	Name	
AE	Adverse Event	An unwanted effect that may be caused by the administration of drugs/intervention. Relationship to study drug/intervention for all Adverse Event should always be documented.
	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, analysed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
AU RED	Australian Research Ethics Database & Online Forms	All researches seeking ethics approval for multi site clinical trials can utilise the on line forms website to develop their application. Allows access to the NEAF and the Victorian Site Specific Assessment Form (SSA). www.ethicsform.org/au
CTSU	Cancer Trials Support Unit	The Cancer Trials Support Unit (CTSU) is a U.S. project sponsored by the National Cancer Institute (NCI) for the support of a national network of physicians to participate in NCI-sponsored Phase III cancer treatment trials. The majority of these trials are sponsored by the adult Cooperative Clinical Trials Groups. The CTSU membership is now managed through the Cancer Therapy and Evaluation Program - Identity and Access Management (CTEP-IAM) registration system. https://www.ctsu.org/public/
CRF	Case Report Form	A paper of electronic form specifically used in clinical trials research as a tool to collect data from each participating site.
CRA	Clinical Research Associate	The main function of a clinical research associate is to monitor clinical trials. He/She may work directly with the sponsor company of a clinical trial, as an independent freelancer or for a Clinical Research Organization (CRO). A CRA ensures compliance with the clinical trial protocol, checks clinical site activities, makes on-site visits, review case report forms and communicates with the clinical research investigators
CRO	Clinical Research Organization	A service organization that provides support to the pharmaceutical/biotech industry. CROs offer clients a wide range of "outsourced" pharmaceutical research services to aid in the drug and medical device research & development process.
CTX	Clinical Trials Exemption scheme	The scheme requires the review of all clinical trials by Human Research Ethics Committees (HREC) and an application to the TGA for the use of an unapproved medication or medical device. Under CTX arrangements, the TGA evaluates the associated scientific data and approve usage guidelines of the particular medication or device used in the trial.
	Clinical Trials Handbook	A simple, practical guide to the conduct of clinical trials to International standards of Good Clinical Practice in the Australian context http://www.tga.gov.au/pdf/clinical-trials-handbook.pdf
CTN	Clinical Trials Notification scheme	The scheme whereby the TGA need only be notified of the clinical trial being undertaken on the condition that a HREC, having reviewed the scientific data and the proposed management of ethical issues, is satisfied that the trial provides a low level of risk to trial participants.
	Cohort	A group of individuals having a statistical factor (as age or risk) in common.
CTCAE	Common Toxicity Criteria Adverse Event	A standardised classification of side effects used in assessing drugs for cancer therapy. Specific conditions and symptoms may have values or descriptive comment for each level, but the general guideline is: 1-mild, 2-moderate, 3-severe, 4-life threatening and 5-death.

	Compassionate Use	A method of providing experimental therapeutics prior to final FDA approval in humans. This procedure is used with very sick individuals who have no other treatment options. Often, a case-by-case approval must be obtained from the FDA for "compassionate use" of a drug therapy.
	Control Group	Control is a standard by which experimental observations are evaluated. In many trials, on group of patients will be given an experimental drug or treatment, with the control group is given either a standard treatment for the illness or a placebo.
	Controlled Trial	In controlled clinical trials, one group of participants is given an experimental drug/treatment, while another group (i.e. Control group) is given either a standard treatment for the disease or a placebo.
DSMB	Data Safety & Monitoring Board	An independent group of experts who monitor patient safety and treatment efficacy data while a clinical trial is ongoing.
	Declaration of Helsinki Protocol	The Declaration of Helsinki Protocol is a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. The Declaration includes principles on safeguarding research subjects, informed consent, minimizing risk, and adherence to an approved research plan/protocol.
DLT	Dose Limiting Toxicity	The toxic effect of a drug that prevents further use of the drug or means that the dosage of the drug has reached its limit and cannot be increased.
	Double-Blind Study	A clinical trial design in which neither the participating individuals nor the study staff knows which participants are receiving the experimental drug and which are receiving a placebo (or another therapy). Double-blind trials are thought tot produce objective results, since the expectations of the doctor and the participant about the experimental drug do not affect the outcome.
	Efficacy	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. In the procedure mandated by the FDA, Phase II clinical trials gauge efficacy and Phase III trials confirms it.
	Eligibility Criteria	Summary criteria for participant selection into a trial; includes Inclusion and Exclusion Criteria. These are the medical or social standards determining whether a person may or may not be allowed to enter a clinical trial. These criteria are based on such factors as age, type and stage of a disease, previous treatment history, and other medical conditions. It is important to note that the eligibility criteria are not used to exclude people, but rather to identify appropriate participants and keep them safe.
	Endpoint	Overall outcome of the protocol is designed to evaluate. Common endpoints include sever toxicity, disease progression or death.
	Epidemiology	The branch of medical science that deals with the study of incidence and distribution and control of a disease in a population.
	Expanded Access	Refers to any of the FDA procedures, such as compassionate use, parallel track, and treatment IND that distribute experimental drugs to participants who are failing on currently available treatments for their condition and also are unable to participate in ongoing clinical trials.
FDA	Food and Drug Administration	The U.S Department of Health and Human Services agency is responsible for ensuring the safety and effectiveness of all drugs, biologics, vaccines, and medical devices, including those used in the diagnosis, treatment, and prevention. http://www.fda.gov/

GCP	Good Clinical Practice	Good Clinical Practice is an international quality standard that is provided by the International Conference on Harmonization (ICH); an international body that defines standards, which governments can transpose into regulations for clinical trials involving human subjects. Good Clinical Practice guidelines include protection of human rights as a subject in clinical trial. It also provides assurance of the safety and efficacy of the newly developed compounds. Good Clinical Practice Guidelines include standards on how clinical trials should be conducted; define the roles and responsibilities of clinical trial sponsors, clinical research investigators, and monitors.
HREC	Human Research Ethics Committee	An independent body constituted by medical/scientific professionals and non-scientists members, whose responsibility is to ensure the protection of rights, safety and wellbeing of subjects involved in clinical trials.
	Informed Consent	A process in which a person learns key facts about a clinical trial, including potential risks and benefits, before deciding whether or not to participate in a study. Informed consent continues throughout the trial.
IRB	Institutional Review Board	An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.
ITT	Intent to Treat	Intention to treat is an analysis based on the initial treatment intent, not on the treatment eventually administered. ITT analysis is to avoid misleading artefact the can arise in intervention research. For the purposes of ITT analysis, everyone who begins the treatment is considered to be part of the trial, whether they finish it or not.
ICH	International Conference on Harmonization	An international body that defines standards, which governments can transpose into regulations for clinical trials involving human subjects. http://www.ich.org/
MTD	Maximum Tolerated Dose	The largest dose of a drug an individual can take without unacceptable adverse side effects.
NCI	National Cancer Institute	U.S. National Institutes of Health - National Cancer Institute's research programs are extensive and their website http://www.cancer.gov/ contains many resources.
NEAF	National Ethics Application Form	NEAF is a web-based tool that has been developed to enable researchers of all disciplines to complete research ethics proposals for submission to Human Research Ethics Committees (HRECs), and to assist HRECs to consistently and efficiently assess these proposals. It has been designed to meet the requirements of relevant guidelines with the aim of increasing the efficiency and quality of the ethical review process for all parties involved.
	National Statement of Ethical Conduct in Human Research (2007)	The statement consists of a series of Guidelines made in accordance with the National Health and Medical Research Council Act 1992 ('the Act'). http://www.nhmrc.gov.au/publications/synopses/e72syn.htm
	Note to File	Notes to File are generated to clarifying a process. Notes to File should contain the issues/errors being documented and what was done to correct the issue (Corrective Action) and what did you do to prevent the recurrence of this issue (Preventative Action)...typically education and/or revision of SOPs

ORI	Office of Research Integrity	"The Lab," an interactive video simulation on research integrity, is available on the U.S. Department of Health and Human Services' Office of Research Integrity (ORI) website and as a DVD. In the simulation, research misconduct causes a noted lab to lose funding, creates bad publicity for the university, and eventually causes the withdrawal of a multimillion dollar endowment. Viewers will have the opportunity to undo the damage by assuming the roles of a graduate student, postdoctoral researcher, principal investigator, and research integrity officer and making decisions to prevent misconduct from occurring unnoticed. The video addresses the handling of misconduct, data management, authorship, mentoring, work-life balance, and other issues that today's researchers face. http://ori.hhs.gov/TheLab/
	Open-Label Trial	A type of clinical trial in which both the researchers and participants know which treatment is being administered. Open-label trials may be appropriate for comparing two very similar treatments to determine which is most effective. An open-label trial may still be randomized. Open-label trials may also be uncontrolled, with all participants receiving the same treatment.
PICF	Patient Informed Consent Form	A document that describes the rights of the study participants, and includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document. The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.
	Peer Review	Review of a clinical trial by experts chosen by the study sponsor. These experts review the trials for scientific merit, participant safety, and ethical considerations.
PKs	Pharmacokinetics	Pharmacokinetics includes the study of the mechanisms of absorption and distribution of an administered drug, the rate at which a drug action begins and the duration of the effect, the chemical changes of the substance in the body (e.g. by enzymes) and the effects and routes of excretion of the metabolites of the drug. Pharmacokinetic blood sampling is often taken at designated time points pre and post study drug administration.
	Phase I Clinical Trial	Initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients.
	Phase II Clinical Trial	Controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks.
	Phase III Clinical Trial	Expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide and adequate basis for physician labelling.
	Phase IV Clinical Trial	Post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use.
	Placebo	A placebo is an inactive pill, liquid, or powder that has no treatment value. In clinical trials, experimental treatments are often compared with placebos to assess the treatment's effectiveness.
	Placebo Effect	A physical or emotional change, occurring after a substance is taken or administered, that is not the result of any special property of the substance. The change may be beneficial, reflecting the expectations of the participant and, often, the expectations of the person giving the substance.

	Placebo-Controlled Study	A method of investigation of drugs in which an inactive substance (the placebo) is given to one group of participants, while the drug being tested is given to another group. The results obtained in the two groups are then compared to see if the investigational treatment is more effective in treating the condition.
	Preclinical	Refers to the testing of experimental drugs in the test tube or in animals - the testing that occurs before trials in humans may be carried out.
PI	Principal Investigator	The PI is the project director and assumes full responsibility for the research project or Clinical Trial conduct. The PI is in charge of preparing the Clinical Trial proposal, securing internal approval for the conduct of the Clinical Trial including institutional ethical committee approval, and overseeing the scientific and technical aspects of the Study. The PIs are responsible for the management of Clinical Trials including patient recruitment, and submission of original case report forms ("CRFs") for each patient or subject participating in the Study ("Study Subject") and, if applicable, regular narrative reports to the Sponsor.
	Protocol	A study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.
	Randomisation	A method based on chance by which study participants are assigned to a treatment group. Randomization minimizes the differences among groups by equally distributing people with particular characteristics among all the trial arms. The researchers do not know which treatment is better. From what is known at the time, any one of the treatments chosen could be of benefit to the participant.
	Randomisation Trials	A study in which participants are randomly (i.e., by chance) assigned to one of two or more treatment arms of a clinical trial. Occasionally placebos are utilised.
SAE	Serious Adverse Event	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.
	Source Documentation	Original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects` 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, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).
SOP	Standard Operating Procedures	In clinical research, SOPs are defined by the ICH as "detailed, written instructions to achieve uniformity of the performance of a specific function". They are essential for standardising processes, for ensuring that current regulatory and organisational policy requirements are met, for training new personnel and for managing workload. They are necessary for a clinical research organisation — whether it concerns a pharmaceutical company, a sponsor, a contract research organization, an investigator site, an Ethics Committee or any other party involved in clinical research—to achieve maximum safety and efficiency of the performed clinical research operations.

	Statistical significance	The probability that an event or difference occurred by chance alone. In clinical trials, the level of statistical significance depends on the number of participants studied and the observations made, as well as the magnitude of differences observed.
SERP	Streamlined Ethical Review Process	The streamlining of ethics review of multi-site clinical trials is an important Victorian Government initiative arising from the Victorian Innovation Statement announced in August 2008. It aims to ensure a faster, more efficient process for organising and conducting clinical trials at multiple sites and to speed-up product development for world markets. The new system is expected to improve delivery of new treatments to patients early in drug/device development.
	Sub-Investigator	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).
SUSAR	Suspected Unexpected Serious Adverse Event	A suspected and unexpected adverse effect is defined as a serious adverse event (see definition above) for which there is some degree of probability that the event is related to the study drug and the adverse reaction is unexpected, i.e. the nature or severity of which is not consistent with the applicable product information.
TGA	Therapeutic Goods Administration	The regulatory body for therapeutic goods (including medicines, medical devices, gene technology, and blood products) in Australia. The TGA is responsible for conducting assessment and monitoring activities to ensure that therapeutic goods available in Australia are of an acceptable standard and that access to therapeutic advances is in a timely manner. http://www.tga.gov.au/
	Toxicity	An adverse effect produced by a drug that is detrimental to the participant's health. The level of toxicity associated with a drug will vary depending on the condition which the drug is used to treat.