Research Study Reports & Publications of Results

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Author:	Lorn Mackenzie
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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 It is important to report all health and care research study results to ensure all research is carried out in a transparent and open way allowing the facilitation of ethical research practice. This improves research integrity and reduces research waste. Reporting study results allows researchers to build on previous findings and help both professionals involved in healthcare and the public to make informed choices.

1.3 Research findings, whether positive, negative, neutral, or inconclusive should be made accessible when the study ends.

1.4 All research that has been reviewed by a Research Ethics Committee (REC) must submit a final report to the REC.

1.5 For clinical trials of investigational medicinal products (CTIMPs), there is a legal requirement to publish a summary of results within 12 months of the end of trial. The definition of the end of trial should be outlined in the protocol.

1.6 Where applicable, end of study summary results must be uploaded to a publicly accessible registry.

2 Purpose

2.1 To describe the procedures for the preparation, review and finalisation of the final report prior to submission to the Sponsor and/or the appropriate REC. This Standard Operation Procedure (SOP) also describes the procedure for notifying the Medicines

and Healthcare products Regulatory Agency (MHRA), where applicable, and making research results publicly available.

3 Scope

3.1 This SOP applies to all personnel involved in the preparation, review and submission of study reports and/or research summary results for studies sponsored by NHSL and/or the UoE.

3.2 This SOP also applies to ACCORD Quality Assurance (QA) staff, acting on behalf of the Sponsor organisation(s).

4 Responsibilities

4.1 The Chief Investigator (CI) is responsible for;

- Drafting the study report in the required format,
- Ensuring the content of the report has been Quality Control (QC) checked for accuracy,
- Sending the draft report to the Sponsor(s), and appropriate members of the study team (including the funder if required), for review,
- Addressing all comments raised by the report reviewer(s),
- Submitting the final report to the Sponsor(s) and the appropriate REC, within the specified timeline,
- Uploading the end of trial summary results to the public registry, where applicable, and informing the Sponsor(s)/MHRA (CTIMPs only).
- Ensuring that, where the study findings are to be submitted for publication in a journal, this is within 12 months of the end of study through an open-access mechanism in a peer-reviewed journal.
- Thanking participants for their contribution and providing them with a clear lay summary of the research findings, where applicable.

4.2 It is the responsibility of the ACCORD QA Manager, or designee, to track final report submission and ensure a copy of the final report is retained in the Trial Master File (TMF) or Sponsor File for studies that have gone through the ACCORD Combined Risk Assessment process (GS002). This will include review of draft reports that will be used to seek a marketing authorisation. For all other studies, this is the responsibility of the CI.

5 Procedure

5.1 Report Preparation, Review & Finalisation

5.1.1 Requirements for end of trial (EOT) notifications are detailed in ACCORD SOP CR009 Study Closure and Archiving.

5.1.2 Once the end of study has been declared and relevant review bodies have been notified, there is a requirement to submit a final report of the research to the Sponsor. The CI, or designee, will draft the final report using an appropriate report template (e.g., as dictated by the funder or for studies requiring NHS REC approval by completion of the IRAS/REC final report form - see Sections 5.2 and 5.3)

5.1.3 For CTIMPs, where the study report will be used to seek a manufacturing authorisation for the IMP, the CI will follow ICH E3 (Structure and content of clinical study reports - Scientific guideline) in the preparation of the study report. The CI, or designee, will ensure that the draft report is QC checked for accuracy prior to circulation for review. The CI, or designee, will send the QC'd draft report to appropriate members of the study team for review e.g., Investigators, Trial Manager and Statistician. If specified in the protocol, the CI, or designee, will send the draft report to the Data Monitoring Committee (DMC) and/or funders for review.

5.1.4 For CTIMPs, where the study report will be used to seek a manufacturing authorisation for the IMP, the CI will e-mail the draft report to the ACCORD QA team for review prior to finalisation (QA@accord.scot). The ACCORD QA Manager, or designee, will review the draft report using CR011-T02 (Report Review Checklist), and with reference to ICH E3 Structure and Content of Clinical Study Reports. and return any comments to the CI within 10 working days of receipt. The CI, or designee, will address comments provided by all reviewers prior to report finalisation.

5.1.5 The CI, or designee, will send the Sponsor(s) an electronic signed copy of the final report (QA@accord.scot) within 12 months of the end of trial notification. This can be the report downloaded from the Integrated Research Application System (IRAS) or the HRA website (see Sections 5.2 and 5.3).

5.2 Combined Review Studies

5.2.1 If the study was submitted via the combined review process, the CI (or designee) will complete and submit the final report form in the relevant part of IRAS within 12

months of the end of trial. Completing and submitting the final report on IRAS will send it to both the REC and the MHRA.

5.3 Submission to the REC

5.3.1 For research reviewed only by an NHS REC, or CTIMPs that have not undergone combined review, the CI or designee will use the webform on the Health Research Authority (HRA) website to submit to the REC within 12 months of the end of trial. Note that there is no need to submit a separate report to the REC for any CTIMP. The information relevant for the REC is captured in the final report form. https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/final-report-form/

5.3.2 When completing the final report form, the CI or designee will use the guidance next to each question to help complete the form. One of the questions in the final report asks for a lay summary of the results. This lay summary will be published alongside the rest of the research summary on the HRA website.

5.3.3 For all other studies which have had no NHS involvement (e.g. student projects, global health studies), the study team should check the requirements for final summary notification with the reviewing body (e.g. institutional ethics).

5.3.4 Where there are concerns of commercial confidentiality, the CI (in consultation with the Sponsors – QA@accord.scot), can make a request to the HRA to defer the publication of the research summary (deferrals@hra.nhs.uk).

5.4 Submission to the MHRA

5.4.1 The CI does not need to submit a separate report to the MHRA for trials where results are made available on a public registry. See Section 5.6.5 regarding MHRA notification following upload of results to the public registry.

5.5 Clinical Investigations of Medical Devices (CIMDs)

5.5.1 The CI, or designee, will send a copy of the CIMD final report to the applicable regulatory body when it is available, and copy the Sponsor(s) (QA@accord.scot).

5.6 Public Registry

5.6.1 For all studies the CI, or designee, will upload the end of study results to the public registry (or registries) where the study was initially registered e.g. ClinicalTrials.Gov,

ISRCTN. If the CI, or designee registered a trial with more than 1 registry, there is a requirement to publish a summary of the trial results in all those registries.

5.6.2 Where the study includes at least one site in the EU/EEA, results must also be uploaded to the EU Clinical Trials Information System (CTIS) in accordance with the EU Clinical Trials Regulation.

5.6.3 Results entered into a public registry (e.g., ClinicalTrials.gov, EU Clinical Trials Register, ISRCTN) are considered a regulatory and ethical requirement for transparency. Such registry postings do not constitute prior publication and do not preclude subsequent submission of trial findings to a peer-reviewed journal. Registry reporting is distinct from scientific publication and is required irrespective of journal submission.

5.6.4 The end of trial summary results must be uploaded to the registry within 12 months of the 'end of trial' as defined in the study protocol. If NHSL/UoE is the holder of a UK marketing authorisation and the trial involves the use of that authorised medicinal product use in a paediatric population, the results must be submitted to the licensing authority within the 6 months beginning with the day on which the trial ended. An exception to the above will be if the trial did not recruit any participants in the UK within 2 years and the approval lapsed. In this case, the CI would not be expected to publish summary results for the trial.

5.6.5 In some circumstances, the Sponsor can request a deferral or a waiver. The CI, or designee should discuss all deferral requests with the Sponsor Representative before the 12 month deadline.

5.6.6 For CTIMP studies, once the CI or designee has published the summary results in the registry, the HRA should be informed by emailing: study.registration@hra.nhs.uk. The HRA will onward report this to the MHRA.

5.6.7 For studies subject to a combined risk assessment, once the HRA have been informed results have been uploaded in the registry (applicable to CTIMPs), and a submission has been made to the REC (see section 5.2 and 5.3), the CI or designee will inform the ACCORD QA team (QA@ACCORD.scot).

5.6.8 If a CI, or designee, submits a summary of trial results to a public registry and the registry does not publish the results within the required timeframe, the CI or designee should notify the HRA by emailing: study.registration@hra.nhs.uk. The email should include confirmation that the summary of results have been submitted

and evidence of this (for example an email confirming submission or a screenshot of the submission page). This information will be shared with the MHRA.

5.7 Publishing Results in a Peer-Reviewed Journal

5.7.1 If trial results are to be published in a peer-reviewed journal, the CI should do this ideally within 12 months of the end of study definition. Delaying clinical trial result reporting to accommodate journal preferences is generally not acceptable and violates ethical and regulatory obligations.

5.8 Informing Participants

5.8.1 The CI, or designee, will comply with the Participant Information Sheet (PIS) with regards to research findings being made available to trial participants e.g. by e-mail/letter, via a secure webpage. When the CI, or designee, submits a final report to the REC, the webform requires confirmation that the results have been shared with participants who want to receive them and/or what arrangements are in place to do so.

5.9 Sponsor Notification & Follow-Up for Risk Assessed Studies (GS002)

5.9.1 For studies subject to a combined risk assessment (GS002), the ACCORD QA Manager, or designee, will track when final end of study reports (e.g. the IRAS/REC final report form) are due and document confirmation of report submission to the Sponsor (QA team), and publication of results (registry reporting requirements). This information will be retained on the ACCORD SharePoint in the QA folder (Registry Reporting Tracker).

5.9.2 The Sponsor Representative will inform the QA Manager, or designee, of trial end dates (confirmed via the end of trial notification). Communication of the trial end date will be confirmed at the monthly Sponsorship meeting.

5.9.3 The QA Manager, or designee, will routinely follow-up with the CI and/or Trial Manager to ensure the final report and registry reporting is completed within the required 12-month timeframe following the global end of the trial as noted in the end of trial form (for example 6, 9, 11 months post-trial end). This follow-up will include scheduled reminders and documented communication until confirmation of submission is received. If the CI, or Trial Manager does not respond to communication, or if the timeline is at risk of breach (e.g. no response 9 months post-trial end), the QA Manager will escalate the matter to the ACCORD Senior Management Team, and if necessary, inform the MHRA. The ACCORD senior

management team will discuss and agree an appropriate course of action and communicate this to the QA Manager. All communication and escalation actions will be documented in the TMF.

5.9.4 Once the final report has been received, and results published in the registry/HRA informed, the QA Manager will inform the assigned Clinical Trials Monitor. The QA Manager will file a copy of the final report and evidence of registry reporting in the TMF or Sponsor File, upload an electronic copy to the study specific folder on the ACCORD SharePoint and update the Registry Reporting Tracker on SharePoint. Evidence of all communication with the HRA confirming that results have been uploaded to the appropriate registry will also be retained.

6 References and Related Documents

- CR011-T02 (Report Review Checklist)
- SOP CR009 Study Closure and Archiving
- SOP GS002 Combined Risk Assessment
- ICH E3 Structure and content of clinical study reports - Scientific guideline https://www.ema.europa.eu/en/ich-e3-structure-content-clinical-study-reports-scientific-guideline

7 Document History

Version Number	Effective Date	Reason for Change
1.0	22 MAR 2011	New procedure.
1.1	20 FEB 2014	Clarified acceptability of summary report or publication in place of CSR, clarified need for draft CSR to be submitted for QA review.
2.0	29 AUG 2016	New SOP template, including responsibilities section (4). Introduction reworded. New QA e-mail address added and reference made to SOP QA008 (section 5.4.4). Text amended throughout to detail requirements for CSR and summary report review and finalisation, including changes in MHRA requirements (addition of section 5.6 on uploading data to the EudraCT database).
3.0	02 OCT 2018	Change of author. Update to references.

4.0	16 FEB 2023	Scope of procedure updated to include reporting/publishing for all locally sponsored clinical research studies. Change of author and SOP title. Procedure updated (all of section 5) to reflect current requirements for trial registration and upload of results to a public registry and change to REC reporting requirements. Inclusion of reporting requirements for combined review studies. Removal of ACCORD report template, with reference to ICH guidelines.
5.0	05 MAR 2025	Change of author. SOP transferred over to new ACCORD template. Addition of reference to ACCORD SOP CR009 at section 5.1.1.
6.0	28 APR 2026	Updated to align with new Clinical Trial Regulations and ICH-GCP (R3). QA004(QA Oversight of Study Reports and Publication of Results) to be discontinued on 28 Apr 2026, as process now added to CR011. Inclusion of CR011-T02 (Report Review Checklist) - previously referenced QA004-T01.

8 Approvals

Sign	Date
L. Mackenzie AUTHOR: Lorn Mackenzie, QA Manager, NHS Lothian, ACCORD	14-Apr-2026
Heather Charles Heather Charles (13-Apr-2026 10:59:44 GMT+1) APPROVED: Heather Charles, Head of Research Governance, NHS Lothian, ACCORD	13-Apr-2026
Gavin Robertson Gavin Robertson (13-Apr-2026 11:10:06 GMT+1) AUTHORISED: Gavin Robertson, QA Coordinator, NHS Lothian, ACCORD	13-Apr-2026

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Signer heather.charles@nhslothian.scot.nhs.uk entered name at signing as Heather Charles
2026-04-13 - 10:59:42 AM GMT+1- IP address: 62.253.82.244

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