

Standard Operating Procedure:

SOP Glossary of Terms with Teletrials

**SOP Number: TT-SOP-Glossary of terms**

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| Author(s): | Hannah CrossVCCC Program Manager |
| Approved by: | VCCC Teletrials Steering Committee |

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**Amendment History**

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Developed by the Victorian Comprehensive Cancer Centre (VCCC) in conjunction with the Parkville Cancer Clinical Trials Unit (PCCTU), based on the Clinical Oncology Society of Australia (COSA) Australasian Tele-trials Model.

**viccompcancerctr.org**

List of Terms and Acronyms

Amendment

Change in a clinical trial document i.e. protocol, patient informed consent form, and investigator brochure etc.

Audit/Inspection

The act of an independent, official review of a clinical trial which could include the examination of facilities, documents, data and any resources deemed relating to the clinical trial. This term includes

**Regulatory inspection**: The act by a regulatory authority of conducting an official review of documents, facilities, records and any other resources that are deemed to be related to the clinical trial and that may be located at the site of the trial, at the sponsor’s/contract research organisation (CRO) facilities, or at any other establishments deemed appropriate by the regulatory authority.

**HREC audit:** The act by the approving HREC of conducting an official review of a clinical trial site during a study to ensure study participant safety and ethical guidelines are being followed.

**Sponsor audit:** The Sponsor may conduct a systematic and independent examination of clinical trial related activities and documents to determine whether the evaluated clinical trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, sponsor’s written procedures, ICH GCP and applicable regulatory requirements.

Auditor/Inspector

The individual(s) responsible for conducting an audit at site, on behalf of the regulatory authority, sponsor or HREC.

Audit Trail

Documentation that allows for reconstruction of the course of events throughout a research trial.

Case Report Form (CRF)

A printed or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial participant. The information in this document must correlate with the information in the source documents/case histories.

Central Samples

Refers to any sample available for research purposes, this may include pharmacokinetics, pharmacodynamics and pharmacogenetics and molecular testing.

Clinical Trial

Any investigation in humans intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

Clinical Trial Participant

An individual participating in a clinical trial.

Clinical Research Associate (CRA)

An individual designated by a sponsor or contract research organisation (CRO) to monitor the sites conduct in the clinical trial.

Clinical Research Organisation (CRO)

An organisation contracted by the sponsor to oversee the conduct of the clinical trial.

Clinical Trial Site

A clinical setting that is utilised for the examination and/or treatment of participants in a clinical study. The site must provide security for the storage of the test article and must be a facility that is clinically appropriate to perform required procedures described in the protocol. In addition, this site must provide adequate storage for all study related materials with appropriate working space for sponsor monitoring.

Confidentiality

Prevention of disclosure of proprietary information to unauthorised individuals.

Curriculum Vitae (CV)

A résumé of academic and professional training, work history, and other qualifications.

Documentation

All records, in any form (including, but not limited to, written, electronic, magnetic, optical records, scans, x-rays and electrocardiograms) that describe or record the methods, conduct, results and information about a trial.

Development Safety Update Report (DSUR)

A periodic analysis of investigational product safety information crucial to the ongoing assessment of risk to clinical trial participants.

Essential Documents

Documents that individually and collectively permit evaluation of the conduct of the study and the quality of the data produced.

Electronic Medical Record (eMR)

An electronic medical record (EMR) is a digital version of a paper chart that contains all of a patient’s medical history. (See VERDI)

Human Research Ethics Committee (HREC)

An independent body (a committee, institutional, regional, or national), constituted of medical/scientific professionals and nonmedical/non-scientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human participants involved in a trial and to provide 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.

**International Conference on Harmonisation Good Clinical Practice (ICH GCP)**

An international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human participants. Compliance with this standard provides assurance that the rights, safety, and well-being of trial participants are protected; consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

Informed Consent

A process by which a potential study participant voluntarily confirms his or her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the respective person’s decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

Investigational Product (IP)

The term used for the agent of investigation in the clinical trial.

Investigator

An individual who conducts a clinical investigation and makes important clinical trial related decisions. Investigators include the principal investigator and sub-investigators delegated on a clinical trial.

Investigator Brochure (IB)

A compilation of the clinical and nonclinical data on the investigational product(s) that is relevant to the study of the investigational product(s) in human subjects.

Investigator Site File (ISF)

The **Investigator** **Site** **File** contains all essential documents held by the Principal **Investigator** conducting a clinical trial which individually and collectively permits the evaluation of the conduct of the trial and the quality of the data produced.

Medical Monitor

The medical monitor, usually a representative from the sponsor, is the person responsible for the safety surveillance of a clinical trial.

Monitoring

The act of overseeing the conduct of a clinical trial, and for ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOP's), GCP, and the applicable regulatory requirement(s).

Named Archivist

A nominated (SITE) staff member who is responsible for ensuring archiving requirements are met as defined and required in the regulations.

Co-Named Archivist

(SITE) staff member authorised to collect, archive, retrieve and destroy items from the archive facility under the direction of the Named Archivist.

National Health and Medical Research Council (NHMRC)

The Council was established to develop and maintain health standards and is responsible for implementing the National Health and Medical Research Council Act 1992.

(SITE) Cancer Clinical Trials Unit Leadership Group

Comprised of the (SITE) Team Leaders, the (SITE) Manager and the (SITE) Business and Operations Lead.

(SITE) Cancer Clinical Trials Unit Manager

Department Manager.

Patient Information and Consent Form (PICF)

The ethically approved document used for providing written patient information about a specific clinical trial and the documentation of Informed Consent in the form of the patient and the investigator signatures and date.

Primary Site

The purpose of the Primary Site is to support trial accessibility across a number of trial sites. The Principal Investigator provides oversight and has ultimate responsibility for the trial and any related Satellite Sites.

Principal Investigator (PI)

Primary individual who is responsible for the overall conduct of a clinical trial.

Protocol

A document that mandates the objective(s), design, methodology, statistical considerations, and organization of a trial.

Quality Assurance (QA)

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 GCP and the applicable regulatory requirement(s).

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.

Randomisation

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.

Randomisation List

A decoded list of randomisation identifiers that is locked away from all personnel who must remain blinded during the clinical trial.

Regulatory Authority

Bodies having the power to regulate. This includes the TGA, FDA, EMA and MHRA.

Research Governance Office (RGO)

A site is responsible for the conduct of research at their site. The research governance office address the management of site risk, site resource and required regulatory reporting.

Satellite Site

A Satellite Site is located in a geographically separate health facility and responsibility is delegated by the Primary Site (clinical trial site) to perform activities associated with the conduct of a clinical trial and to support trial accessibility of remote participants to a clinical trial. Satellite Sites can be located in metropolitan, regional or rural settings. Delegated activities to be performed by the Satellite Site are trial specific and should be agreed and documented at the time of site selection via a delegation log and a supervision plan.

For each trial, infrastructure and training requirements for Satellite Sites are the same for both the Primary and Satellite sites.

A satellite site should have the following:

* Appropriately contracted qualified and trained investigator(s) and delegated staff to undertake trial related activities including obtaining informed consent (if required). Study staff are trained in the protocol, IB, study procedures, Adverse Event (AE)/Serious Adverse Event (SAE) reporting. A system for safety reporting duties is in place for all study staff
* Study related documentation including a Satellite Site Study File, procedures for managing the security of information and trial data and a process for managing data security or privacy breeches.
* An understanding of the process for securely and suitably storing and ensuring accountability for the Clinical Trials Investigational Medicinal Product (CTIMP).

Satellite Site Study File (SSSF)

A folder containing all the Satellite Site study relevant documents generated during the course of the trial. The content of the Satellite Site study file can be decided with the study team and the sponsor. The SSSF may be a sub-set of the SMF and should be prefaced with an index of contents as well as indicate the location(s) of all essential /source documents.

Serious Adverse Event (SAE)

* Any untoward medical occurrence that:
* Results in death
* Is life-threatening
* Requires inpatient hospitalization or prolongation of existing hospitalization
* Results in persistent or significant disability/incapacity
* Is a congenital anomaly/birth defect

Source Data

All information in original records of a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents.

Site Close-out Visit

A visit conducted at the end of a study. The purpose is to ensure the completeness of all activities including the collection and verification of study data, the final counting and disposition of the investigational product and the verification of complete and accurate investigator files of essential documents.

Site Initiation Visit

A visit conducted at the start of a study. The purpose is a thorough review of the protocol and study related procedures. All study site personnel meet together to clarify the actual process of implementing the protocol.

Site Qualification Visit

A process to determine that the clinical investigational site is adequately equipped and has appropriate facilities to conduct a specific study. Qualified sites should have ample secured storage for all study related materials, access to patient population under study, sufficient staffing to conduct study related procedures, data collection and reporting, and have space for sponsor monitoring.

Source Documents

Original documents, data, and records (laboratory reports, participant diaries, pharmacy dispensing records, recorded data from automated instruments, x-rays, participant study files).

Sponsor

An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.

Standard Operating Procedures (SOPs)

Detailed written instructions to achieve uniformity of the performance of a specific process.

Study Team

This incorporates all staff members listed on the delegation log of an individual study.

Sub-investigator (SI)

A medically qualified individual delegated and supervised by the principal investigator to perform clinical investigations and make important clinical trial related decisions.

Supervision Plan

A document utilised to establish a satellite site in a Teletrial which outlines the roles and responsibilities of the study team.

Suspected Unexpected Serious Adverse Reaction (SUSAR)

Is an adverse event assessed by the sponsor and or investigator as being unexpected, serious and having a reasonable possibility of causal relationship with the investigator product.

Unexpected Adverse Drug Reaction

An adverse reaction, the nature or severity of which is not consistent with the available product information (e.g., Investigator Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product).

VERDI (Clinical Viewer)

An electronic medical record

Work Practice Guideline (WPG)

A tool to be used for reference.