Standard Operating Procedure CCTU/SOP024

Initiation Meeting for CTIMPs

1. Scope

This SOP applies to staff managing 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 unless by agreement.

2. Purpose

- To ensure that trials are commenced in accordance with Trust, Regulatory, Research Governance and GCP requirements
- To document 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 managing 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 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
CI	Chief Investigator
CTC	Clinical Trials Coordinator
CTM	Clinical Trials Monitor
CTO	Clinical Trials Officer

IMP	Investigational Medicinal Product
PI	Principal Investigator
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

More clarity in the aims section.
Criteria for when re-initiation is required.

7. Method

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

7.1. Initiation Meetings Aims

The purpose of the initiation meeting is to provide full, documented trial procedure and regulatory requirement training to all relevant trial staff to ensure compliance with the protocol, GCP & regulatory requirements. Timely trial training (initiation) and site activation is key for:

- Site staff engagement
- Prompt participant recruitment
- Protocol and trial procedure compliance
- Reduced burden of retraining and non-compliance reporting for site and central trial staff

The initiation meeting is an opportunity to for all trial staff to:

- Ask questions
- Clarify/consolidate their trial specific knowledge
- Highlight any potential issues particularly at a site level, prior to site activation and/or recruitment of the first patient. This is important at site initiation meetings where the patient pathway at a given site should be considered within the context of the protocol and assessment schedule.

- For example, does the patient visit allow time for IMP prescribing and dispensing or will this require patients to a)wait around for hours after their appointment or b) come back at a later time point
- Is a site-specific process required to manage this? If so, this should to be formalised and documented at this stage.

7.2. Sponsor Site Initiation Meeting

The initiation meeting can 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 according to the agenda CCTU/TPL029
- The minimum attendance should include:
  - CI/PI
  - Named co-investigators
  - Trial Coordinator and Research Nurses
  - Allocated Clinical Trials Monitor
  - Pharmacy or IMP Manufacture e.g. WBIC representative
  - 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 ACRC/CCRC, 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 generated by the CTO

7.3. 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.

Initiation meetings should only be scheduled once all essential documentation has been returned from the site and contracts are ready for signature. Delays between initiation and site activation should be avoided whenever possible.

- 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. 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 by the Clinical Trial Coordinator

7.4. 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
- The time frame between site initiation and site activation (both Sponsor and participating site initiations if applicable) should be as short as possible
- This will be communicated to the trial team by the CTO at the Sponsor initiation meeting and can be found in the risk assessment
- If this is not met a second site initiation visit will be required prior to the site opening

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

7.4.1. Training

Protocol and Trial Procedures Overview

To be generated by the CI or trial team delegate and cover all aspects of the trial design and trial procedures, including the recruitment process, sample and data handling and system usage, Patient safety (withdrawal criteria, safety assessment and review, dose reduction and cessation criteria.)

IMP Overview

To be generated by the CI and the pharmacy representative and cover all aspects of trial level and local site IMP management, prescribing, dispensing & administration, treatment titration (if applicable), criteria for stopping treatment.

Pharmacovigilance Overview

To be generated by the Pharmacovigilance Coordinator and cover all aspects of safety data management, categorisations and onward reporting responsibilities.

Monitoring Overview

To be generated by the Clinical Trials Monitor (Sponsor) or the Clinical Trials Coordinator (Participating Site) to include key aspects of the monitoring process, expectations for source data, EPIC and essential document management, non-compliance reporting processes and expectations (including timelines.)

Sponsor Requirements (Sponsor initiation meeting only)

Sponsor specific requirements will be detailed in the meeting, including:

- Requirement to record training of all delegate trial team members using CCTU/FRM051 Trial Specific Training Form
- Attendance at TSC/IDMC meetings
- Requirement to adhere to sponsor SOPs and the location of these

7.5. 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 and onward notification to the relevant systems providers (eg database programmer)
- The trial will be officially activated (opened to recruitment) upon provision of the following:
- The Sponsor letter
- The site activation email from the CTO
- Evidence of a functional database (unless approved by Sponsor in limited and risk assessed circumstances)
- A final review of the risk assessment just prior to trial activation, to ensure it is still fully applicable
- The review will be documented and any changes required will be implemented in accordance with this SOP

7.6. Participating Site Initiation Form CCTU/FRM086

- Following the site initiation meeting, the site initiation form CCTU/FRM086 will be updated/completed by the CTC and provided for signature
- The form must be signed by the CTC and the PI of the participating site
- The fully completed participating site initiation checklist CCTU/FRM064 should be provided to the CTO for inclusion in the sponsor file as confirmation of site activation
    - If the site is outside of the site initiation & activation window permitted in the trial risk assessment, the CTO will confirm if a re-initiation meeting is required
- 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 IMP Supplier (as appropriate)

7.7. Re-Initiation meetings

- Following the initiation meeting, if there are delays with site activation outside of the activation window stipulated in the trial risk assessment, a full re-initiation meeting will be required
- During the trial, if there is a change of CI or PI, the trial and/or site must be re-initiated. The level of re-initiation will be determined in conjunction with the CTO & CTM, by risk assessing the trial specific experience/involvement of the new CI/PI and also any other significant changes that have occurred within the trial since last initiation meeting/documented training event

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
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