

Standard Operating Procedure:

Clinical Trial Feasibility and Start-up with Teletrials

**SOP Number: TT-SOP-05**

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| Approved by: | VCCC Teletrials Steering Committee |

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**Amendment History**

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| Version | Date | Amended By | Amendment Details |
| 1.0 | 03 October 2018 | Hannah Cross | New |
| 2.0 | 13 September 2019 | Alana Donaldson | Additional information regarding electronic documentation on Site Docs Portal. |

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.

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Description generated with very high confidenceviccompcancerctr.org**

1. Introduction and Background

International Conference on Harmonisation Good Clinical Practice (ICH GCP) outlines the requirement of clinical trial conduct to ensure high scientific, ethical and financial standards are maintained throughout the course of the clinical trial. As such sites must assess all clinical trial protocols against an agreed set of criteria before undertaking clinical trial conduct.

All clinical trials taking place within (SITE) undergo a thorough feasibility assessment to determine protocol validity, site ability to comply with protocol requirements, ability to recruit the proposed participant population, current clinical trial portfolio, competing clinical trials and the registration landscape.

1. Objective

To describe the procedure of clinical trial feasibility and start-up undertaken at (SITE).

1. Scope

This SOP applies to all clinical trials coordinated by (SITE), including any trials undertaken via the Teletrials Model

1. Ownership and Responsibility

The principal investigator is responsible for obtaining the appropriate approvals prior to commencement. The administrative process of ethical and governance submission may be undertaken by an external provider, where required.

1. Glossary of Terms

Please refer to (SITE) TT-SOP-Glossary-of-Terms (see Related Documents) for full supporting glossary of terms.

1. Procedure
2. Potential Clinical Trials

All potential clinical trials undergo feasibility and site selection review process prior to acceptance:

* On receipt of the protocol or supporting documentation, (SITE) review the clinical trial in collaboration with the principal investigator. In a Teletrial, the local sub-investigator must also review the protocol and supporting documentation.
* A full feasibility assessment is commenced identifying current services across the SITE and additional services/supplies required to facilitate protocol requirements. Recruitment projection is determined and evaluated to best support the proposed participant population.
* The principal investigator presents the potential clinical trial for peer review at the (SITE) tumour stream meeting to access suitability and ability to recruit the proposed participant population taking into consideration competing clinical trials and the registration landscape. In a Teletrial, the local sub-investigator will present the potential clinical trial.
* The (SITE) team leader will review the functionality of the protocol and forecasts resources to facilitate the clinical trial.

Site selection and qualification:

* Once a clinical trial has been deemed feasible a site qualification visit may be performed between sponsor/contract research organisation (CRO), principal investigator and (SITE). The purpose of this is to evaluate the site’s ability to perform the clinical trial in accordance with the study design and protocol. In a Teletrial, the local sub-investigator will attend the site qualification visit in place of the Principal Investigator.
* Attendees may include sponsor/CRO representative(s), principal investigator, sub-investigators or (SITE) study team, as indicated and available.
* A facility tour is conducted during the qualification visit to confirm required equipment, space and services are satisfactory to facilitate the clinical trial protocol and all storage of clinical trial supplies and materials are secure with limited access.
* The sponsor/CRO representative should provide copies of relevant clinical trial materials to attendees prior to qualification visit.
* The principal investigator will confirm (SITE) has ability to recruit the proposed number of participants within the protocol specified time frame. In a teletrials, this responsibility will be delegated to the local sub-investigator.
* On request, (SITE) will provide the sponsor/CRO representative with appropriate documentation to support site qualification.
* The feasibility and study start-up coordinator will provide the sponsor/CRO representative(s) with information on (SITE) clinical trial practices including responsibilities of clinical trial personnel. (International Conference On Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1996, sec. 4.2)

1. Clinical Trial Start-Up

Once feasibility and site selection is completed the clinical trial start-up process will commence.

The following documents are completed and collected prior to site initiation visit (SIV) in collaboration with the(SITE) study team and sponsor/CRO representative, as outlined in TT-SOP-11: Essential Document Management (see Related Documents) and may be provided electronically on Site Docs Portal:

* Investigator and (SITE) study team’s abbreviated CV.
* Investigator and (SITE) team’s ICH GCP certification.
* Statement of Investigator (1572), as required.
* Financial disclosure forms (FDF), as required.
* Site specific vendor’s accreditation (as listed on 1572).
* Site qualification survey(s) as required (i.e. imaging and electronic medical record capabilities).

Before the site can be initiated and commence recruitment the following approvals must be received:

* Ethical approval, as outlined in (SITE) TT-SOP-06: Ethics and Governance with Teletrials (see Related Documents).
* Governance approval as outlined in (SITE)-TT-SOP-06: Ethics and Governance with Teletrials (see Related Documents).
* Regulatory authority acknowledgement (Therapeutic Goods Administration (TGA) via Clinical Trial Notification (CTN) or approval via the Clinical Trial Exemption (CTX)). In a Teletrial, the CTN will be managed by the primary site.

1. Site Initiation

All approvals and all clinical trial supplies (i.e. essential documents, investigator site files (ISF), laboratory manual, central sample kits, pharmacy and imaging manuals etc.) must be received at site prior to SIV, to be ready to recruit once the visit concludes. The delegation log will be completed at SIV when the study team have been suitably trained by the sponsor/CRO.

After the SIV concludes the sponsor/CRO representative will confirm the site is activated and ready commence recruitment.

1. Dissemination and Implementation

Approved SOPs can be disseminated electronically by (SITE) through Site Docs Portal. SOPs will be made available in hard copy format or electronically upon request. Any updates to the existing approved SOPs will be disseminated internally, and will be effective immediately.

1. Monitoring Compliance and Effectiveness

Compliance with this SOP will be monitored as part of the (SITE) monitoring and audit process. Any queries concerning the effectiveness of this SOP identified during the (SITE) monitoring process or through use will be addressed and may result in the requirement to update the SOP.

1. Review and Updating

This SOP will be reviewed every three years, or when changes to legislation or working practices that impact upon the content of this document. This SOP may be merged with another SOP if appropriate or removed entirely if it becomes redundant.

1. Reference(s)

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. (1996). Guideline for Good Clinical Practice E6(R1).

1. Related Document(s)

(SITE) TT-SOP-Glossary-of-Terms

(SITE) TT-SOP-11: Essential Document Management

(SITE) TT-SOP-06: Ethics and Governance

Integrated addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)