STU-SOP-TS-004 – Standard Operating Procedure on Selection and Oversight of Vendors

1. Purpose and Definitions

This Standard Operating Procedure (SOP) describes the procedure for selection, evaluation and oversight of vendors for functions, services or products required for clinical trial conduct and management for clinical trials which are on the Swansea Trials Unit (STU) portfolio. The method used for assessing the suitability of the vendor will depend on the risk associated with the task/service required and previous experience of the vendor.

Definitions	
Vendor	A person, organisation, agency, supplier or service provider contracted by SU and/or a collaborating organisation to provide functions, services or products related to the conduct of trials. Note: *The above definition does not include research collaborators or trial sites for a research project but does include Clinical Trials Units, Laboratory Services (even if they are internal to SU and/or the collaborating organisation) and Contract Research Organisations including drug and/or medical device suppliers/distributors.*
Clinical trial	For this standard operating procedure (SOP), 'clinical trial' shall mean any research project which is looking at the safety or efficacy of a medicine / foodstuff / device. This would include such trials whether or not they fall under the remit of the UK regulations as a Clinical Trial of an Investigational Medicinal Product (CTIMP) or the applicable device trial regulations.

2. Background

Clinical trials, as defined above, may require services from a different institution or commercial entity external to the organisation(s) with sponsor responsibilities. These are known as a 'vendor', a 'supplier' or 'third party service provider'. This SOP refers to 'vendors'.

The sponsor may delegate tasks associated with a trial to the Chief Investigator (CI) and to vendors. Regardless of delegation, the sponsor retains responsibility for the clinical trial and ensures compliance with applicable legislation and Good Clinical Practice (GCP).

Vendors must show due diligence when performing any delegated functions.

3. Roles and Responsibilities

Sponsor has responsibility to facilitate appropriate oversight of vendors, and to ensure the development and completion of appropriate contracts with vendors. Some tasks may be delegated to the CI.

Swansea Trials Unit (STU) when assigned by CI or sponsor, has responsibility to ensure completion of proportionate due diligence for potential and contracted vendors on clinical trials included on the STU portfolio. This is normally undertaken by STU Quality Assurance (QA) personnel. STU QA or delegate will document the assessment of the vendors and liaise with

expert sponsor staff e.g. Clinical Trials Pharmacist (CTP) and finance staff to raise any identified issues as required with the sponsor or delegate.

Chief Investigator (CI) has responsibility for identifying potential vendors and ensuring that trial tasks do not begin until the relevant contracts and approvals are in place. The CI is also responsible for providing the approved protocol, any amendments and any other documents required by the vendor. The CI may delegate any or all their responsibilities as appropriate to suitably qualified individuals.

External use of SOP: this SOP and Associated Documents (AD) may be used for research projects not adopted by STU where Swansea University (SU) staff and associated NHS organisations require guidance. In such instances, oversight responsibility for any associated tasks will not be the responsibility of STU.

4. Procedure

4.1 Identification of a suitable vendor

During clinical trial development, the CI as sponsor delegate will identify the requirement for vendors and confirm a budget is available for the activity.

When required, STU will aid in the identification of prospective vendors using the following criteria where appropriate:

- Previous positive experience of vendor;
- Review of marketing material;
- Preferred providers list of University/NHS organisation/Sponsor (depending on procurement);
- Recommendations from other credible users e.g. UKCRC registered Clinical Trials Units;
- Review of vendor Quality Management System and written procedures;
- Recommendations from the funding body or sponsor
- Complete a competency questionnaire;
- Obtain suitable references;
- Conduct an audit of the vendor's facilities.

The CI or delegate will initiate proportionate, pre-contract due diligence checks on any required vendor. This may include requesting copies of relevant accreditations /certificates/licences or requesting references. The CI or delegate will complete a Vendor Assessment Questionnaire (STU-AD-FRM-014) to record the evaluation(s) performed at this stage.

Should an alternative vendor need to be identified, required due diligence checks will be repeated.

4.2 Procurement of a product/service

The pathway for procurement will depend on where the research grant/funding is held:

- If Swansea University (SU) hold the grant, procurement should be initiated via SU procurement team.
- If an NHS organisation holds the grant, procurement should be initiated via their pathways. Contact is usually through the R&D team.
- Procedures for all external sponsors will be followed as required.

Where procurement requires specialist or technical knowledge input from specialists will be sought e.g. if an Investigational Medicinal Product (IMP) is required, this must involve a Clinical Trials Pharmacist.

STU will liaise with the sponsors, REIS, vendors and NHS organisations where required to aid with contract completion in relation to vendor approval.

4.3 Trial Set-Up

The CI will confirm the vendors they wish to engage to deliver specific research activities. If there has been a period of greater than 6 months prior to identification the process will be reviewed and repeated as required.

When further assessment of a vendor's capability is required, a Vendor Competency Questionnaire (STU-AD-FRM-015) will be completed at this stage.

As required STU QA or delegate will coordinate any further proportionate due diligence on vendors e.g. request copies of relevant accreditation or licenses, obtain references, conduct audits. Due diligence will be documented and sponsor processes followed for review.

Oversight of vendors will be documented in the monitoring plan prior to the commencement of the service being provided.

Evidence of selection and review of vendors will be documented in the Trial Master File (TMF).

For vendors providing laboratory services a Laboratory Services Requirements questionnaire (STU-AD-TMP-018) must be completed by the CI and Laboratory Manager prior to contract set up with the vendor. Should the vendor use their own contract template STU QA will assess whether a separate Laboratory Services Requirements is also required.

All local contracts required for the vendors will be completed in alignment with STU-SOP-TS-001 Contracts or external sponsor processes where required.

Vendors will be reviewed at least annually for the duration of the clinical trial. Sponsor processes for ongoing/annual review will be followed where applicable.

4.4 Vendor Oversight

Oversight will be maintained for the duration of the vendor's activities usually involving the TM or CI. This can be in the form of:

- Regular contact with vendors throughout the trial, ensuring that key correspondence and meeting minutes are documented and retained in the TMF.
- Regular written update reports from the vendor
- Periodic review of the standard of work and activities completed to date
- Including the vendor in discussion and dissemination of amended key trial documents. The CI will notify the appropriate sponsor contact when a change to contract(s) is required.
- Developing an escalation plan for reporting significant non-compliance issues as documented in the contract between the Sponsor and vendor.
- STU QA or delegate will raise any identified issues with vendor performance with the sponsor and coordinate appropriate intervention to facilitate resolution with the vendor.

Should an alternative supplier be required, the due diligence described in section 6.1 will be repeated.

4.5 Project Closure

At project closure, feedback on overall vendor performance will be reviewed by the CI and sponsor. Feedback will be documented and used in the assessment of vendors for future trials.

5. References

- Health Research Authority website (HRA) - http://www.hra.nhs.uk/
- Medicine and Healthcare products Regulatory Agency website (MHRA) - https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information
- UK policy framework for health and social care research (2017) - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- UK Medicine for Human Use (Clinical Trials) Regulations 2004 - http://www.legislation.gov.uk/uksi/2004/1031/contents/made
- UK Medical Devices Regulations 2002 - http://www.legislation.gov.uk/uksi/2002/618/made

It is assumed that by referencing the principal regulations that all subsequent amendments are included in this citation.

6. Associated Documents

Number	Title	Location
STU-AD-FRM-014	Vendor Assessment Questionnaire	Q-Pulse
STU-AD-TMP-018	Laboratory Services Requirements	Q-Pulse
STU-AD-FRM-015	Vendor Competency Questionnaire	Q-Pulse

7. Abbreviations

List of Abbreviations	
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
MHRA	Medicines and Healthcare products Regulatory Agency
QA	Quality Assurance
R&D	Research and Development
REIS	Research, Engagement and Innovation Services
REC	Research Ethics Committee
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
SU	Swansea University
TM	Trial Manager
TMF	Trial Master File (may also be called a project or research file)

8. Appendices

Appendix 1: Document History

Version No:	3	**Effective Date:**	26-Mar-2024
Description of changes:	Transferred to SOP template v5 Minor changes to process and vocabulary corrected.		