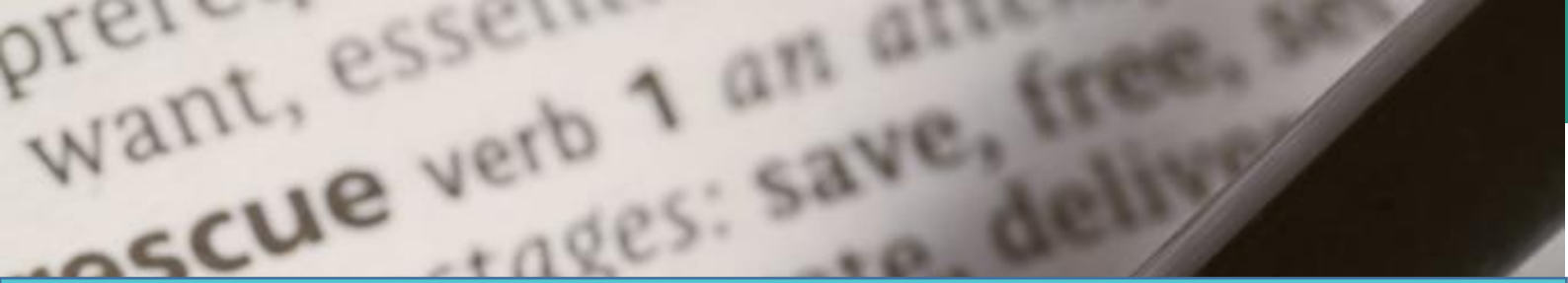

Clinical Trials Jargon Buster

ACCESSCR
Clinical Trial Solutions

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Introduction

AccessCR's Research4Me initiative aims to improve access to and involvement of the public in medical research, clinical trials and the development of better care and treatments.

We recognise that an important first step is to help people understand the language used in these settings. As such, this guide aims to explain in simple terms some of the language you may come across around clinical trials in Australia and internationally.

We want this to be a living, useful, document, so if there are words or concepts we've missed that you'd like added, or explanations that aren't clear, please drop us a line at connect@accesscr.com.au.

Janelle Bowden

Managing Director, AccessCR Pty Ltd

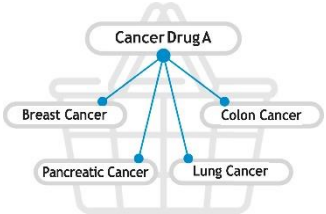
Common Acronyms

Acronym		Explanation
ARTG	Australian Register of Therapeutic Goods	The ARTG contains therapeutic goods that can be lawfully supplied in Australia. More information on the ARTG here: https://www.tga.gov.au/australian-register-therapeutic-goods Search the ARTG here: https://tga-search.clients.funnelback.com/s/search.html?query=&collection=tga-artg
ANZCTR	Australian New Zealand Clinical Trials Registry	A publicly accessible online listing (register) of clinical trials being undertaken in Australia and New Zealand. Available at: http://www.anzctr.org.au/about.aspx [2]
EMA	European Medicines Agency	European agency responsible for regulation of medicines and medical devices for human and veterinary use http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/Home_Page.jsp&mid=
EU	European Union	
FDA	Food and Drug Administration	US agency responsible for regulation of food and therapeutic agents (eg drugs, devices, biologicals) https://www.fda.gov/
GCP (or ICH- GCP)	Good Clinical Practice	An international standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of the trial participants are protected. It was developed by EMA, FDA and PMDA to harmonise the expectations for how clinical trials for medicines to be approved should be conducted internationally. Depending on country, may be applicable to a broader range of clinical trials than just those for new medicine trials. http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html In Australia, this guidance has been annotated by the TGA: https://www.tga.gov.au/sites/default/files/ich13595an.pdf
HREC	Human Research Ethics Committee	Human Research Ethics Committees (HREC's) are responsible for providing Ethics approval for a clinical trial to be conducted with patients. [2] More information about HRECs is available from Australia's NMHRC, who is responsible for their oversight: https://www.nhmrc.gov.au/health-ethics/human-research-ethics-committees-hrecs

Acronym		Explanation
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use brings together regulatory authorities and the pharmaceutical industry to discuss scientific and technical aspects of drug registration. ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. More information is available here: http://www.ich.org/home.html
IRB	Institutional Review Board.	This is a term used predominantly in the US[5]. Under FDA regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human participants. More information about IRB's from the FDA can be found here: https://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm
MRFF	Medical Research Future Fund	The MRFF) was established on 26 August 2015 by the Medical Research Future Fund Act 2015. The Fund is a financial asset fund and represents an endowment that will support medical research and innovation into the future. http://health.gov.au/internet/main/publishing.nsf/Content/mrff
NIH	US National Institutes of Health	The NIH is the primary agency of the United States government responsible for biomedical and public health research. More information about the NIH is available here: https://www.nih.gov/
NHMRC	National Health and Medical Research Council	The National Health and Medical Research Council (NHMRC) is Australia's leading expert body promoting the development and maintenance of public and individual health standards. NHMRC brings together within a single national organisation the functions of research funding and development of advice. www.nhmrc.gov.au
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)	Government Agency overseeing regulation of medicines and medical devices in Japan. http://www.pmda.go.jp/english/
TGA	Therapeutic Goods Administration	Government Agency in Australia responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods including medicines, medical devices, blood and blood products. www.tga.gov.au
WHO	World Health Organisation	The World Health Organization is a specialised agency of the United Nations that is concerned with international public health. More information is available here: http://www.who.int/en/

For noting: An additional Acryonms Guide specific to the Australian Therapeutics Industry is available via the AccessCR website Resources page

Common Terms in Clinical Trials

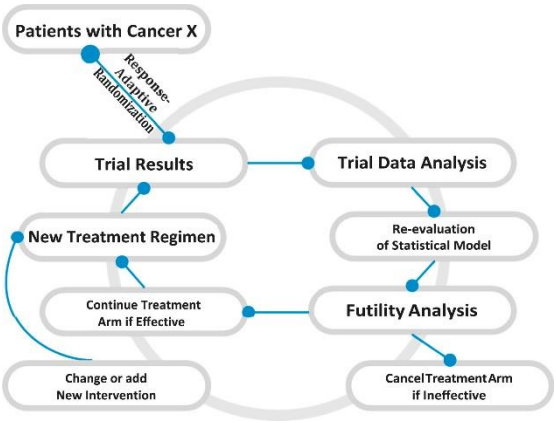
Term/Phrase	Definition
Adaptive Clinical Trials	These are a type of trial deisgn that allow for prospectively planned changes to one or more aspects of the trial, depending on the data that accumulates from participants over time. This video explains a little more about this growing type of trial design in plain language: https://youtu.be/ZoKlWl3H5tg
Adverse Drug Reaction (ADR)	In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established: all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase responses to a medicinal product means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out. Regarding marketed medicinal products: a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).[1]
Adverse Event (AE)	Any untoward medical occurrence in a patient or clinical trial participant administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting). [1]
Arm	Any of the treatment groups in a randomised trial. Most randomised trials have two or more 'arms'. [2]
Assent	A child or young person's agreement to take part in a clinical trial.[5] This may be done informally or formally, depending on the age and/or capacity of the child or young person and the regulations of the state/country in which the trial is occurring. Whether or not assent is obtained, a parent/guardian/carer/authorised person will always be required to consent to the participation of a child or young person in a clinical trial.
Audit	A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s). [1]
Audit Trail	Documentation that allows reconstruction of the course of events. [1]
Baseline measures	These are the 'baselines', 'starting points' or 'benchmarks' which are objective measures upon which outcomes can be judged against. [3]
Basket Trials	A protocol testing a single intervention in multiple patient populations divided into parallel substudies (see example [8]). If a subgroup shows good responses, it may be expanded to achieve statistical significance. 

Term/Phrase	Definition
Blinding/ Masking Blind	A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). In a single blind trial, the trial participant is not told which arm of the trial he/she is on and is therefore unaware of whether he/she is in the experimental or control arm of the trial; also called masked. In a double blind trial, the trial participant, investigator(s), monitor, and, in some cases, data analyst(s) are unaware of the treatment arm the participant has been assigned to. [1,3] 'Blinding' is not always possible (e.g. research into the benefits of massage). Whenever blinding is used, there will always be a method in which the participants treatment can be unblinded in the event that information is required for safety. [3]
Case Report Form (CRF)	A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial participant. [1]
Clinical Significance	A change in a person's clinical condition that is deemed to be important, whether or not it relates to a trial intervention.[5]
Clinicaltrials.gov	A database of privately and publicly funded clinical studies, provided by the US National Library of Medicine. Every clinical trial being conducted in the US must be registered on clinicaltrials.gov. It can be used to register trials in other countries, but does not list every clinical trial running globally. A listing does not mean it has been evaluated by the US govt.
Clinical Trial/ Study Report	A written description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in human participants, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report (see the ICH Guideline for Structure and Content of Clinical Study Reports). [1]
Comparator (Product)	An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial [1]
Completed	A trial is considered completed when trial participants are no longer being examined or treated (i.e. no longer in follow-up); the database has been 'locked' and records have been archived. [2]
Confounding factors	A confounding factor is anything which might have influenced the trial that was unplanned. For example, 'everyone on the trial caught the flu during the trial' or 'there was a transport strike and people couldn't get in for blood tests'. A confounding factor would not be something caused by the trial intervention. [3]
Contract	A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract. [1]
Control group	The group that does not receive the new treatment being studied but receives the current standard treatment. [4]
Coordinating Committee	A committee that a sponsor may organize to coordinate the conduct of a multicentre trial. [1]
Coordinating Investigator	An investigator assigned the responsibility for the coordination of investigators at different centres participating in a multicentre trial. [1]
(CRO) Contract Research Organization	A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions. [1]

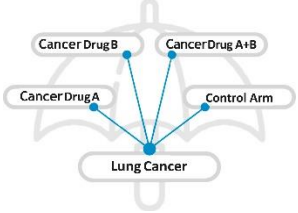
Term/Phrase	Definition
Decentralised Clinical Trials	Clinical trials that are conducted through telemedicine and mobile/local healthcare providers, using procedures that vary from the traditional clinical trial model (e.g., the investigational medical product [IMP] is shipped directly to the trial participant). See also 'virtual clinical trials'.
Direct Access	Permission to examine, analyse, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsor's monitors and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of participant's identities and sponsor's proprietary information [1]
Documentation	All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken. [1]
Double-blind study	Neither the patients nor the research team know which treatments they are receiving - either the new treatment or the current standard treatment. When safety concerns arise, treatment can be 'un-blinded'. [4]
Efficacy	(Of a drug or treatment). The maximum ability of a drug or treatment to produce a result regardless of dosage. A drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed. [2]
Eligible Patient	A patient selected in accordance with, and who meets, the eligibility criteria specified for the trial. [2]
Eligibility Criteria/ Inclusion and Exclusion Criteria	Any medical or social criteria that would include or exclude someone from research (e.g. gender, age, medications, disease type and status, previous treatment history other conditions). They ensure patients enrolling in a clinical trial share similar characteristics so that researchers have greater confidence that the results of the study are due to the treatment(s) studied rather than other factors. [2, 3, 4] It is important to note that inclusion and exclusion criteria are not used to reject people personally, but rather to identify a group of trial participants with similar characteristics to make analysis of the results easier, and to enrol only those for whom it is thought safe to include. [2]
Engagement	See "Patient/Public/Consumer **Engagement** in Research"
Endpoint	Main indicator(s) used for assessing the primary question (i.e., hypothesis) of a clinical trial, typically a variable linked with safety or how well the intervention works. An endpoint is more specific as compared to an outcome since it relates to the planned objective of the study.[5]
Essential Documents	Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced
Ethics approval	Approval given by a Human Research Ethics Committee (HREC) for a clinical trial to be conducted with patients. [2]
Follow-up	A process of periodic contact with participants enrolled in a trial for the purpose of monitoring health status, administering trial treatments, modifying the course trial treatment, observing the effects of the trial treatment, or for data collection. [2]

Term/Phrase	Definition
Good Clinical Practice (GCP)	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected. [1]
Human Research Ethics Committees (HRECs)	The name for the Committees in Australia that review all research proposals involving human participants to ensure that they are ethically acceptable and scientifically valid, per the requirements of the Australian the National Statement on Ethical Conduct in Human Research[6]. (See also 'Independent Ethics Committee')
Hypothesis	A testable statement regarding the trial intervention that is used to design the clinical trial and that can be accepted or rejected based on the results of the clinical trial and statistical calculations.[5]
Independent Data-Monitoring Committee (IDMC) (or DSMB)	An independent data-monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial. (also called Data and Safety Monitoring Board (DSMB), Monitoring Committee, Data Monitoring Committee (DMC)) [1]
Impartial Witness	A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the participant or their legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the participant. [1]
Independent Ethics Committee (IEC)	An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human participant involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favourable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial participants. The legal status, composition, function, operations and regulatory requirements pertaining to Independent Ethics Committees may differ among countries. See also "Human Research Ethics Committee" for information specific to Australia.
Informed Consent	A process by which a patient voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the patient's decision to participate - including benefits, risks and side effects, and alternative options. Informed consent is documented by means of a written informed consent form (which has the name of the trial clearly displayed). It must be signed and dated by the trial participant (or the trial participant's legally acceptable representative) and the Investigator, in the presence of each other. [1,2,4]
Inspection	The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organization's (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority(ies). [1]
Institution (medical)	Any public or private entity or agency or medical or dental facility where clinical trials are conducted [1]
Interim Clinical Trial/ Study Report	A report of intermediate results and their evaluation based on analyses performed during the course of a trial [1]

Term/Phrase	Definition
Intervention	This word is often used to describe what the research is testing or trying out. It could be a drug, a new kind of treatment pathway or something as simple as a massage. [3]
Investigator	A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. See also Subinvestigator. [1]
Investigator's Brochure	A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human participants [1]
Involvement	See "Patient/Public/Consumer **Involvement** in Research"
Legally Acceptable Representative	An individual or other authorised under applicable law to consent, on behalf of a prospective participant, to the participant taking part in the clinical trial. [1]
Lost to Follow-up	Where there are no results from certain participants on a trial (e.g. People who leave a trial without completing all the requirements of the trial) [1]
Master Protocol	A general term for a trial design with multiple sub-studies which may have different objectives and evaluate one or more interventions and/or one or more diseases (ie it has multiple subgroups). Examples include basket trials, umbrella trials, and platform trials.
Monitoring	The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s). [1]
Monitoring Plan	A document that describes the strategy, methods, responsibilities, and requirements for monitoring the trial. [1]
Multicentre Trial	A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator. [1]
Outcome	Events or experiences that are measured in a trial because the researchers believe they may be influenced by the trial intervention or exposure. An outcome is more general than endpoint in that it does not necessarily relate to a planned objective of the study. [5]
Outcome Measures	These are the outcomes that are measured at the end of the research. They must be the same as what is measured at the start (baseline) to allow for comparison. [3]
Participant	An individual who participates in a clinical trial, either as a recipient of an intervention or as a control. [1]. It is a preferred term, though may be used interchangeably with the term "subject", which is part of some countries regulations (eg US FDA).
Participant Identification Code	A unique identifier assigned by the investigator to each trial participant to protect the participant's identity and used in lieu of the participant's name when the investigator reports adverse events and/or other trial related data. [1]
Participation	See "Patient/Public/Consumer **Participation** in Research"
Patient/ Public/ Consumer **Engagement** in Research	Where information and knowledge about research is provided and disseminated. Examples of engagement include science festivals open to the public with debates and discussions on research, open days at a research centre where members of the public are invited to find out about research, raising awareness of research through media such as television programmes, newspapers and social media, and dissemination to research participants, colleagues or members of the public on the findings of a study. [7]

Term/Phrase	Definition
Patient/ Public/ Consumer **Involvement** in Research	Where people are actively involved in research projects and in research organisations. For example, they might be co-applicants on research grants, involved in identifying research priorities, members of a project advisory or steering group, provide comment or help develop participant information or other participant-facing research materials, undertaking interviews with research participants or perhaps even carrying out the research. [7]
Patient/ Public/ Consumer **Participation** in Research	Where people take part in a research study. For example, people that are recruited to a clinical trial to take part, or the completion of a questionnaire or participating in a focus group as part of a research study. [7]
Patient Reported Outcome (PRO)	An outcome based on a report that comes directly from the patient about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else. Symptoms or other unobservable concepts known only to the patient can only be measured by PRO measures. PROs can also assess the patient perspective on functioning or activities that may also be observable by others. [5]
Phase I, II, III and IV	These phases typically apply only to clinical trials testing new medicines. These sequential phases are necessary to reduce the risk of safety issues. Phase I and II trials involve small numbers of patients, including those for whom current treatments are no longer viable. Phase III trials are large-scale trials involving thousands of patients where new treatment options are compared with current treatments. New treatments become part of standard care when their value is proven in Phase III trials. Phase IV trials continue to collect information about treatments that have become part of standard care after they have passed through Phase III. [4, 5] As attempts are made to increase the efficiency of medicine development, one clinical trial can cover more than one phase. And, if there is overwhelming evidence of a product working, being safe and addressing unmet need, a new medicine may be approved after phase 2, conditional on running additional trials to collect more evidence.
Placebo / sham device	A placebo is an inactive or 'dummy' treatment. In the case of medical device trials, it may be called a Sham Device. These tools are used to make it easier to evaluate the effect of the treatment being tested versus "no treatment" (current standard care). [5] It should be noted that if used, a placebo is usually used in addition to the current standard care. If there is no agreed standard care that is effective, then the placebo arm may receive no treatment. It is widely accepted as unethical to use a placebo if there is a known effective treatment, and an ethics committee will carefully consider this during their review of the risks and benefits of the trial for participants when deciding whether to approve a clinical trial. [5]
Platform Trial	A type of trial design where a clinical trial is run with a single master protocol in which multiple treatments are evaluated simultaneously for a single disease. They are adaptive clinical trials by nature. They have some similarities with umbrella trials but, unlike umbrella trials where all the subgroups go the initial predefined distance irrespective of the outcome, in platform trials the information generated early in the trial is used to adjust its subsequent flow. See example algorithm [8]. 

Term/Phrase	Definition
Pre-screening	Efforts to identify people that might be eligible to take part in a clinical trial, prior to their consent to be fully evaluated and enrol in the clinical trial (see "Screening"). This might include for example reviewing databases or medical records for people with key eligibility criteria (eg age, health condition), online prescreening questionnaires, or speaking with people that have made enquiries about a trial as a result of a referral of advertising.
Protocol	A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. A protocol details the number of patients, the duration, the trial, the treatments, tests and how the results will be interpreted for each trial. Protocols are reviewed and approved by human research ethics committees before a trial is initiated. [1,3]
Protocol Amendment	A written description of a change(s) to or formal clarification of a protocol [1]
Quality Assurance (QA)	All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with Good Clinical Practice (GCP) and the applicable regulatory requirement(s). [1]
Quality Control (QC)	The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled.
Randomised controlled trials (RCT)	Treatments are assigned randomly to patients in a trial. Patients do not choose which treatments they receive. Randomisation helps reduce the risk of bias being intoruced when comparing treatments. [4, 5]
Randomization	The process of assigning trial participants to treatment or control groups using an element of chance to determine the assignments in order to reduce bias. [1]
Recruitment	Active efforts to find and enrol the requirement number of people as participants in a clinical trial, according to the numbers and eligibility requirements defined in the protocol. [5]
Regulatory Authorities	Bodies having the power to regulate. In the ICH GCP Guideline the expression Regulatory Authorities includes the authorities that review submitted clinical data and those that conduct inspections. These bodies are sometimes referred to as competent authorities [1]
Retention	Activities undertaken to support and encourage clinical trial participants to remain enrolled and take part in a clinical trial. [5]
Sample Size*	How many people were involved in the trial. The sample size required is usually calculated by a statistician based on the hypothesis for the trial and expected treatment effect necessary to establish a difference between the treatment arms. [1]
Screening	A process of active evaluation of potential participants for enrollment in a trial. Screening activities occur once a participant has consented to the trial, to see if they meet the inclusion and exclusion criteria. If they meet the criteria, the participant is eligible to enroll in the trial. [5]
Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR)	Any untoward medical occurrence that at any dose: - results in death, - is life-threatening, - requires inpatient hospitalization or prolongation of existing hospitalization, - results in persistent or significant disability/incapacity, or - is a congenital anomaly/birth defect (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting). [1]
Single-Blind/ Single-blind study	This is where the participant is not informed which arm of a trial on the participant has been assigned to, but the research team know whether patients are receiving the standard treatment or the new treatment under trial. [3,4]

Term/Phrase	Definition
Site	See “Trial Site”
Source Documents	Documents Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, participants' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, participant files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial). [1]
Sponsor	An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial. [1]
Sponsor-Investigator	An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a participant. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator. [1]
Standard Operating Procedures (SOPs)	Detailed, written instructions to achieve uniformity of the performance of a specific function. [1]
Subinvestigator	Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). [1]
Subject/Trial Subject	See “Participant”.
Tele-trials	Teletrials are a developing Australasian model for running clinical trials designed to increase access of rural and remote patients to clinical trials. In a teletrial, a clinician at a larger centre (primary trial site) can enrol, consent and treat patients on clinical trials in partnership with smaller regional and rural centres (satellite sites), allowing patients to participate closer to home.
Termination	When a trial sponsor, regulator, institution or HREC/IRB discontinue or withdraw a trial, prior to its planned completion. This may occur at the level of a trial site, country or entire study.
Trial Site	The location(s) where trial-related activities are physically conducted. [1]
Trial Arm*	Trials might have multiple ‘arms’ which are groups that are being tested simultaneously. One arm may be the ‘control’ group that receives the best available standard of care. In some cases that may be a placebo (dummy treatment), if there is no medical community agreement that there is any effective treatment for a condition. A dummy treatment may also be used to facilitate blinding of treatment arms, if two treatments look different (eg one is a pill and one is an injection). Different arms might start interventions at different times. Sometimes, protocols require a crossover, where participants change to the alternative treatment They may or may not know when this happens. [1]
Umbrella Clinical Trials	A protocol with more than one intervention studied for a single disease (see example[8]). Participants are divided into multiple parallel treatment arms, receiving different interventions or a control. They may include multiple doses of the same drug for dose-finding purposes, or different drugs for different gene mutations (changes) or biomarkers. 

Term/Phrase	Definition
Underserved Populations	Populations where their voices and needs are often unintentionally overlooked. These may include for example, the economically disadvantaged, racial and ethnic minorities, specific genders, the uninsured, those with rare conditions, rural residents, children and the elderly.
Unexpected Adverse Drug Reaction	An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product) (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting). [1]
Validation of Computerized Systems	A process of establishing and documenting that the specified requirements of a computerized system can be consistently fulfilled from design until decommissioning of the system or transition to a new system. The approach to validation should be based on a risk assessment that takes into consideration the intended use of the system and the potential of the system to affect human participant protection and reliability of trial results [1]
Virtual Clinical Trials	A true virtual clinical trial is one in which all the participant interactions and data collection is virtual (ie. no physical visits to a trial site and uses participant-facing technologies, such as tablets, smartphone apps, or wearable sensors). As this is a rapidly evolving area, the term is not well defined and used interchangeability with other terms (e.g. decentralized trials, remote trials, direct-to-patient trials, and hybrid trials).
Vulnerable Participants	Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable participants include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent, [1]
Well-being (of the trial participants)	The physical and mental integrity of the individuals participating in a clinical trial. [1]

Acknowledgements/Sources:

This glossary was produced with input from Janelle Bowden, Jack Nunn, Janelle Morrissey, and the sources below:

1. http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html

2. https://www.trog.com.au/Glossary

3. McMillian Cancer UK Original resources

4. https://www.moga.org.au/patients-carers/clinical-trials

5. https://www.fda.gov/media/108378/download

6. https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

7. https://www.invo.org.uk/find-out-more/what-is-public-involvement-in-research-2/

8. https://doi.org/10.1016/j.conctc.2020.100568

For more resources to support to Australian clinical trial participation and involvement, visit the AccessCR website, join our Research Gamechangers Facebook Group, or visit the Australian Government's Clinical Trials website.

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