Standard Operating Procedure CCTU/SOP024

Initiation Meeting for CTIMPs

1. Scope

This SOP applies to staff involved in Cambridge Sponsored clinical trials of investigational medicinal products (CTIMPs).

This SOP does not apply to commercially sponsored trials or research sponsored by an external non-commercial organisation.

This SOP can be used as guidance for non CTIMP studies.

2. Purpose

To ensure that trials are commenced in accordance with Trust, Regulatory, Research Governance and GCP requirements.

To have a process that documents the expectations of the sponsor and the trial teams

To ensure that Investigators are fully informed of their responsibilities during the conduct of the trial and that staff involved in a Cambridge Sponsored CTIMPs are trained in the trial procedures.

3. Definitions and Abbreviations

The headings below contain the definitions of terms and meaning of abbreviations used within the document.

3.1. Definitions

Term	Definition
Cambridge Sponsored	Sponsored by Cambridge University Hospitals NHS Foundation Trust (CUH); or the University of Cambridge (UoC); or jointly by CUH and UoC OR Sponsored by: Cambridge University Hospitals NHS Foundation Trust (CUH) or CUH jointly with the University of Cambridge or Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) or CPFT jointly with the University of Cambridge
Trial Team	Includes the Chief Investigator (CI), Principal Investigator (PI), Clinical Trial Coordinator (CTC), Data Manager (DM), trial Statistician, Database Programmer, Research Nurse(s) as identified and delegated by the CI and/or Sponsor
EPIC	Electronic patient record at CUH

3.2. Abbreviations

Abbreviation	Meaning
ACRC|CCRC	Addenbrooke's Clinical Research Centre | Cambridge Clinical Research Centre
AE	Adverse Event
AESI	Adverse Events of Special Interest
AR	Adverse Reaction
CI	Chief Investigator
CRF	Case Report Form
CTC	Clinical Trials Coordinator
CTM	Clinical Trials Monitor
CTO	Clinical Trials Officer
IMP	Investigational Medicinal Product
PI	Principal Investigator
SAE	Serious Adverse Event
SUSAR	Suspected Unexpected Serious Adverse Reaction
WBIC	Wolfson Brain Imaging Centre

4. Undertaken by

Trial teams and members of the regulatory team as appropriate

5. Items Required

CCTU/FRM051 Trial Specific Training Form
CCTU/SOP047 CTIMP Start-up Procedure for Trial Teams or
CCTU/SOP048 CTIMP Start-up Procedure for the Regulatory Team
CCTU/FRM012 Trial Initiation Form
CCTU/FRM086 Participating Site Initiation Form
CCTU/TPL028 Participating Site Activation Letter
CCTU/TPL029 Trial Initiation Meeting Agenda
CCTU/FRM064 Site Initiation Checklist

6. Summary of Significant Changes

Reminder to use research tab in EPIC
More clarity in consent process

7. Method

The following sections provide a description of the processes to be followed when implementing this document's procedures.

7.1. Sponsor Site Initiation Meeting

The initiation meeting will only proceed if all documentation and responses to queries have been provided to the CTO in accordance with CCTU/SOP047 and CCTU/SOP048.

- The CTO will organise the meeting and invite all the identified trial team members and the regulatory team members according to the agenda CCTU/TPL029
- The minimum attendance should include:
    - CI/PI
    - Named co-investigators
    - Trial Coordinator and/or Research Nurses (as appropriate)
    - Allocated Clinical Trials Monitor
    - Pharmacy or IMP Manufacture e.g. WBIC representative
    - Allocated Statistician
    - Allocated Data Manager and/or Database Programmer
    - PV Coordinator
- The CI is responsible for ensuring that all relevant trial team members attend the initiation meeting as required
- Any associated departments should be invited to attend e.g. a representative from the ACRCICCRC, radiology, WBIC, nuclear medicine, etc as appropriate
- The initiation meeting agenda will be sent out to all attendees by the CTO prior to the meeting
- The meeting will be chaired by the CTO
- The CI must be present for the entire initiation meeting
- The Trial Initiation Form CCTU/FRM012 will be completed during the initiation meeting by the CTO

7.2. Participating Site Initiation Meeting

A participating site can only be initiated and opened for recruitment following the full sponsor initiation. No participating site initiation activities should be undertaken prior to this.

- The Clinical Trials Coordinator (CTC) or delegate will organise the meeting and invite all the identified participating site trial team members.
- The meeting can be conducted either face to face, by teleconference or by webinar as deemed appropriate by the CI. The minimum attendance should include:
    - PI
    - Named co-investigators
    - Research Nurses
    - Pharmacy representative

  - Allocated Data Manager
- The CTC is responsible for ensuring that all relevant trial team members attend the initiation meeting as required
- Any associated departments at the participating site should be invited to attend e.g. a representative from the clinical research facility, radiology, etc as appropriate
- The meeting will be chaired by the CTC
- The initiation meeting agenda will be sent out to all attendees by the CTC prior to the meeting
- The PI must be present for the entire initiation meeting
- The Participating Site Initiation Form CCTU/FRM086 will be completed during the initiation meeting by the Clinical Trial Coordinator

7.3. Initiation Meeting Requirements

- All attendees must record the training provided as part of the initiation meeting process on CCTU/FRM051 Trial Specific Training Form
- Presentation materials required for the meetings must be provided for the meeting by the relevant person
- Presentation materials must be provided to the trial team(s) for printing and inclusion in the TMF, ISF and Sponsor file.

As a minimum, the following topics will be covered during the initiation meeting:

7.3.1. Protocol and Trial Procedures Overview and Training

- To be generated by the CI or trial team delegate
- Trial design
- Target population and enrolment criteria
- Informed consent process, particularly where there are optional consents
- Trial specific procedures – especially where these differ from routine standard of care for the patient population
- All translational aspects of the trial
- Sample handling requirements
- Dosage modifications
- Data handling (CRF completion and submission/data entry)
- Use of any trial specific documents, SOPs and manuals etc as appropriate
- Any other information relevant to the trial

7.3.2. IMP Training

To be generated by the CI and the pharmacy representative

- Details of IMP supply and delivery
- Prescribing arrangements & forms to be used
- Route of delivery (dispensing to patient or trial team)
- IMP returns (unused medication or empty bottles for reconciliation)
- Any other information relevant to the trial

7.3.3. Pharmacovigilence Training

To be generated by the Pharmacovigilance Coordinator

- Reporting requirements for SAEs and SUSARs
- Recording requirements for AEs and ARs
- Use of the trial specific pharmacovigilence forms
- Any additional special procedures for reporting for example AESI's, onward reporting to IMP manufacturer, as appropriate

7.3.4. Monitoring Requirements

To be generated by the Clinical Trials Monitor (Sponsor) or the Clinical Trials Coordinator (Participating Site)

- The specific requirements for the monitoring of the trial will be discussed and the expectations for the provision of information and follow-up of monitoring activities provided
- A list of common monitoring findings will be provided prior to the meeting by the CTM for discussion
- Best practice guidance will be provided for the following topics as a minimum:
    - The informed consent process (including ongoing consent)
    - Recording of information for all visits in the source files & use of medical alert stickers/flags
    - TMF & ISF filing requirements
    - Compliance with the enrolment processes for the patient, including providing GP letters in a timely manner etc
    - Sample management documentation
    - Delegation log maintenance (including the inclusion of key personnel for example pharmacy representative)
- Reference cards will also be provided as appropriate

7.3.5. Sponsor Requirements (Sponsor initiation meeting only)

The specific requirements of the sponsor will be detailed in the meeting, including:

- Review of the trial initiation form information
- Recruitment of the first patient to time and target timelines
- Amendment review process and associated timelines
- Annual reporting responsibilities
- Completion of all outstanding items within the agreed timelines as per trial risk assessment
- Requirement to record training of all delegate trial team members using CCTU/FRM051 Trial Specific Training Form
- At CUH the use of EPIC to record patient visits and the appropriate use of the research tab
- Use and storage of personal identifiable data from participants
- Confirmation of the committees involved in the trial for example, Data Monitoring Committee or Trial Steering Committee

- Requirement to adhere to sponsor SOPs and the location of these
- Publication and archiving requirements

7.4. Trial Initiation Form CCTU/FRM012 (Sponsor initiation)

- Following the meeting, CCTU/FRM012 will be updated/completed by the CTO and provided for signature
- This form must be signed by the CI and the CTO
- Once fully signed, CCTU/FRM012 will be provided to :
    - The CTC and CI for inclusion in the TMF
    - The CCTU Randomisation Manager (as appropriate)
    - The CCTU Database Programmer (as appropriate)
- The sponsor letter and R&D approval will be provided once CCTU/FRM012 is fully signed
- The trial will be officially opened upon provision of the Sponsor letter and R&D approval

7.5. Participating Site Initiation Form CCTU/FRM086

- Following the site initiation meeting, CCTU/FRM086 will be updated/completed by the CTC and provided for signature
- The fully completed participating site initiation checklist CCTU/FRM064 should be provided to the CTO for inclusion in the sponsor file
- The form must be signed by the CTC and the PI of the participating site
- Once fully signed, the participating site initiation form CCTU/FRM086 and the participating site activation letter CCTU/TPL028 are:
    - Provided to the participating site for inclusion in the ISF
    - Filed in the TMF
- Confirmation of the site opening will be provided by the CTC to:
    - The CCTU Randomisation Manager (as appropriate)
    - The IMP Supplier (as appropriate)

8. Monitoring Compliance with and the Effectiveness of this Document

a. Process for Monitoring Compliance and Effectiveness

As part of routine monitoring visits, audit and inspection

b. Standards/Key Performance Indicators

This process forms part of a quality management system and is reviewed according to CCTU procedures. Standard Operating Procedures are reviewed every two years.

9. References

The Institute of Clinical Research, Abbreviations used in Clinical Trials.

MHRA, Good Clinical Practice "Grey Guide"

10. Associated Documents

CCTU/SOP039 Setting up and Opening a Participating Site

11. Equality and Diversity Statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

12. Disclaimer

It is the user's responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

Review date	2 years (or earlier in light of new evidence) from approval date
Owning department:	CCTU QA
Supersedes:	CCTU/SOP024 V1
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