Standard Operating Procedure CCTU/SOP045

Selection and Use of Vendors

1. Scope

The standard operating procedure (SOP) applies to trial-specific arrangements with vendors and contractors used in CCTU Led Cambridge Sponsored clinical trials

This SOP does not cover:

- Vendors and contractors for the provision of investigational medicinal products and related services, this should be discussed with the trial pharmacist
- The selection of participating sites
- Procurement processes
- The setting up of contracts
- The assessment of laboratories

2. Purpose

The purpose of this SOP is to:

- Ensure consistency and quality of functions or services
- Describe the process for the selection, evaluation, approval and oversight of external vendors (suppliers) and contractors of functions related to:
    - The understanding and compliance with Good Clinical Practice
    - Trial conduct
    - Trial management and Coordination (e.g. project management, monitoring)
    - Other trial related services (e.g. data management, data archiving, archiving, statistics, sample shipments)

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 jointly by CUH and UoC or Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) or CPFT jointly with the University of Cambridge
Collaborator	A person or organisation that works jointly on the trial and is wholly responsible for their role in the trial.

Sponsor	An individual, company, institution or organisation that takes responsibility for the initiation, management, and/or financing of a clinical research project or trial.
Vendor/contractor	A person, organisation, or agency that provides functions and services related to the conduct of clinical trials but shall exclude research collaborators and clinical trial participating sites/investigators.

3.2. Abbreviations

Abbreviation	Meaning
CCTU	Cambridge Clinical Trials Unit
CI	Chief investigator
CTC	Clinical Trials Coordinator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTO	Clinical Trials Officer
CTU	Clinical Trials Unit
CUH	Cambridge University Hospitals NHS Foundation Trust
QA	Quality Assurance
TMF	Trial Master File
UoC	University of Cambridge

4. Undertaken by

The CCTU Operations Director, Quality Assurance (QA) Manager, Regulatory Team, Chief Investigator (CI) and delegated trial team members

5. Items Required

CCTU/TPL084 Initial Vendor Assessment Form

CCTU/TPL085 Follow Up Vendor Questionnaire

CCTU/TPL091 Sponsor Response Form

CCTU/GD057 Use of the Vendor Module in Q Pulse

6. Summary of Significant Changes

All vendors should be identified and assessed as accepted for use before the start of the trial

7. Method

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

7.1. Responsibilities

- The Sponsor retains ultimate responsibility for all functions

- The CI is responsible for identifying the trial functions that may be outsourced to an external vendor and for determining the level of risk associated with the tasks being delegated
- The CI or delegate is responsible for selection, and assessment of any vendors they wish to use in their trial, including periodic review of existing vendors
- The trial team are responsible for sending updated trial documents to vendor(s) wherever appropriate
- The QA Manager is responsible for maintaining the vendor register

7.2. Requirements of Vendor

Vendors must have sufficient, demonstrable knowledge and experience to perform their delegated functions and contractual obligations.

- Vendors that perform trial-specific responsibilities must be able to demonstrate that they are:
    - Trained to applicable sections of the trial protocol
    - Have systems to report potential serious breaches to the sponsor
    - Aware of all relevant trial specific documents (including updated versions of documents implemented during the trial)
    - Where appropriate, trained to CCTU procedures, Sponsor requirements and computer systems
    - In possession of applicable employment documentation for provision of services to the NHS

7.3. Identification of a Suitable Vendor

Prospective vendors (for laboratories follow CCTU/SOP071) should be identified as early in the trial set-up process as possible. They must meet the operational requirements of the CCTU.

Before the start of the trial there must be an assessment accepted by The CCTU logged in Q Pulse this includes vendors used within the trial and at the end of the trial

The following criteria may be used to identify suitable vendors:

- Previous experience with the vendor(documented in the Q Pulse vendor module)
- Approved NHS and/or University suppliers (depending on procurement via Trust or University)
- Recommendations from other users
- Recommendations by funding body and/or Sponsor
- In the first instance check the vendor module in Q-Pulse refer to CCTU/GD057 Use of the Vendor Module in Q Pulse
    - Is the vendor known to the CCTU
    - Has a previous assessment has been carried out
- This will determine if this is a new vendor of if further assessment is required

7.3.1. New Vendors (Appendix1)

The ability of a vendor to provide the service or product according to specification and on time can be evaluated by requesting the provider to complete the vendor assessment form CCTU/TPL084 or the University equivalent.

- CTC will forward the completed questionnaire to the CCTU in box
- The QA manager will add the proposed vendor to the Q Pulse vendor module as pending and upload any documentation
- If the QA manager is informed of a vendor before receipt of the documents the vendor module can be populated and recorded under questionnaire sent

7.3.2. Existing Vendors

- If a proposed vendor has supplied the same service to another trial and has been accepted for use by the CCTU check the previous assessment to determine if further information is required
- If no further assessment is required confirm this with the CCTU QA Manager who will add this trial to the record in Q Pulse

7.4. Amending an Existing Vendor

- Where an existing vendor has previously supplied a:
  - Different service or supplies to another trial
  - New service during the course of this trial
- The vendor will be assessed for the new service/supplies as a new vendor
- A new vendor assessment form (CCTU/TPL084) should be completed and submitted for review
- The trial risk assessment form should be updated if necessary and reviewed and agreed by the relevant trial team members and Sponsor representative

7.5. Review

The reviewers usually the QA Manager and the CCTU Operations Director will:

- Review and upload the documents submitted into Q Pulse
- Populate and upload the sponsor response form
- If the vendor is not initially accepted the QA /designee will advise the CTC if any supporting documentation/actions are required
- Change the status of the review using the status box in q pulse on a case by case basis to either:
  - CCTU Not accepted
  - Questionnaire sent
  - Pending

If accepted

- Populate and upload the Sponsor Response Form CCTU/TPL091 and send a copy to the CTC
- Update the status box
- Populate the acceptance date

- Set a renewal date for reassessment on a case-by-case basis.
- Reminders for reassessment will automatically be sent to the CTC via Q pulse

- The CTC can track progress using the vendor module refer to CCTU/GD057 Use of the Vendor Module in Q Pulse

7.6. Contracts

Once a vendor has been selected to provide a trial related service an appropriate contract between the Sponsor(s) and the appropriate legal team must be negotiated with the vendor

7.7. Maintaining Oversight and Ongoing Vendor Assessment

The process of ensuring vendor oversight and the associated risk rating should be documented in the TMF and Sponsor file see appendix 1.

Oversight can be maintained by methods such as:

- Regular communications with the vendor (e.g. teleconferences or regular meetings). A formal communication plan can be developed to define the level and frequency of communication between parties
- Review of specific activities
- Regular written update reports from the vendor
- Periodic review of the standard of work completed to date including frequency of review
- Review and reassessment according to the frequency set in Q Pulse this is determined on a case by case basis

- The QA Manager/designee will liaise with the CTC and ensure that follow up vendor questionnaires (CCTU/TPL085) are completed and kept in the vendor module of Q-Pulse.
- The form will be reviewed by the Regulatory& Quality Manager for CTIMPs and QA Manager for Non CTIMPs If there have been:
  - No changes since the previous assessment the form will be filed with a new review date in Q pulse, and the process repeated as required
  - Changes have occurred in the past year then the changes should be evaluated for their impact on the trial(s)
  - The sponsor response form will be populated and a copy sent to the CTC

7.8. Vendor Register

The QA Manager/designee will maintain a central register of vendors in Q-Pulse

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

R&D/SOP005 Management of Contracts for Research Projects
CCTU/GD057 Use of the Vendor Module on Q Pulse

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/SOP045 V4
Local reference:	CCTU/SOP045 V5

Appendix 1: New Vendor selection process flow chart