Site Feasibility

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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 International Conference Harmonisation (ICH) Good Clinical Practice (GCP) E6 (R2) section 4.1 states: '*the investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial'.* The Sponsor must ensure the investigator and host organisation(s) are competent and can manage and perform their delegated sponsor functions. For this a pre-assessment of the capabilities of the investigator and host site should be initiated capturing whether the inclusion of each site in the study is feasible in terms of the resources required, recruitment capability and finance.

2 Purpose

2.1 To describe the processes of site feasibility and site selection, to be applied to each Clinical Trial of an Investigational Medicinal Product (CTIMP), Clinical Investigation of a Medical Device (CIMD) and other selected complex studies sponsored by the NHSL and/or UoE which will be subject to a Combined Risk Assessment as per ACCORD SOP GS002.

3 Scope

3.1 This Standard Operating Procedure (SOP) applies to investigators, trial management staff and trial site staff designing and participating in complex studies sponsored by NHSL and/or UoE where a combined risk assessment is deemed appropriate.

3.2 This SOP also applies to ACCORD Clinical Trials Monitors and NHSL and UoE Sponsor Representatives (including Heads of Research Governance, Principal R&D Manager,

Research Governance Manager, Clinical Research Facilitator and Research Governance Coordinators).

4 Responsibilities

4.1 The Sponsor(s) is responsible for selecting appropriate investigator sites to conduct clinical trials. This task is delegated to the Chief Investigator (CI), or designee (for example Trial Manager).

4.2 The CI, or designee, is responsible for assessing the suitability of Investigator sites for their trial, filing the completed feasibility assessment documentation in the Trial Master File (TMF) and informing the site of the outcome of the feasibility assessment process.

4.3 The Principal Investigator (PI), or designee, is responsible for completing the feasibility assessment for their trial site and ensuring the completed feasibility form is filed in the Investigator Site File if the site is taken forward.

4.4 The assigned Sponsor Reviewer, as defined by GS003 (Sponsorship Approval), is responsible for;

- Review of the feasibility assessment conducted by the CI or designee
- Informing QA of any outsourcing of trial procedures or use of unaccredited labs identified
- Passing the completed feasibility questionnaire to the lead Clinical Trial Monitor and advising the CI, or designee, of the outcome of the Sponsor site suitability review.

4.5 Where sites include the addition of vendors, the QA Manager or QA Coordinator will be responsible for assessing vendor suitability following SOP QA009 (Vendor Assessment).

4.6 The Clinical Trials Monitor, or designee, is responsible for assessing the risk associated with an individual investigator site by completing the site specific risk tool and filing the completed feasibility questionnaire including Sponsor suitability assessment with in the Sponsor File held by ACCORD.

5 Procedure

5.1 Assessing Feasibility

5.1.1 The Feasibility Questionnaire (GS013-T01) will be used by the CI, or designee, to document and collect information in order to assess the suitability of an Investigator site, GS013-T01 will be completed for each hospital site unless otherwise agreed by the Sponsor Reviewer or designee. For single site trials which include only hospital locations in NHS Lothian, feasibility information for the site is considered at combined risk assessment (GS002) and therefore GS013-T01 will only be completed if a specific risk to feasibility is identified. A requirement to complete GS013-T01 will be documented in the combined risk assessment tool (GS002-T01).

5.1.2 GS013-T01 will be targeted and adapted for the study and site specificity (including international sites), by the CI or designee, and submitted to the Sponsor Reviewer, or designee, prior to the Combined Risk Assessment (GS002).

5.1.3 Specific questions and content to be included in the Feasibility Questionnaire (GS013-T01) will be agreed by the assigned Sponsor Reviewer and lead Clinical Trial Monitor post Combined Risk Assessment via email. Locked sections within the template will not be removed by the CI, or designee, without prior agreement from the assigned Sponsor Reviewer and lead Clinical Trial Monitor. Feasibility Questionnaires (GS013-T01) will not be circulated to sites until after the study specific content has been agreed by all relevant parties.

5.1.4 Minimum requirements for inclusion of sites e.g. recruitment target; site team experience; facilities; electronic health records (EHR) will be discussed and agreed upon between the assigned Sponsor Reviewer and the CI, or designee, This pre-defined criteria will be documented in email correspondence and at combined risk assessment.

5.1.5 The CI, or designee, will send the trial specific feasibility questionnaire to each site when confirmation is received of each respective site's intended participation.

5.1.6 The trial specific feasibility questionnaire will be completed by the site PI or designee, and returned to the CI, or designee. The signed and completed section 1 will be filed in the Investigator Site File (ISF), if the site is taken forward to conduct the trial, by the PI or designee.

5.1.7 The CI, or designee, will assess the suitability of the site to conduct the trial according to the pre-defined criteria agreed with the assigned Sponsor Reviewer. The outcome of the suitability assessment will be documented in section 2 of the feasibility questionnaire. The completed section 1 and 2 will be filed in the Trial

Master File by the CI, or designee, where maintenance of this file is delegated by the Sponsor.

5.1.8 The CI, or designee, will return the feasibility questionnaire, with sections 1 and 2 completed, to the Sponsor Reviewer, or designee.

5.1.9 The Sponsor Reviewer, or designee, will review the site suitability. The outcome of the review will be documented in the section 3 of the feasibility questionnaire. Where the study team have selected to take a site forward to become an Investigator site the Sponsor Reviewer will ensure the site meets the pre-defined criteria previously agreed (see section 5.1.4). Any issues identified at review will be escalated to the CI, or designee via email.

5.1.10 The Sponsor Reviewer will inform the ACCORD QA team of any proposed outsourcing of clinical trial activity or use of additional vendors, including unaccredited labs, identified on review of the questionnaire. The QA team will assess vendor suitability following SOP QA009 (Vendor Assessment).

5.1.11 Once the Sponsor Reviewer has resolved any issues and has signed section 3, they will pass the completed questionnaire to the assigned lead Clinical Trials Monitor with the QA mailbox in CC for QA to obtain UKAS accreditation information as applicable (see section 5.2).

5.1.12 The Sponsor reviewer will inform the CI, or designee, of the outcome of the Sponsor site suitability review by email. Where the CI, or designee, and Sponsor Reviewer agree to take a site forward with additional support the Sponsor Reviewer will discuss and agree the additional steps required with the CI, or designee. The Sponsor Reviewer will file these email communications in the Sponsor File held in ACCORD. Where a site is rejected by the CI or Sponsor they can resubmit an amended feasibility questionnaire for consideration at a later date if circumstances at the site change.

5.1.13 Where the study team have selected not to take a site forward the Sponsor Reviewer will complete section 3 of the questionnaire and file in the Sponsor file held by ACCORD.

5.1.14 The CI or designee will inform the PI or designee at the Investigator site of the outcome of the feasibility assessment. If they have been assessed as suitable to take part in the study a copy of the email confirmation will be filed by the PI or designee in the ISF along with the feasibility questionnaire.

5.2 Assessing Site Specific Risk

5.2.1 Where required the lead Clinical Trials Monitor, or designee, will allocate a site specific risk level (high, medium, low) to the Investigator site using GS013-T02. The risk level assigned will be documented in section 4 of the feasibility questionnaire by the lead Clinical Trials Monitor. The requirement for Individual site risk levels will be documented at the combined risk assessment (GS002). Monitoring strategies for low, medium and high risk sites will be documented in the study specific monitoring plan (CM004 Developing a Monitoring and SDV plan) and will be applied according to the site risk level allocated by GS013-T02.

5.2.2 The lead Clinical Trial Monitor will file the completed feasibility questionnaire in the Sponsor File held by ACCORD.

5.2.3 The feasibility questionnaire must be completed prior to Site Initiation Visit (CM001 Site Initiation and Sponsor Authorisation).

5.3 Change of PI at Site

5.3.1 For sites where the Lead Monitor, or designee, is allocating a site specific risk level, if there is a change of PI at site following completion of the feasibility questionnaire the Sponsor Reviewer, or designee, will provide the PI specific questions from the feasibility questionnaire (e.g. PI experience and percentage of PI time) to the new PI, or designee, via email for consideration. The Sponsor Reviewer will provide the answers to these questions to the Lead Monitor who will confirm whether these change the site specific risk level currently assigned to that site.

5.3.2 The Monitor will inform the Sponsor Reviewer, or designee, of the outcome via email. The Monitor will file this correspondence, and the email containing the new PI answers, in the Sponsor File held by ACCORD.

5.3.3 The Lead Monitor, or designee, is responsible for informing the CI (or designee) of any change to the assigned site specific risk level where required. The Monitor will file this correspondence in the Sponsor File held by ACCORD.

6 References and Related Documents

- GS013-T01 Feasibility Questionnaire
- GS013-T02 Feasibility Site Risk Indicator
- FA001 Facilitating a Regulated or Complex Research Project
- GS002 Combined Risk Assessment

- GS003 Sponsorship Approval
- CM001 Site Initiation and Sponsor Authorisation
- CM004 Developing a Monitoring and SDV plan
- QA009 Vendor Assessment

7 Document History

Version Number	Effective Date	Reason for Change
1.0	11 SEP 2020	New SOP
2.0	06 JUN 2023	Update to section 5.1.1 to clarify requirements for single centre trials run in NHS Lothian. Addition of statement to GS013-T01 to ensure questionnaire content is agreed with Sponsor prior to dissemination to sites.
3.0	08 AUG 2025	- Clarification throughout that for multi-site trials the Sponsor will hold a Sponsor File - Update to 5.1.3 to clarify that feasibility questionnaires should not be circulated to sites until the study specific content has been agreed by the relevant parties Addition of section 5.3 to document the process to be followed when there is a change of PI at site following completion of the feasibility questionnaire

8 Approvals

Sign	Date
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