VENDOR ASSESSMENT

DOCUMENT NO.:	**QA009 v5.0**
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1 INTRODUCTION

1.1 The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).

1.2 Sponsors must maintain oversight of vendors, also termed as suppliers or third party providers, which provide services in the conduct of clinical trials, as they retain ultimate responsibility for the trial.

1.3 Vendors must be suitable to carry out the delegated tasks and must show due diligence when performing the required service. Assessment of vendor suitability by the Sponsor can be carried out using a variety of methods, as detailed in this Standard Operating Procedure (SOP).

2 PURPOSE

2.1 This SOP defines the process to evaluate current and potential vendors who provide services for clinical research sponsored by NHSL and/or the UoE.

3 SCOPE

3.1 This SOP applies to the Chief Investigator (CI), Sponsor Representative(s) (from the UoE and/or NHSL Research Governance team) and Quality Assurance (QA) staff.

3.2 Clinical research covered by this SOP is most often CTIMPs/CIMD (Clinical Trials with Investigational Medicinal Products/Clinical Investigations with Medical Devices), but may also include other invasive, experimental or complex research involving one or more research sites subject to a Combined Risk Assessment (GS002).

3.3 This SOP also covers the evaluation of vendors who provide services relating to the Sponsor Quality Management System (QMS) and study management functions e.g. monitoring, data management, statistics, archiving, etc.

4 RESPONSIBILITIES

4.1 The Sponsor Representative (from the UoE and/or NHSL Research Governance

team) is responsible for highlighting new potential vendors or new services provided by existing vendors, during the Combined Risk Assessment process (GS002 Combined Risk Assessment) or on receipt of protocol amendments (GS011 Sponsor Approval of Amendments). Furthermore, they are responsible for the initiation of contracts with potential vendors, if deemed appropriate.

4.2 The QA Manager, or designee, is responsible for assessment/reassessment of vendors, and for maintenance of the ACCORD List of Vendors on the ACCORD SharePoint. In addition, the QA Manager, or designee, will ensure vendors have appropriate access to current and updated ACCORD SOPs.

4.3 The Senior Clinical Trials Monitor is responsible for ensuring contract monitors are appropriately trained and have the necessary qualifications to carry out their role and that there is a contract within ACCORD (UoE and/or NHSL), where applicable.

4.4 The CI, or designee, is responsible for highlighting potential vendors to the Sponsor Representative and ensuring the QA Manager is aware of updates to vendor during study conduct. The CI is also responsible for ensuring that no work is conducted by a new vendor until they have been assessed and approved by the Sponsor.

5 PROCEDURE

5.1 Vendor Identification

5.1.1 New potential vendors, or additional services provided by existing vendors, will be identified by the CI and study team and will be highlighted during the Combined Risk Assessment (GS002 Combined Risk Assessment) or on receipt of protocol amendments (GS011 Sponsor Approval of Amendments). Vendors may be identified from; previous experience, approved NHSL/UoE suppliers, recommendations from accredited units/funding body etc. New potential vendors may also be identified by ACCORD members of staff in relation to the ACCORD QMS.

5.1.2 If considered appropriate, the QA Manager, or designee, will add the potential vendor to the ACCORD List of Vendors located in the QA Vendors Folder on the ACCORD SharePoint. The potential vendor will be listed as ‘to be approved’.

5.1.3 The Sponsor Representative will advise the CI that no study specific activities can be initiated until the vendor assessment is complete and the vendor has been approved by the QA Manager, or designee, and if applicable contracts are in place.

5.2 Vendor Evaluation

5.2.1 The method for assessing the suitability of a vendor will vary depending on previous experience/knowledge of the vendor and risks as identified during the Combined Risk Assessment (GS002 Combined Risk Assessment). The process for Sponsor oversight of vendor selection/evaluation may be documented in the Combined Risk Assessment if there is a level of risk associated with the tasks being delegated. Where applicable, a vendor oversight plan may be implemented to track multiple vendors for a study. The need for a Vendor Oversight Plan (QA009-T04) will be documented in the Combined Risk Assessment.

5.2.2 Study specific activities that involve a new vendor, or the addition of services from an existing vendor, the QA Manager, or designee, in collaboration with the Sponsor Representative and CI, will determine whether assessment should be conducted via a pre-qualification Quality Questionnaire (QA009-T01 GMP Quality Questionnaire or QA009-T02 Lab Quality Questionnaire or QA009-T03 Vendor Questionnaire). Where appropriate, the Sponsor Representative may initiate a contract with the vendor in tandem to the vendor assessment by the QA Manager.

5.2.3 If considered appropriate, the QA Manager, or delegate, will send the appropriate Quality Questionnaire to the vendor and follow up to completion.

5.2.4 An assessment of a vendor by the QA Manager, or designee, may include a review of the relevant staff curriculum vitae (CV), accreditation certificates, remote audit of the vendor quality system and written procedures or obtaining references. If the vendor has been subject to an audit by a collaborating unit within the co-sponsors organisations (e.g. Edinburgh Imaging), the QA Manager will review the audit report, assessing the suitability of the vendor and whether study specific activities fall under the scope of the audit conducted by the collaborating unit.

5.2.5 If deemed necessary by the QA Manager, or designee, a pre-qualification/facility audit will be conducted by the QA Manager and/or designee (QA002 Audit Preparation, Conduct and Reporting).

5.2.6 Where the services of a contract monitor/auditor are required, this will be documented in the combined risk assessment (GS002). The Clinical Trials Monitor will ensure the contract monitor is appropriately trained and has the necessary qualifications to carry out their role. There may also be a requirement to initiate a contract with ACCORD (UoE and/or NHSL), where applicable. The Clinical Trials Monitor will inform the QA team once review is complete. The QA Administrator will file and maintain all documents reviewed by the Clinical Trials Monitor in central QA files on SharePoint and update the Contract Monitor/Auditor GCP Training tracker.

5.2.7 The QA Manager, or designee, will inform the CI, research team and Sponsor Representative once the vendor assessment and/or audit is complete and the

vendor is considered as 'Approved' for use. The QA Manager, or designee, will add the approved vendor to the ACCORD List of Vendors located in the QA Vendors Folder on the ACCORD SharePoint. The potential vendor will be listed as 'approved'.

5.2.8 The QA Manager, or designee, will ensure vendors have appropriate access to current and updated ACCORD SOPs by adding the vendor contact to the ACCORD SOP distribution list.

5.2.9 The QA Manager, or designee, will save any vendor assessment documents and communication to the appropriate vendor folder located in the QA Vendors Folder on the ACCORD SharePoint and to the appropriate study Trial Master File (TMF) or Sponsor File.

5.2.10 If during the conduct of the research project there is an addition of a vendor or a change to a vendor including addition of services of an existing vendor the CI, or designee, will inform the QA Manager. The QA Manager, or designee, will conduct a vendor evaluation following section 5.2.

5.3 Status of Vendors

5.3.1 The QA Manager, or designee, will assign the current status of vendors within the ACCORD List of Vendors located in the QA Vendors Folder on the ACCORD SharePoint; vendors may be designated as 'Approved', 'Pending Approval' or 'Not Approved'.

5.3.2 If, following assessment, a vendor represents an unacceptable risk to the conduct of the study, then the status of the vendor will be set to 'Not Approved' and the decision will be communicated to the CI, Sponsor Representative and NHSL Head of Research Governance.

5.3.3 If a suitable vendor has yet to be identified or approved by QA prior to Sponsor Authorisation To Open (SATO) this will be escalated to the Senior Management Team who will make an assessment on whether a study can begin recruitment with the vendor status set as 'Pending'. A member of the Senior Management Team will communicate this to the CI via e-mail.

5.3.4 The ACCORD List of vendors will form the 'preferred providers' list and vendors which are designated as 'Approved' may be selected by individuals conducting a trial Sponsored by NHSL and/or the UoE as long as the service falls under the initial approval scope. If the vendor is requested to provide services which do not form part of the 'approved' status, then further evaluation will be required following section 5.3.

5.3.5 The QA Manager, or designee, will update the ACCORD List of Vendors with any required changes.

5.4 Review of Vendors

5.4.1 Vendors will undergo a re-evaluation as part of QA003 (Risk Analysis used to Develop Annual Audit Schedules).

5.4.2 Where applicable, the QA Manager, or designee, will contact the vendor to enquire whether there have been any procedural or staff changes and determine whether re-assessment by questionnaire or audit of the vendor is required in the coming year and if the frequency of audit needs to be amended.

6 REFERENCES AND RELATED DOCUMENTS

- QA009-T01 GMP Quality Questionnaire
- QA009-T02 Lab Quality Questionnaire
- QA009-T03 Vendor Questionnaire
- QA009-T04 Vendor Oversight Plan
- GS011 Sponsor Approval of Amendments
- GS002 Combined Risk Assessment
- QA002 Audit Preparation, Conduct and Reporting
- QA003 Risk Analysis used to Develop Annual Audit Schedules
- Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples

7 DOCUMENT HISTORY

Version Number	Effective Date	Reason for Change
1.0	15 APR 2016	New SOP.
2.0	19 APR 2018	Change of author. Minor administrative changes
3.0	28 MAR 2019	Addition of vendor questionnaire QA009-T03. Added responsibility for Sponsor Representative to initiate vendor contracts, if applicable. In addition, added responsibility of the Senior Clinical Trials Manager to review contract monitor qualifications. Escalation process of vendor disqualification added. Minor clarifications made throughout.
4.0	16 FEB 2021	Reference to use of vendor oversight plan (QA009-T04) at section 5.2.1. Section 5.3.3 added to detail escalation process regarding vendor status to the Senior Management Team.
5.0	28 FEB 2024	Section 5.2.6 updated with regards to approval of contract monitors/auditors. Clarification added at section 5.2.7 regarding vendor approval status.

8 APPROVALS

Sign	Date
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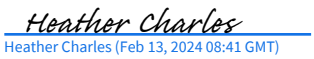
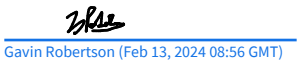
 Heather Charles (Feb 13, 2024 08:41 GMT) APPROVED: Heather Charles, Head of Research Governance, NHS Lothian, ACCORD	Feb 13, 2024
 Gavin Robertson (Feb 13, 2024 08:56 GMT) AUTHORISED: Gavin Robertson, QA Coordinator, NHS Lothian, ACCORD	Feb 13, 2024

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