Study Progression Oversight

DOCUMENT NO.:	POL014 v1.0
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ISSUE DATE:	04 FEB 2026
EFFECTIVE DATE:	02 MAR 2026

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 The Sponsor, Chief Investigator (CI), Trial Manager (TM), Clinical Trial Unit (CTU), Funder and other key stakeholders (e.g. Trial Steering Committee (TSC)) has shared responsibility for maintaining and documenting oversight of how a study is performing against defined progression criteria (sometimes called continuation, stopping or go/no-go criteria).

1.3 The nature and frequency of oversight activities will vary according to the study design and the defined progression criteria set at the start of the study by the Sponsor and/or Funder.

1.4 The Central Portfolio Management System (CPMS) is a cloud-based system that holds the National Institute for Health and care Research (NIHR) Research Delivery Network (RDN) Portfolio, as well as the network portfolios of Northern Ireland, Scotland and Wales. CPMS supports the management of research studies, from set-up to completion e.g. projected/actual study start/end dates and recruitment figures.

1.5 The NIHR Sponsor Engagement Tool (SET) enables Sponsors and their delegates to efficiently and effectively manage the progression of their studies.

2 Scope

2.1 This policy applies to all stakeholders involved in a study sponsored by the UoE and/or NHSL. This includes, but is not limited to ACCORD Sponsor representatives (including Research Governance (UoE/NHSL), Pharmacovigilance, Monitoring and Quality Assurance (QA) teams), CIs, TMs and research teams e.g. CTU staff, or other

research groups (including Trial Management, Data Management and/or Statistics teams, where applicable).

2.2 This policy applies to clinical trials, defined as;

- A clinical trial of an investigational medicinal product (CTIMP),
- A clinical investigation or other study of a medical device (CIMD),
- A combined trial of an investigational medicinal product and an investigational medical device,
- Any other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

2.3 This policy applies throughout the lifetime of the study to ensure stakeholders are aware of requirements around regular review and documentation of how the study is performing against progression criteria.

3 Policy

Sponsors, Funders, CIs, grant holders (if different to the CI) and TMs, in consultation with other relevant stakeholders and where applicable, will put in place mechanisms to;

- Maintain oversight of how a trial is performing against agreed progression criteria,
- Identify where studies are not meeting their progression criteria,
- Fully document why progression criteria are not being met e.g. Funder reports, TSC meeting minutes,
- Agree a recovery plan,
- Review the progress of the recovery plan at an agreed time,
- Make a final decision about stopping or continuing the study.

3.1 Study Progression Criteria

3.1.1 The Funder will agree study progression criteria (and/or 'stop/go' criteria) with the CI at the start of a study e.g. first participant first visit (FPFV), pilot phase completion, number of participants recruited and/or sites open within agreed timescales.

3.1.2 Where the Funder does not specify study progression criteria, study milestones will be discussed and agreed with the CI and relevant stakeholders e.g. using the grant application to create a study timeline with key milestones documented.

3.1.3 The study progression criteria/milestones may change throughout the duration of the study following agreement with relevant stakeholders.

3.1.4 Study progression criteria agreed with the Sponsor, Funder and CI are not required to be in the study protocol but must be documented in the Trial Master File (TMF) e.g. final funding application, risk assessment report (Standard Operating Procedure (SOP) GS002 Combined Risk Assessment), TSC Charter, relevant contract and/or meeting minutes, Funder progress reports.

3.1.5 Projected and actual opening and closing dates, and recruitment figures entered in CPMS (SOP GS009 Recruitment Figures) will be used by the NIHR Portfolio Support programme to prompt study progression assessment by Sponsors using the NIHR SET.

3.2 Study Progression Assessment

3.2.1 The CI, or designee (e.g. TM), will determine when/how stakeholder review of study performance against the progression criteria is conducted. These assessments will be made at defined points through the pathway of the study e.g. study team meetings, TSC meetings (see Section 3.3), Funder progress reports (see Section 3.4).

3.2.2 The Sponsor will also be prompted to regularly assess study progression within the NIHR SET. This will involve assessing compliance with study progression criteria/milestones and required recruitment rates.

3.2.3 Reasons for failing to meet progression criteria must be documented (e.g. progress report to the Funder or the TSC or in TSC meeting minutes) and may include, but are not limited to;

- CI capacity and performance,
- Staff capacity and performance in the clinical trials pathway,
- Regulators' timelines for approval,
- Site engagement,
- Recruitment and retention,
- Intervention supply (e.g. drug availability, shelf life, industry collaboration).

Reasons will also be documented in the NIHR SET.

3.2.4 The CI, or designee, must make the Sponsor and CTU senior team (where applicable) aware if there are any concerns around meeting study progression criteria.

3.2.5 The CI must determine the appropriate course of action when a study is not meeting progression criteria. Potential options are listed below;

- No action required e.g. criteria not met for number of sites open by a specific date, but recruitment is on target so no impact,

- CI and TM (where applicable) agree and document mitigation strategy where impact of not meeting progression criteria considered low,
- Arrange a meeting with relevant stakeholders to discuss potential options and recommendations e.g. TM, Sponsor, CTU senior management, Edinburgh Research Office (ERO),
- Discuss with the TSC (see Section 3.3),
- At the request of the Funder, draft a study recovery plan and seek support from key stakeholders e.g. Sponsor, Funder, CTU (where applicable) TSC. This can include a costed study extension (see Section 3.5).
- Early closure of study (see Section 3.6).

3.2.6 The Sponsor and CTU (where relevant) will maintain oversight of study progression and may do this in a number of ways;

- A database, dashboard or tracker accessible to the Sponsor and CTU e.g. on the ACCORD SharePoint,
- Regular internal meetings and/or stakeholder meetings e.g. ACCORD/CTU operational meeting, sponsorship meeting, portfolio review meeting,
- Writing or reviewing Funder reports,
- TSC meeting attendance and review of TSC reports,
- Maintenance of the NIHR SET (see Section 3.2.2).

3.2.7 The Sponsor will be responsible for liaising with the CI and relevant stakeholders to ensure the NIHR SET is kept up to date for all studies requiring assessment e.g. studies not meeting key milestones such as open to recruitment date or the study is recruiting at a lower rate than expected.

3.3 Trial Steering Committee (TSC) Oversight

3.3.1 Where a study has a TSC, they will review how the study is progressing against study progression criteria at regular intervals defined in the study TSC Charter (SOP CR015 Data Monitoring Committee and Trial Steering Committee Charters).

3.3.2 A representative of the Sponsor will sit on the study TSC. This representative will be from the ACCORD Research Governance team (UoE or NHSL), Pharmacovigilance team or the QA or Monitoring team.

3.4 Funder Progress Reports

3.4.1 The CI, or designee, must maintain oversight of when progress reports to the Funder are due.

3.4.2 The CI, or designee, will provide a copy of the progress report submitted to the Funder to the Sponsor by sending to the assigned Sponsor representative or to resgov@accord.scot.

3.4.3 The Sponsor representative is responsible for reviewing the Funder report and sharing any relevant information with the wider ACCORD sponsorship and/or senior management team at relevant meetings.

3.5 Recovery Plans

3.5.1 Where it has been identified by the Funder that a recovery plan is needed, the CI, or designee, must seek Sponsor, CTU (where applicable), TSC and Funder approval e.g. where the aims/objectives of the study cannot be met within the original study timelines and with existing funds.

3.5.2 A recovery plan must include agreed mitigation strategies and include specific, measurable milestones with timelines.

3.5.3 Consideration must be given to strategic allocation of resources to support the recovery plan.

3.5.4 The CI, or designee, must discuss and agree costs associated with a study extension with ERO and all relevant stakeholders e.g. the CTU.

3.5.5 A timeline to review study performance against updated progression criteria must be included in the recovery plan.

3.5.6 The CI, or designee, will provide a copy of the final recovery plan submitted to the Funder, to the Sponsor by sending to the assigned Sponsor representative or to resgov@accord.scot.

3.6 Study Extension or Closure

3.6.1 Where it is determined that a study extension is required, the CI, or designee, must agree the plan and associated costs with the Sponsor, CTU (where applicable), ERO and the Funder.

3.6.1 Where it is determined that a study should close early, the CI, or designee, must agree the plan and associated costs with the Sponsor, CTU (where applicable), ERO and the Funder.

3.6.2 Plans and associated costs for study extension or early closure must be agreed well in advance of current recruitment/study end dates.

3.7 Clinical Trials Oversight Group (CTOG) Referral

3.7.1 Where the Sponsor, CTU (where applicable), CI and relevant stakeholders in UoE/NHSL are unable to agree on next steps for a study (e.g. progression, study extension, closure), the study can be referred to the UoE CTOG (ctog@ed.ac.uk).

3.7.2 Prior to referral to CTOG, the CI, or designee, will draft a 'for internal use only' options appraisal paper for their consideration. The content of this paper must be agreed with the Sponsor, CTU (where applicable) and any other relevant stakeholders prior to referral.

3.7.3 Where the Sponsor or CTU drafts the options appraisal paper, this must be done in consultation with the CI e.g. where stakeholders do not agree on next steps for the study, all stakeholder options must be presented.

3.7.4 The options appraisal paper must include the following;

- A brief summary of the study including the original and any updated study progression criteria,
- A summary of study progression assessments and decision making e.g. rationale for not meeting progression criteria, dates of assessment and stakeholders involved,
- Justification for referral to CTOG,
- Options for CTOG to consider e.g. costed extension, early closure.
- Named person responsible for communicating CTOGs recommendation to the CI and following up any actions proposed.

3.7.5 Following consideration of the options appraisal paper, CTOG recommendations will be communicated to the CI by the named responsible person (agreed with CTOG). This may include;

- A request for further information,
- A request for an alternative strategy,
- A decision that the study is not viable,
- A decision that the study may progress with an appropriate costed recovery plan,
- Escalation to the UoE College of Medicine and Veterinary Medicine (CMVM) senior management.

3.7.6 CTOG will notify the Head of the College (CMVM), or delegate, of CTOG's final recommendation regarding study progression/closure.

3.7.7 If CTOG is unable to reach a decision regarding study progression or closure, the final decision will be escalated by CTOG to the Head of the College (CMVM), the Dean of Clinical Medicine (CMVM), or delegate. CTOG will communicate this decision to the named responsible person, who will communicate this to the CI.

3.7.8 The named responsible person will follow-up with the CI/TM until all actions associated with the CTOG recommendation are complete. This will include discussions with the Sponsor, Funder and the TSC. Further advice can be sought from CTOG if required.

3.7.9 If the CI wishes to appeal the decision made by the CTOG, they can do so in writing to the CTOG Secretariat (ctog@ed.ac.uk).

3.7.10 Sponsor, CTU (where applicable), and CI/TM oversight of new or updated study progression criteria will follow Section 3.2 of this policy.

3.7.11 Where CTOG has recommended a recovery plan, they may request that the CI/TM notify them on how the trial is performing against updated progression criteria (ctog@ed.ac.uk). Where it is evident that the trial has not progressed as planned, CTOG may recommend trial closure with CMVM senior management approval.

3.8 Study Progression Assessment Documentation

3.8.1 The following documents, to evidence CI and key stakeholder oversight of study progression assessment, must be retained in the TMF and/or Sponsor File (where applicable);

- Study progression criteria (can be a stand-alone document or part of another essential document e.g. final funding application, risk assessment report),
- Study progression assessment meetings e.g. team meeting/TSC meeting minutes, Funder meeting minutes,
- Progression reports e.g. TSC, Funder reports,
- Study progression e-mail communications with key stakeholders,
- Recovery plan(s),
- CTOG referral, recommendation and follow-up of actions

4 References and Related Documents

- SOP CR015 Data Monitoring Committee and Trial Steering Committee Charters
- SOP GS002 Combined Risk Assessment
- SOP GS009 Recruitment Figures

5 Document History

Version Number	Effective Date	Reason for Change
1.0	02 MAR 2026	New policy.

6 Approvals

Sign	Date
Heather Charles Heather Charles (02-Feb-2026 14:19:04 GMT) AUTHOR: Heather Charles, Head of Research Governance, NHSL, ACCORD	02-Feb-2026
Paul Dearie Paul Dearie (02-Feb-2026 14:03:38 GMT) APPROVED: Paul Dearie, Clinical Research Facilitation Manager, UoE, ACCORD	02-Feb-2026
L. Mackenzie AUTHORISED: Lorn Mackenzie, Quality Assurance Manager, NHSL, ACCORD	03-Feb-2026

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Final Audit Report 2026-02-03

Created:	2026-02-02 (Greenwich Mean Time)
By:	Roisin Ellis (v1relli8@exseed.ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAgmNkR0qLrXBaJ_sB3Jl0iGpnDoNbi-ws

"POL014 Study Progression Oversight v1.0" History

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2026-02-02 - 1:58:44 PM GMT- IP address: 104.47.11.254

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2026-02-03 - 8:27:39 AM GMT- IP address: 52.102.17.117

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