signing an informed consent document.

Institutional Review Board (IRB): At all health care facilities, a designated group of scientists, doctors, consumers and other individuals that reviews and approves the protocol for a clinical trial (see Ethics Committee).

Investigator: Another term for a researcher.

ISRCTN number: An international standard Randomised Controlled Trial Number, (ISRCTN) is an eight-digit number used to identify clinical trials worldwide.

In vitro study: Experiments undertaken in test tubes or cell culture.

In vivo study: Experiments undertaken in animals.

Laboratory research: Research that is carried out in a laboratory.

Literature review: A review of previous research that has been done in a particular area and which relates to a current problem being investigated.

Longitudinal study: A study done over a long period of time – often decades – with the participants being asked the same questions or having the same tests periodically to assess how their health changes.

Maximum tolerated dose (MTD): Determined by testing increasing doses, this is the highest dose of a drug or treatment that does not cause unacceptable side effects. Multimodal therapy: Using a combination of treatment methods, e.g., radiotherapy and chemotherapy.

Medical intervention: Medical tests, procedures or treatments that are aimed at relieving illness or injury, or curing disease.

Medical oncologist: A doctor who specialises in treating cancer with chemotherapy. Medical science: An area of study focusing on maintaining health and preventing and treating disease.

Meta-analysis: A process in which the results of a number of studies researching the same questions are combined and compared to see whether the results have more weight when analysed together.

Molecular research: Laboratory research that focuses on discovering which genes are responsible for certain diseases and how the disease develops.

Molecule: Very small particles in the body that can join with other molecules to form larger substances. A gene is a type of molecule.

MRI scan: A magnetic resonance imaging scan. A scan that uses magnetism and radio waves to take detailed cross-sectional pictures of the body.

Multi-centre research: Research that is conducted at more than one site. Neoadjuvant therapy: Administering a treatment before the main therapy is undertaken, e.g., chemotherapy before surgery.

Oncology: The study, diagnosis and treatment of cancer.

Overall survival rate (OS): The percentage of people who are alive for a designated period of time (e.g., 5 years) after they were diagnosed with or treated for a disease, such as cancer.

Outcome: A specific result or effect that can be measured in a study, such as reduced tumour size.

Outpatient: A person who receives medical treatment without being admitted into hospital.

Palliative care: Any form of medical care or treatment that reduces disease symptoms and helps improve quality of life.

Parallel group: When a trial evaluates two or more treatments at the same time in separate groups of subjects.

Participant information: An information sheet that explains everything a participant needs to know about the trial and treatment.

Peer review: A process in which independent experts check research to make sure it is accurate and reliable.

Pharmacodynamic study: A study that explores the effect a medicine has on the body.

Pharmacogenetic study: A study investigating a genetic variation that leads to differing responses to drugs.

Pharmacokinetic study: A study that explores what the body does to a medicine. Pharmacology: The study of drugs and how they can be used to treat diseases. Phase: A stage of a clinical trial. There are usually four phases of testing.

Pilot project: A small project that is carried out to see whether a similar large-scale study is realistic to run.

Placebo: A dummy pill, injection or other treatment that is made to look, taste or feel like a real treatment but doesn't have any active ingredients (if a medicine) or any remedial effect (if another type of treatment).

Prevention trial: Trials that test new approaches that researchers and doctors believe may lower the risk of people developing cancer.

Primary endpoint: Established before the study begins, this is the main result that is measured at the end of a study to determine if a given treatment worked (e.g., progression-free survival).

Principal Investigator (PI): The lead health-care specialist in a clinical trial. Progression-free survival (PFS): The length of time during and after treatment in which a patient is living with a disease which does not become more serious. It is often used in a clinical study to help determine how well a new treatment has worked.

Prospective study: Research that looks at what happens to different groups of people from the start of the study up to a point in the future.

Protocol: The outline, design or plan to be followed in a study.

Psychosocial research: Research into the emotional and psychological effects of disease and how people can be helped through supportive care measures.

Qualitative study: Research that focuses on individual responses rather than numerical data to obtain the results.

Quality of life: Your comfort and satisfaction, based on how well your physical, emotional, spiritual, sexual, social and financial needs are met within the limitations of your health and personal circumstances.

Quantitative study: A study that focuses on collecting numerical data and analysing the results using statistics.

Radiation oncologist: A doctor who specialises in treating cancer with radiotherapy. Randomisation: The process by which trial participants are assigned to treatment groups by chance rather than by choice in order to reduce bias.

Randomised controlled trial: A trial in which participants are randomly allocated to receive the experimental (test) treatment or the standard treatment (the control). Retrospective study: Research that looks at what has happened in the past to gain an understanding about why something is occurring now.

Screening: An organised programme to identify disease in people before any symptoms appear.

Side effect: Unintended effects of a drug or treatment.

Single-blind study: When study participants are unaware which medication they are being administered, in order to reduce bias.

Stage: The extent of a cancer and whether the disease has spread from an original site to other parts of the body.

Standard treatment: The best treatment known and in current use, based on the results of past research.

Statistics: A type of mathematics used to collect and analyse large quantities of numerical data.

Study arm: A segment of a study where participants receive the same treatment, e.g., the control arm or the active treatment arm.

Study sponsor: The company, organisation or institution that is responsible for carrying out a study.

Supportive care: Care that extends beyond treating the actual cancer. It covers wider issues that occur due to cancer and includes counselling, practical assistance, physiotherapy, occupational therapy, spiritual care and complementary therapies.
Surgical oncologist: A doctor who specialises in the surgical treatment of cancer.
Survival rate: The proportion of patients diagnosed with the same disease who are still alive after a particular period of time.

Tissue: A collection of cells that make up a part of the body. When removed from the body, tissue is sometimes called a biospecimen.

Tissue bank: A secure place with freezers where body tissue, such as blood, is stored for future research.

Tissue banking: When people donate their tissue for use in research in the future.
Translational research: When the results of research done in the laboratory, clinical or population studies are used to develop new ways to diagnose and treat disease (e.g., using a bench-to-bedside approach). Research can also be conducted with the aim of enhancing best treatment practices.

X-ray: A type of scan that shows solid areas in the body such as bone. It is used to diagnose different conditions.

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