RESEARCH STUDY REPORTS & PUBLICATION OF RESULTS

DOCUMENT NO.:	**CR011 v4.0**
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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 Research findings, whether positive, negative, neutral, or inconclusive should be made accessible when the study ends.

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

1.4 For clinical trials of investigational medicinal products (CTIMPs), a summary of results should be published within 12 months of the end of study or 6 months of the 'end of trial' for paediatric trials.

1.5 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, and the MHRA (where applicable) within the specified timeline,
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- 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.

5 PROCEDURE

5.1 Report Preparation, Review & Finalisation

5.1.1 The CI, or designee, will draft the report using an appropriate report template e.g., as dictated by the funder or by completion of the IRAS/REC final report form (see Sections 5.2 and 5.3, respectively).

5.1.2 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.

5.1.3 The CI, or designee, will ensure that the draft report is QC checked for accuracy prior to circulation for review.

5.1.4 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.

5.1.5 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.

5.1.6 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).

5.1.7 The ACCORD QA Manager, or designee, will review the draft report and return any comments to the CI within 10 working days of receipt.

5.1.8 The CI, or designee, will address comments provided by all reviewers prior to report finalisation.

5.1.9 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, respectively).

5.2 Combined Review Studies

5.2.1 It 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. 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. 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 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 MHRA when it is available, and copy the Sponsor(s) (QA@accord.scot).

5.6 Public Registry

5.6.1 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. EudraCT, ClinicalTrials.Gov, ISRCTN.

5.6.2 For CTIMPs registered on EudraCT (i.e., with a EudraCT number), the CI, or designee, will follow the instructions in the table below regarding reporting end of trial results on a publicly accessible registry;

Trial Type	Instruction
Trial was registered on EudraCT, with a Clinical Trial Authorisation (CTA) dated prior to 1st January 2021	Upload end of trial results to the EudraCT register
Trial was registered on EudraCT, with a CTA dated from 1st January 2021 – 31st December 2021	Register and upload results to ISRCTN or ClincalTrials.Gov (no requirement to upload results to EudraCT)
From 1st January 2022, all clinical trials submitted for combined review will be automatically registered by the Health Research Authority (HRA) on the ISRCTN registry	No action to register on ISRCTN. If trial is or will be registered with ClinicalTrials.gov, can request not to be registered on ISRCTN in IRAS application (study information, section C). Upload results to ISRCTN or ClinicalTrials.gov.

5.6.3 The end of trial summary results must be uploaded within 12 months of the 'end of trial', and within 6 months of the 'end of trial' for paediatric trials.

5.6.4 Steps to follow for upload of trial summary results to EudraCT are described in the EMA webpage 'Tutorials on posting results'.

5.6.5 For CTIMPs, the CI or designee will send a short confirmatory email to CT.Submission@mhra.gov.uk once the result-related information has been uploaded to the public registry and provide a link. The subject line of the e-mail notification must state 'End of trial: result-related information: EudraCT XXXX-XXXXXX-XX' and/or IRAS ID XXXXXXX'. The Sponsor(s) will be copied in this e-mail (QA@accord.scot). It should be noted that you will not receive an acknowledgment e-mail or letter from the MHRA.

5.6.6 Upload of end of trial results to the public registry should not be delayed until after publication of results in a journal (section 5.7).

5.7 Publishing Results

5.7.1 Where the main findings are to be submitted for publication in a journal, the CI should do this within 12 months of the end of study through an open-access mechanism in a peer-reviewed journal.

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, on request, on the trial website.

5.8.2 The CI will also consider whether it is appropriate to thank participants for their contribution.

5.9 Sponsor Notification & Follow-Up

5.9.1 The ACCORD QA Manager, or designee, will track when end of study reports are due and document confirmation of report submission (only for trials that have undergone combined risk assessment). This information will be retained on the ACCORD SharePoint in the QA folder.

5.9.2 The QA Manager, or designee, will follow-up with the CI and/or Trial Manager where the Sponsor(s) have not been notified of report submission via IRAS, the HRA webform or upload of results to the public registry.

5.9.3 On receipt of a report, the QA Manager or designee will file a hard copy of the report in the TMF or Sponsor File and upload an electronic copy to the study specific folder on the ACCORD SharePoint.

6 REFERENCES AND RELATED DOCUMENTS

- SOP GS002 Combined Risk Assessment
- SOP QA004 Clinical Study Report Review - CTIMPs
- 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.

8 APPROVALS

Sign	Date
Heather Charles Heather Charles (Jan 30, 2023 13:07 GMT) AUTHOR: Heather Charles, Head of Research Governance, NHS Lothian, ACCORD	Jan 30, 2023
Marise Bucukoglu (Feb 6, 2023 09:59 GMT) APPROVED: Marise Bucukoglu, Head of Research Governance, University of Edinburgh, ACCORD	Feb 6, 2023
Gavin Robertson (Jan 30, 2023 13:06 GMT) AUTHORISED: Gavin Robertson, QA Coordinator, NHS Lothian, ACCORD	Jan 30, 2023

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