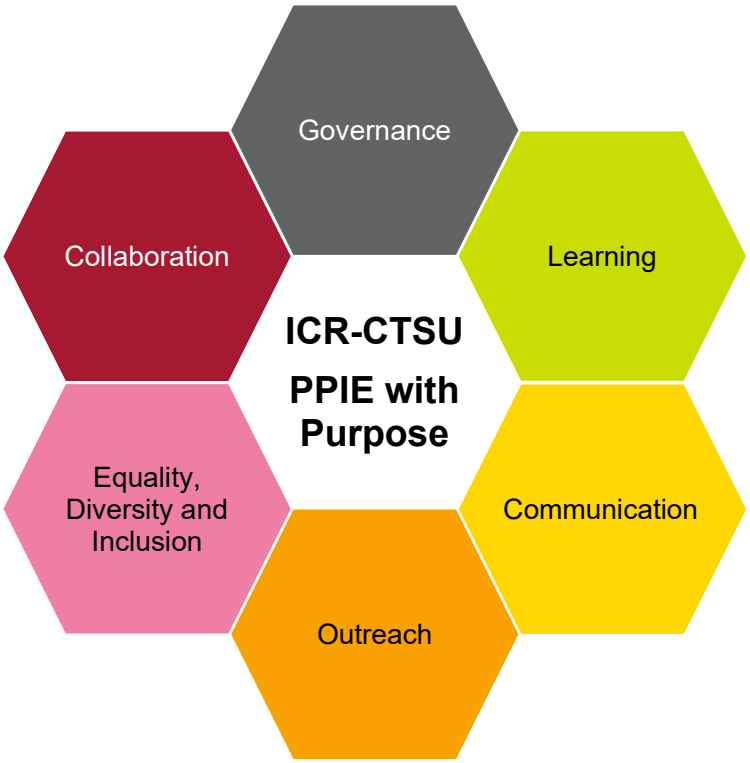
Patient and Public Involvement and Engagement (PPIE) at The Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU)



ICR-CTSU PPIE Research Advisory Group

Jargon Buster

Version 1.0

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CONTENTS

There are a lot of words, terms and acronyms used in cancer research trials that may be unfamiliar to you. This jargon buster provides definitions for some of the more common acronyms and terms found in medical research trials. There is also a list of other useful sites at the end.

Click on any letter to direct you to that page.

JARGON BUSTER

This '***Jargon Buster'*** has been co-developed by patient advocates and members of trial staff at the Institute of Cancer Research Clinical Trials and Statistic Unit (ICR-CTSU). It has been designed to support patient advocates and trial professionals involved in UK cancer clinical trials and covers some of the most frequently used terms. We encourage individual trial teams to produce a trial-specific glossary that builds upon this to include any additional terms/concepts bespoke to the trial to support patient involvement.

Our other resources to support patient and public involvement can be accessed here.

Suggestions for the correction of content and inclusion of new terms can be sent to us on ppi-icrctsu@icr.ac.uk

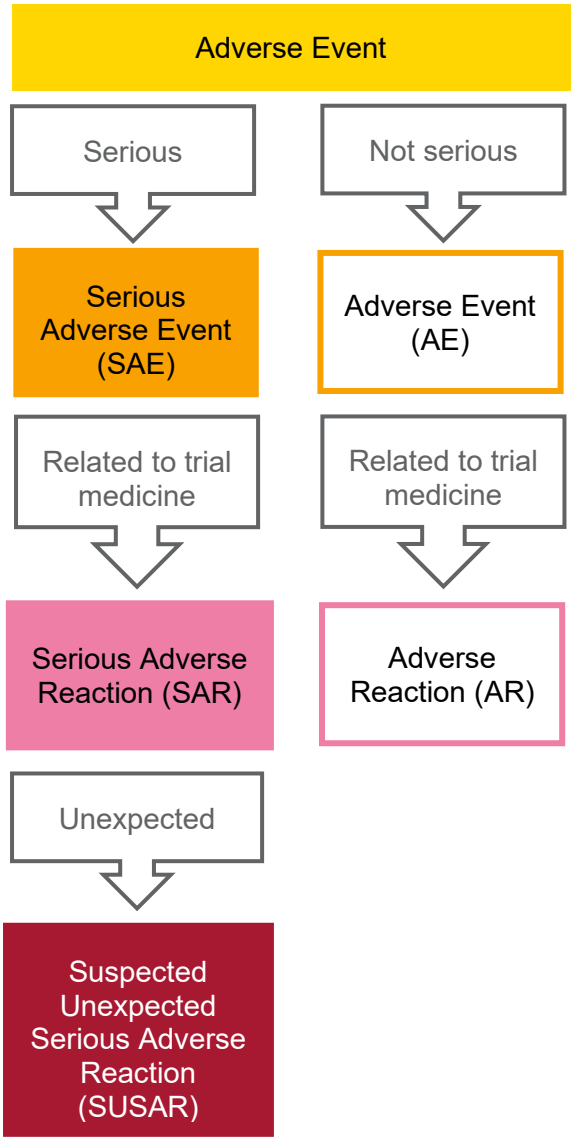
Document Control

The controlled version of this document is maintained by the ICR-CTSU PPIE Lead.

A

Term		Definition
Ablation		A treatment to destroy cancer cells using heat or lasers.
Absolute Risk		The risk of a certain event happening. For example how likely it is that a person will develop cancer over a certain period of time.
Abstract		A brief summary of a longer research paper.
Acute		Symptoms that start and worsen quickly but do not last over a long time.
Adherence		How much a person follows the recommendations from a healthcare provider, or the requirements of a clinical trial (for example taking medicine).
Adjuvant Therapy		Treatment given after the main treatment to reduce the chance of cancer coming back. It usually refers to chemotherapy, radiation therapy, hormone therapy, and/or immunotherapy given after surgery.
Administration of Radioactive Substances Advisory Committee	ARSAC	A committee that reviews research which involves the use of radioactive materials. An ARSAC research certificate is required for all trials involving more radiation exposure than participants would receive in their normal care.
Adverse Event	AE	An Adverse Event is any 'untoward medical occurrence' (symptom) in a participant who has had treatment within a clinical trial. The event may or may not be related to the trial medicine, and may or may be serious. This is decided by healthcare professionals involved in the trial and leads to Adverse Events being reported under different categories: • Adverse Reaction (AR): is an Adverse Event that is thought to be caused by the trial medicine • Serious Adverse Event (SAE): is an Adverse Event that results in death, is life-threatening, needs admission to hospital, or staying longer in hospital, results in disability or incapacity or a birth defect • Serious Adverse Reaction (SAR): is a Serious Adverse Event is thought to be caused by the trial medicine

- Suspected Unexpected Serious Adverse Reaction (SUSAR): is a Serious Adverse Reaction that was not expected based on what is already known about the trial medicine



Adverse Reaction	AR	Any symptom in a patient that is thought to be related to the trial medicine. (See Adverse Event)
Advisory Group		A group that helps to develop, support, advise and monitor a project. The group often includes people who use services, carers, researchers and other health and social care professionals.
All-Cause Mortality		The total number of deaths, due to any cause, that occur during a clinical trial.

Anonymised	The process of removing all information that could lead to an individual being identified (see Pseudonymised).
Arm	A group of participants in a clinical trial receiving a specified treatment.

B

Term		Definition
Background Therapy		The current medication taken as a standard of care (see standard of care) for a particular disease.
Benign		A tumour that does not spread to other parts of the body.
Bias		Bias happens when a trial's results are affected by factors that are not related to the treatment being tested. Biased results can lead to the wrong conclusions being made about a treatment.
Biomarker		A substance in the body that doctors can measure to help them tell how a disease is developing or a treatment is working. Short for biological marker.
Biomedical Research Centre	BRC	BRCs are partnerships between universities and NHS organisations. They bring together researchers and doctors to turn lab-based research into new treatments, diagnostics and medical technologies.
Biopsy		The removal of a small amount of tissue to examine under a microscope or to do different tests on.
Blinding		Where individuals involved in a clinical study (e.g. medical professionals, patients) do not know which treatment the patient has been given.
Brachytherapy		Treatment where a small radioactive material called a source is put inside or close to a cancer tumour (also called internal radiation therapy).
British Association of Cancer Research	BACR	A professional membership association for all those working and studying in cancer research in the United Kingdom and beyond.

C

Term		Definition
Cancer		A group of diseases where cells grow uncontrollably. They can go beyond their usual boundaries to invade nearby tissues and can spread to other organs. Cancer can begin almost anywhere in the body.
Case Report Form	CRF	A document which records all the information collected for each trial participant.
Chemoprevention		The use of medicines to lower the risk of developing cancer.
Chemotherapy		The use of drugs to kill cancer cells.
Chief Investigator	CI	A doctor with expert knowledge in the area of research who leads and has overall responsibility for the trial.
Chronic		Refers to a disease or condition that persists, often slowly, over a long time.
Clinical Significance		Clinical significance suggests that the difference between two treatments is clinically important (i.e. one treatment improves medical care significantly more than another).
Clinical Trial	CT	A type of research trial that tests how well new medical approaches work.
Clinical Trial Authorisation	CTA	Authorisation to run a clinical trial of a medicine by a regulator (the Medicines and Healthcare Products Regulatory Agency [MHRA] in the UK).
Clinical Trial of an Investigational Medicinal Product	CTIMP	A study that looks at how safe or effective a medicine is.
Clinical Trials Regulations	CTR	The laws which specify how clinical trials must be run – in the UK this is the Medicines for Human Use (Clinical Trials) Regulations (SI 2004 1031) and its amendments.
Cluster Randomised Trial		A trial where individuals are grouped (e.g. by clinics, families, regions) and then randomly assigned to different treatments.
Co-applicant		A person involved in the development of a grant application and has some responsibility for the management and/or delivery of a study. Patient

		advocates can be involved in a research project or trial as co-applicants.
Cohort (Study)		A type of study that follows a group of participants over a period of time, looking at how certain factors affect their health. The people in the cohort have a trait in common, such as age or illness.
Comorbidity		The presence of two or more medical conditions in a patient at the same time.
Comparator		A treatment or placebo compared against a treatment being investigated in a clinical trial. (See placebo)
Computed (Axial) Tomography	C(A)T	A scan that uses specialised X-ray equipment to produce cross-sectional images of the body.
Concomitant treatment		Treatment given at the same time as another treatment.
Confidence Interval		A measure of the uncertainty around the main finding of a statistical analysis. Wider intervals indicate lower precision and narrow intervals indicate greater precision. (See precision). For example, a 95% confidence interval for an estimated treatment effect indicates that if the same experiment were to be repeated 100 times, the true treatment effect would on average fall in the range of the interval 95 times.
Confounder (Also known as Confounding Variable)		A factor that is associated with both a treatment and the outcome of interest. For example, if one treatment group in a controlled trial is younger than the control group, it will be difficult to decide whether a lower risk of death in one group is due to the treatment or the difference in age. Age is then said to be a confounder. Randomisation tries to reduce any difference in confounders between experimental and control groups.
Consent		Permission given by a patient to join a clinical trial or receive a specific treatment.
Contra-Indication		A specific circumstance when the use of certain treatments could be harmful.
Control Group		The comparison group in a randomised trial. Those in the control group (or arm) will not receive the trial treatment, but will provide a comparison to see how the trial treatment compares against no treatment or another known treatment.

Co-Production	An approach in which researchers, practitioners and the public work together on a project.
Co-researcher	Someone who researches together with one or more other people. Patient advocates can be involved in a research project as co-researchers.
Cross-Over Trial	Comparison of treatments in which patients are switched to the other treatment after a certain amount of time.

D

Term		Definition
Data Protection		All personal information is protected in the UK by the Data Protection Act 2018. This means that researchers must protect the confidentiality of the information they collect about research participants.
Drug Development		The process of bringing a new drug to market.
Drug Development Unit	DDU	A group at the Institute of Cancer Research specialising in drug development.
Dependent variable		A variable that is measured during a study. For example the blood pressure of trial participant.
Disease Free Survival	DFS	The proportion of patients for which no sign of cancer is found for a certain period after trial entry.
Dissemination		Communicating the findings of a research project to people who might find it useful.
Dosing Discontinuation		The point when a trial participant permanently stops taking the study drug. This may be at the end of the study, or before the end if the participant wants to stop taking the medicine for any reason.
Double Blind		A trial where both the investigators and trial participants do not know which treatment is being given.

E

Term		Definition
Early Career Researchers	ECR	Researchers in the first four years (full-time equivalent) of their research activity, including the period of research training.
Effectiveness		How well a trial treatment works under 'real-world' conditions.
Efficacy		How well a trial treatment works under an ideal and controlled setting.
Electronic Data Capture	EDC	The collection of data using an electronic system rather than paper Case Report Forms (CRFs) (See Case Report Forms).
Eligibility Criteria		Requirements that patients must meet to take part in a particular clinical trial. For example a trial might only accept participants who are above certain ages.
Endpoint		The results measured at the end of a study to see whether the research question was answered.
Enrolment		A participant's entry into a clinical trial. The same term may also be used to refer to the number of participants in a clinical trial.
Equipoise		Where it is believed to be equally likely that either of two treatment options is better.
Equality, Diversity and Inclusion	EDI	EDI aims to prevent discrimination on the basis of an individual or group of individuals' protected characteristics. It aims to give fair treatment and opportunity for all.
European Medicines Agency	EMA	An agency of the European Union that oversees the use of medicinal products.
European Organisation for Research and Treatment of Cancer	EORTC	A European non-profit cancer research organisation.
Event-free Survival	EFS	The time after trial entry that a group of people in a clinical trial have not had their cancer come back or get worse.

Evidence Base	The best scientific research available about a disease or health problem. This is used to make decisions about the best treatment to give.
Exclusion Criteria	Requirements that set out who cannot take part in a clinical study. For example, people with a certain medical condition which may make it dangerous for them to take part.
Experimental Group	The group of patients who receive the intervention or treatment that is the focus of the clinical trial.
Experts by Experience	People who are experts through their experience of a particular illness or disability and services.
Explanatory trial	A trial that measures the benefit of a treatment under ideal and controlled conditions.

F

Term	Definition
Factorial Design	A clinical trial design in which groups of participants receive one of several combinations of interventions. For example a two-by-two factorial design involves four groups of participants. Each group receives one of the following pairs of interventions: 1) drug A and drug B; 2) drug A and a placebo; 3) drug B and a placebo, or 4) a placebo and a placebo. During the trial, all possible combinations of the two drugs (A and B) and the placebos are given to different groups of participants.
Feasibility Study	Research done before a main study to answer the question 'Can the main study be carried out?'. They aim to find out things such as whether patients and doctors are happy to take part, or how long it might take to collect the data.
Focus Group	A small group of people brought together to talk. The purpose is to listen and gather information. It is a good way to find out how people feel or think about an issue, or to come up with possible solutions to problems.
Follow Up (Care)	Where further data is obtained relating to a study/ trial participant after active treatment over a specified amount of time. Follow up care can check a patient's recovery, monitor for any new problems and suggest further test and/or treatment.
Funder	The organisation providing funding for running the clinical trial.

G

Term		Definition
General Data Protection Regulation	GDPR	The rules around the use of personal data within the European Union. In the UK this is covered by the Data Protection Act 2018.
Generalisability		How well the trial findings can be applied to other patients and settings.
Gold Standard		The method, procedure, or measurement that is widely accepted as being the best available. New developments should be compared against the gold standard.
Good Clinical Practice	GCP	A set of internationally recognised standards which must be followed during all aspects of clinical trials involving human participants.

H

Term		Definition
Health Economics	HE	A study of the cost effectiveness of a healthcare treatment or service.
Health Research Authority	HRA	An NHS organisation established to protect and promote the interests of patients and the public in health research. The National Research Ethics Service (NRES) is now part of the HRA.
Hormone Therapy		Treatment that removes, blocks, or adds hormones to destroy or slow the growth of cancer cells. It is also called hormonal therapy or endocrine therapy.
Human Tissue Authority	HTA	An organisation that ensures human tissue samples are used safely and ethically and with proper consent. It regulates organisations that remove, store, and use tissue for research, medical treatment, post-mortem examination, teaching and display in public.
Hypothesis		A statement that predicts the expected outcome of a study. This is made on the basis of current available evidence. In a trial, this would be proven or disproven based on the data collected.

I

Term		Definition
Investigator-Initiated Trials	IIT	Clinical trials which are developed and run by clinicians and researchers based at universities and the NHS rather than being led by pharmaceutical companies.
Imaging		A procedure that creates pictures of internal body parts, tissues, or organs to make a diagnosis. The images are used to plan treatment, find out whether treatment is working, or observe a disease over time.
Immunotherapy		A type of cancer treatment designed to boost the body's own immune system into action against cancer. It may also be called biological therapy.
Incidence		The number of events of a certain outcome in a population during a given period of time.
Inclusion Criteria		Requirements that set out who can take part in a clinical study. For example people within a certain age range.
Independent Data Monitoring Committee	IDMC	A group of independent experts who monitor the safety and scientific integrity of a clinical trial. The group can recommend to the Trial Steering Committee (See Trial Steering Committee) that the study be stopped or amended if it is not effective, is harming participants, or is unlikely to serve its aims.
Independent variable		A variable in a study that is controlled by researchers. For example the treatment given to a patient. The variable is independent of other variables recorded in the study.
Indication		A disease, symptom, or set of circumstances that make a particular test, medication, procedure, or surgery advisable. For a treatment, an indication refers to the use of that treatment for a particular disease.
Informed Consent		A process by which a patient learns about and understands the purpose, benefits and risks of participating in a trial and then voluntarily confirms if they want to take part. This includes reading and understanding the relevant patient information sheet (PIS) (See Patient Information Sheet).

Informed Consent Form	ICF	The document signed by the patient to confirm their agreement to take part in a trial.
In Situ		'In place'. Refers to cancer that has not spread to nearby tissue, also called non-invasive cancer.
Institute of Cancer Research	ICR	The Institute of Cancer Research, one of the world's most influential cancer research organisations. It is a UK charity and member institution of the University of London.
Integrated Research Applications System	IRAS	The online application system used to apply for most permissions and approvals for research in health and social care in the UK.
Integrative Medicine		A combination of medical treatments to help manage symptoms and side effects.
Intention to Treat		Where all trial participants are included in the statistical analysis according to the treatment they were originally assigned regardless of what treatment (if any) they received.
Interaction		Where the effect of one independent variable (see independent variable) on the outcome is affected by the value of a second independent variable. For example, when the effect of an experimental statin on blood cholesterol is influenced by the age of the trial participant.
Interim Analysis		An analysis of the current available data from an ongoing trial. This can be used to inform decisions about whether or not the trial should continue. The timing and frequency of interim analyses should be specified in the protocol.
Intervention		Any trial treatment, medical device, procedure or activity under investigation in the trial.
Interventional Trial		A trial where participants receive specific interventions (or no intervention) according to the research plan or protocol created by the investigators. These interventions may be medical products, such as drugs or devices, procedures, or changes to participants' behaviour, for example diet.
Invasive Cancer (Infiltrating Cancer)		Cancer that has spread outside the layer of tissue where it started and has the potential to grow into other tissues or parts of the body.

Investigational Medicinal Product	IMP	Medicinal products are substances that are used to prevent illness from occurring, treat disease or relieve symptoms. An IMP is a medicinal product being tested within a clinical trial or a substance used as a comparison e.g. a placebo within a trial.
Investigator		A person who is conducting a clinical trial. The expert leading the overall research in multiple hospitals is referred to as the Chief Investigator and those responsible for the conduct of a trial at a specific hospital are Principal Investigators.
Investigator's Brochure	IB	A record of data available on the investigational medicinal product which are relevant to the study of the product in humans. This is maintained by a drug developer, manufacturer or investigator. It provides the reasons for key features of a protocol such as dose, methods of administration and safety monitoring.

L

Term	Definition
Late Effects	Side effects of cancer treatment that may occur months or years after treatment has finished.
Lay Person	The term ‘lay’ means non-professional. In research it refers to people who are neither researchers nor health care professionals.
Lay Summary	A summary of a research idea, protocol or explanation of results that can be easily understood by members of the public. It should be written in plain English, avoid the use of jargon and explain any technical terms that are used.
Localised Cancer	Cancer that is confined to the area where it started and has not spread to other parts of the body.

M

Term		Definition
Magnetic Resonance Imaging	MRI	A type of scan that uses strong magnetic fields and radio waves to produce detailed images of the inside of the body.
Malignant		A tumour that has the ability to spread to other parts of the body.
Medical Research Council	MRC	The Medical Research Council is responsible for coordinating and funding medical research in the United Kingdom.
Medicines and Healthcare Products Regulatory Agency	MHRA	The Government agency responsible for ensuring that medicines and medical devices work and are safe.
Medicines for Human Use	MHU	The Medicines for Human Use (Clinical Trials) Regulation is the UK response to the European Union Clinical Trials Directive 2001/20EC. It covers the legal requirements for clinical trials involving an investigational medicinal product.
Meta Analysis		A comparison using multiple independent pieces of prior research, such as clinical trials, that investigated the same research question. Results are combined across the sources of research to provide an overall conclusion to the research question of interest.
Metadata		Summarises basic information about data (for example, author, date created, date modified, file size).
Metastasis		The spread of cancer from the place where it began (primary tumour) to another part of the body. Cancer cells can break away and travel around the body through the blood or lymphatic system. The cells form new tumours where they settle and grow.
Methodology		Describes decisions made about what data will be collected, from whom, and how it will be collected and analysed. It also describes why a particular method has been chosen.
Monitoring		The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted and recorded in accordance with the protocol, Standard Operating

		Procedures (SOPs), Good Clinical Practice (GCP) and the applicable regulatory requirement(s).
Morbidity		The state of having an illness, disease or medical condition.
Mortality (Rate)		The number of deaths in a particular population during a certain time.
Multicentre Trial		A trial which takes place at more than one site (usually a hospital).
Multi-disciplinary team	MDT	A group of professionals from one or more clinical disciplines who together make decisions regarding treatment of individual patients.

N

Term		Definition
National Cancer Institute - Common Terminology Criteria for Adverse Events	NCI-CTCAE	A descriptive terminology which can be used for Adverse Event (AE) reporting. A severity scale is provided for each AE term.
National Cancer Registration and Analysis Service	NCRAS	NCRAS provides near-real time, cost-effective, comprehensive, quality-assured data services covering the entire cancer pathway on all patients in England.
National Health Service	NHS	The UK Government-funded medical and health care services which are free to those living in the UK.
National Institute for Health Research	NIHR	The health research system funded by the Department of Health to improve the health of the population through research. The NIHR provides substantial funding for many clinical trials to support important medical research.
National Research Ethics Service	NRES	The National Research Ethics Service (NRES) is a part of the Health Research Authority (HRA). The NRES has two roles: • to protect the rights, safety, dignity and well-being of research participants • to facilitate and promote ethical research that is of potential benefit to participants, science and society.
Neoadjuvant Therapy		Treatment given before the main treatment. For example chemotherapy before surgery may shrink the tumour so it is easier to remove.
Non-Inferiority Trial		A trial designed to show that the effect of a new treatment is not worse than the standard treatment.

O

Term		Definition
Observational Study		A study which investigates health outcomes amongst groups of people in the course of their everyday life. In these studies, researchers do not intervene; they collect data through observation only.
Oncologist		A doctor provides medical care for a person diagnosed with cancer.
Oncology		The study of cancer.
Open Label		A trial where the investigators and the patients know which treatment is given.
Outcome Measure		A pre-determined measurement designed to assess the effect of a clinical trial intervention.
Overall Survival	OS	The proportion of people in a study or treatment group who are still alive for a certain period after trial entry.

P

Term		Definition
Palliative Care		Treatment given to patients with incurable disease to reduce that patient's symptoms or treatment side effects. Also called supportive care.
Parallel Design		A clinical trial design where two or more groups of participants receive different interventions. For example a two-arm parallel design involves two groups of participants. One group receives drug A, and the other group receives drug B, and the results are compared.
Participant		An individual who is taking part in a trial.
Pathologist		A doctor who specializes in interpreting laboratory tests to diagnose disease.
Patient and Public Involvement	PPI	PPI is where research is designed and carried out with the input of: • people with lived experience of the condition being investigated (patients), or • members of the public.
Patient and Public Engagement	PPIE	PPIE is about raising awareness and sharing the results of research with the public.
Participant Information Sheet	PIS	A document for potential trial participants to help them understand the expectations and requirements of participation in a clinical trial.
Patient Reported Outcome (Measures)	PRO(M)s	Patients' perspectives about the impact of disease and treatment on their own health.
Peer Review		The review of a clinical trial by experts chosen by the Study Sponsor. These experts review the trials for scientific merit, participants safety and ethical considerations.
Phase		Clinical trials follow certain steps called "phases". There are four phases of clinical trials, and each is designed to ask specific questions about the intervention or drug being tested. The intervention or drug must be successfully tested in 3 phases (phase 1-3) to be approved for use in the general population.

Phase 0 (also known as Early Phase 1)	Exploratory trials sometimes run before traditional phase 1 trials to check that a low dose of a treatment is not harmful. Usually 10-20 people.
Phase 1 (I) Trial	Phase 1 trials investigate whether a treatment is safe for people to take, to find the best dose, and to find out what the side effects are. In cancer trials, phase 1 participants are cancer patients. Usually 20-50 people.
Phase 2 (II) Trial	Phase 2 trials aim to check the best dose and learn more about side effects, whilst looking at effectiveness of treatment too. Usually 100-300 people.
Phase 3 (III) Trial	If previous trials have indicated a treatment is safe and effective, phase 3 trials will begin. Usually, several hundred to several thousand patients. Phase 3 trials test the new intervention against standard treatments, or a “dummy drug” (placebo).
Phase 4 (IV) Trial	A phase of research to describe clinical trials occurring after a drug has been approved for marketing. These trials gather additional information about a drug's long-term safety, efficacy or optimal use.
Pilot Study	A pilot study is a smaller version of the main study used to test whether the main study can work on a larger scale. For example, to ensure that recruitment, randomisation, treatment, and follow-up assessments all run smoothly.
Placebo	A placebo is an inactive control substance (a dummy treatment) that allows researchers to test for the 'placebo effect'. This is a psychological response where patients feel better even though the substance that they are taking has no effect. By comparing people's responses to the placebo and to the drug being tested, researchers can tell whether the drug is having any real benefit. In cancer clinical trials placebos are rarely used, although they may be used when there is no standard treatment available.
Plain English Summary	A clear, brief summary of the research that has been written for members of the public, rather than researchers or professionals.
Platform Trial	A platform trial is a clinical trial with a single master protocol in which multiple treatments are evaluated at the same time. It also allows new treatments to be added and removed from the study without having to

		pause enrolment or resubmit the entire clinical trial protocol for regulatory review.
Positron Emission Tomography	PET	A positron emission tomography scan produces detailed 3-dimensional images of the inside of the body.
Power		The probability of detecting a proposed effect if there is one to detect. In clinical trials power is the probability that a trial will detect the proposed effect of the intervention being tested. Ideally, we want a test to have high power so we can be confident that it will show us the effect of the intervention (if there is one) often in comparison to a control treatment (i.e. standard of care).
Pragmatic Trial		A trial that aims to test the effectiveness of a treatment policy in a 'real life' situation. This differs from explanatory trials where the effectiveness of an intervention is tested under ideal conditions.
Precancerous (Premalignant)		Refers to cells that are not cancerous but have the potential to become cancerous.
Precision		How close a set of measurements are to each other in value.
Prevalence		Prevalence of cancer is the proportion of people within a population who have cancer at a given time. Prevalence is often described as a percentage. For example, if 5/10 people in a focus group have breast cancer, the prevalence of breast cancer in that focus group is 50%.
Primary Cancer		Describes the location of the original cancer in the case that it has spread elsewhere.
Primary Endpoint		The main result that is measured at the end of a study to see if a given treatment worked. It is a way of measuring whether the primary outcome has been met. An example of a primary endpoint is the number of deaths between the treatment group and the control group. The primary endpoint is decided before the study begins.
Primary Outcome		The outcome of greatest importance. See “Outcome Measure”.
Principal Investigator	PI	If the trial involves more than one hospital, the PI is the designated person at each hospital responsible for the day-to-day running of the clinical trial.

Prognosis		Chance of recovery; a prediction of the outcome of a disease.
Progression Free Survival	PFS	PFS measures the proportion of people among those treated for a cancer whose disease does not worsen at a certain time after trial entry. For example a progression-free survival rate of 80% at 2 years means that the cancer did not grow or spread in 4 out of 5 (80%) of the study participants at the 2-year time point.
Protocol		A document that describes the objective(s), design, methodology, statistical considerations and organisation of a trial.
Protocol Development Group	PDG	The team of people with expertise in the area being researched, such as doctors, researchers and statisticians who help to write the protocol for the trial.
Pseudonymised		The processing of personal data so that an individual cannot be identified from this data alone.

Q

Term		Definition
Qualitative Research		Qualitative research is used to explore and understand people's beliefs, experiences, attitudes, or behaviours. It asks questions about how and why. Qualitative research might ask questions about why people want to stop smoking. It won't ask how many people have tried to stop smoking. This research does not collect data in the form of numbers but might collect data in the form of interview transcripts or notes from focus groups.
Quality Control		The steps taken during a trial to ensure that it meets protocol and procedural requirements and is reproducible.
Quality of Life	QoL	Clinical trials may assess the effect of treatment on a patient's well-being and ability to function in daily life. These are measured using QoL tools (questionnaires) which have been developed sometimes by particular cancer type to assess specific aspects of QoL for each condition. Some trials now include Patient Reported Outcomes (PROs) as one of the ways to measure QoL. These measures are particularly important for patients as they show the impact of the treatment on everyday life.
Quantitative Research		Quantitative research is used to explore and analyse relationships between treatments, interventions, or person's traits, and a health outcome of interest. It captures these relationships with numerical results and figures. Quantitative research might ask questions about the most effective ways to stop smoking e.g. what percentage of people that try to quit smoking through the NHS are successful? This type of research collects data in the form of numbers (e.g. measurements), categories and dates. The data is often collected by an investigator or supplied by a participant.

R

Term		Definition
Radiation Therapy		The use of high-energy X-rays or other particles to destroy cancer cells. The most common type of radiation treatment is called external-beam radiation therapy, which is given from a machine outside the body.
Random allocation		When the treatment given to trial participants is chosen at random. This means that the participant or investigator cannot influence which treatment is given.
Randomised Controlled Trial (Also called Randomisation or Randomised Allocation)	RCT	A trial where participants are randomly allocated to either an experimental or control treatment to ensure that each group of patients are as similar as possible. By randomly assigning patients to the treatment or control group, any differences seen in the groups at the end of the trial can be attributed to the difference in treatment alone and not to differences in the groups caused by bias.
Real-World Data	RWD	Data relating to a patient's health or the delivery of healthcare, collected outside of a controlled trial. This can be routinely collected from electronic health records (hospitals, medical practices) or patient registries.
Regimen		A treatment plan that includes expected treatments and procedures, medications and their doses, the schedule of treatments, and how long the treatment will last.
Relative Risk		Compares the risk of disease between two groups of people.
Relative Survival		Compares the proportion of people surviving between those with a certain disease and those without.
Remission		The disappearance of the signs and symptoms of cancer but not necessarily the entire disease. The disappearance can be temporary or permanent.
Research and Development	R&D	The testing of a drug or procedure in humans to determine its safety and effectiveness.
Research Ethics Committee	REC	Research Ethics Committees review research applications and give an opinion about whether the

	research is ethical. RECs are independent of the research sponsors (the organisation responsible for the management of the research), funders and investigators.
Retrospective Study	A study where outcomes have happened before the study started. Case-control studies and cohort studies can be retrospective but randomised controlled trials never are.
Risk Benefit Ratio	The risk to individual participants versus the potential benefit. The risk benefit ratio may differ depending on the condition being treated.
Run-In Period	The time before a trial starts when no trial drug is given to participants. During this time patients may still receive standard treatments for their disease if these treatments are allowed within the trial period.

S

Term		Definition
Sample Size		The number of participants in the trial. The intended sample size is the number of participants planned to be included in the trial, usually determined using a statistical power (see power) calculation. This will be based on the clinically significant effects that trial organisers hope to see.
Screening		The process of checking whether a person has a disease or has an increased chance of developing a disease when the person has no symptoms.
Secondary Cancer		Describes either a new primary cancer (a different type of cancer) that develops after treatment for the first type of cancer, or cancer that has spread to other parts of the body from the place where it started (see metastasis).
Secondary Endpoints		The results that are measured at the end of a study, in addition to the main result (primary endpoint), to see if a given treatment worked, and to explore other aspects of the treatment.
Secondary Outcome		An outcome used to evaluate extra effects of an intervention viewed as being less important than the primary outcomes.
Serious Adverse Event	SAE	A serious adverse event is one that either: • results in death, • is life-threatening, • requires inpatient hospitalisation or extends a current hospital stay, • results in an ongoing or significant incapacity or disability, • or causes a congenital anomaly or birth defect. However, medical events that do not result in death, are not life-threatening, or do not require hospitalisation may still be considered serious adverse events if they put the participant in danger or require medical or surgical intervention to prevent one of the results listed above. (See Adverse Event)

Serious Adverse Reaction	SAR	A serious adverse event (see SAE) occurs if it is thought that the event is an unwanted reaction to the trial medicine. (See Adverse Event)
Side Effect		If the symptom or problem is caused by the trial treatment it is known as a side effect.
Single Blinded		A trial where participants included in the trial do not know which treatment they are given but the investigator does.
Specificity		A measure of a diagnostic test's ability to correctly identify people who do not have the disease.
Sponsor		The trial sponsor is legally responsible for ensuring that there are proper arrangements in place to plan and manage the clinical trial.
Staging		A way of describing cancer, such as where it is located, whether or where it has spread, and whether it is affecting the functions of other organs in the body.
Standard of Care		The currently accepted best practice treatment for a disease or condition.
Standard Operating Procedure	SOP	A procedure that describes the activities necessary to complete a task in accordance with industry regulations, laws or even just local standards for running a business.
Statistical Analysis		Statistical analysis uses a set of mathematical rules to analyse numerical and categorical data. It can help researchers decide what data means. For example, statistical analysis can assess whether any difference seen between two groups of people (for example between the groups of people in a clinical trial) is likely to be a reliable finding or simply due to chance.
Statistical Significance		Results are said to be statistically significant if the trial data has answered the research question of interest with enough certainty. Statistically significant results often describe a reliable difference between two treatment groups.
Stereotactic Radiotherapy		Stereotactic radiotherapy gives radiotherapy from different angles around the body with the beams meeting at the tumour. The tumour receives a high dose of radiation and the tissues around it receive a much lower dose thus lowering the risk of side effects.
Stopping Rules		A set of criteria that specify when a participant's, and/or cohort's trial's treatment should be stopped.

		They are usually based on the occurrence and number of severe and serious adverse events (SAEs) or if insufficient treatment benefit is found at interim analyses.
Stratification		Stratification is a way of grouping subsets of patients and is used in randomised trials when factors that can influence the treatment's success are known. For example participants whose cancer has spread from the original tumour site can be separated (or stratified) from those whose cancer has not spread, since it might be expected that these patients could respond differently to treatment. Evaluating results within different groups allows researchers to assess the impact of treatment without differences in stratification factors influencing results.
Study Completed Date		The date that the last trial participant made the last visit to the study location, and the last samples were collected or last tests performed.
Sub-group Analysis		An analysis where the intervention effect is assessed in a specific subset of the participants in a trial, such as those of a certain sex or age.
Substantial Amendment		A change to the terms of the approval given by either the MHRA (in the UK) or the Research Ethics Committee (REC), or a change to the protocol or any other document submitted with the applications which significantly affects one of the following: • the safety or physical or mental integrity of study participants, • the conduct or management of the study, • the scientific value of the study, or • the quality or safety of any investigational medicinal product used in the study.
Suspected Unexpected Serious Adverse Reaction	SUSAR	If a serious adverse reaction is 'unexpected' it is called a SUSAR. In this case 'unexpected' means that the adverse reaction does not match with the safety information available about the trial medicine (See Adverse Event).
Sub-Study		A sub-study is a study performed on a sub-group of the patients included in the main clinical trial.
Systemic Anti-Cancer Treatment	SACT	SACT is any drug treatment used to control or treat cancer. The drug types may include chemotherapy, immunotherapy, targeted therapy, hormonal therapy, or a combination of these. SACT can be given on its own, before or after surgery or with radiotherapy.

Systematic Review	SR	A systematic review aims to bring together the results of all studies that have been carried out around the world addressing a particular area of research. The method to search for and select relevant studies for the review must be documented before beginning the review. This ensures that the process can be reproduced and reduces bias. The characteristics and findings of the included studies are combined and presented for the review.

T

Term		Definition
Targeted Therapy		Treatment that targets specific genes, proteins, or other molecules that contribute to cancer growth and survival.
Translational Research		The process by which the results of research done in the laboratory are used to develop new ways to diagnose and treat disease.
Treatment Summary		A written summary of the therapies that the patient had during the active treatment period.
Trial Identification Number	Trial ID	Every patient is assigned a unique trial ID when they are enrolled into a trial. This number is used to identify the patient during the treatment and follow up phase.
Trial Management Group	TMG	A group which monitors a trial to ensure that the protocol is followed and ensure the safety of participants and the quality of the trial. Usually consists of key trial personnel such as the Chief Investigator, statistician and trial manager, Principal Investigators at certain sites, and patient advocates.
Trial Master File	TMF	The collection of essential documents which allows a clinical trial to be reconstructed and evaluated. It is basically the story of how a trial has been managed.
Trial Participant		An individual whose reactions or responses to certain interventions are evaluated during a clinical trial.
Trial Site		A hospital site where a trial is being conducted.
Trial Steering Committee	TSC	A group with overall responsibility for a trial. The TSC makes sure that a trial is conducted properly and that the protocol is followed. The TSC is made up of independent experts in the area of research plus the Chief Investigator and members of the trial team.
Tumour		A mass formed when normal cells begin to change and grow uncontrollably. A tumour can be benign (non-cancerous) or malignant (cancerous). Also called a nodule or mass.

V

Term	Definition
Variable	Information collected during a clinical trial. For example, one variable might be “weight,”. This would then be checked at set time points throughout the trial.

W

Term		Definition
Wash-Out Period		The time given for a medicine to leave the body.
World Health Organisation	WHO	The part of the United Nations responsible for global public health.

USEFUL SITES

Cancer Research UK

Types of Clinical Trials

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are/types-of-clinical-trials

Cancer Statistics Terminology Explained

https://www.cancerresearchuk.org/health-professional/cancer-statistics/cancer-stats-explained/statistics-terminology-explained

Phases of Clinical Trials

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are/phases-of-clinical-trials

About Cancer

https://www.cancerresearchuk.org/about-cancer/what-is-cancer#:~:text=A%20primary%20tumour%20is%20the,systems%2C%20and%20the%20hormone%20system.

National Institute for Health and Care Excellence (NICE)

Glossary of terms used in research trials

https://www.nice.org.uk/glossary?letter=a

National Institute for Health and Care Research (NIHR)

Glossary of terms used in research trials

https://www.nihr.ac.uk/glossary

Glossary available from NIHR Clinical Trials Toolkit:

https://www.ct-toolkit.ac.uk/glossary/?letter=A#SKPostAToZ

National Health Service

Glossary of terms used in NHS
https://www.england.nhs.uk/get-involved/resources/involvejargon/

National Health Service Health Research Authority (HRA)

Glossary of terms used by NHS Research Authority and Research Ethics Committees
https://www.hra.nhs.uk/approvals-amendments/glossary/