CLINICAL STUDY REPORT REVIEW - CTIMPs

DOCUMENT NO.:	**QA004 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 When a Clinical Trial of an Investigational Medicinal Product (CTIMP) is completed, or prematurely terminated, the Clinical Study Report (CSR) or summary report must be sent to the appropriate Research Ethics Committee (REC) and the Sponsor within 12 months of the 'end of the trial'.

1.3 The CSR will be prepared using the CSR template (CR011-T01), if the data generated from the study are intended to be used towards a marketing authorisation submission. If the data will not be used for this purpose, a publication of the study details and outcomes or a summary report to the funder may suffice as a CSR.

1.4 In addition, for CTIMP studies, the end of trial summary results must be uploaded to the European Clinical Trials Database (EudraCT) within 12 months of the 'end of trial' for trials involving adults and within 6 months of the 'end of trial' for paediatric trials.

2 PURPOSE

2.1 To document the methods by which ACCORD Quality Assurance (QA) personnel review study CSRs or summary reports for CTIMPs sponsored by NHSL and/or the UoE.

3 SCOPE

3.1 This SOP applies to ACCORD QA personnel, and any individuals that may conduct a review of study CSRs or summary reports on behalf of ACCORD QA.

4 RESPONSIBILITIES

4.1 The QA Manager, QA Coordinator, or designee, is responsible for reviewing CSRs and summary reports on behalf of the Sponsor, and for following up with the CI regarding the status of end of study reports.

4.2 The Clinical Trials Monitors are responsible for informing QA personnel, at regular Sponsorship meetings, that a CTIMP study is about to be closed out, and for providing training and guidance on reporting procedures in accordance with ACCORD monitoring procedures CM001 (Site Initiation Visit and Sponsor Authorisation) and CM003 (Close Out Visits) .

5 PROCEDURE

5.1 End of Trial Reporting

5.1.1 ACCORD QA personnel will be informed by the clinical trials monitors that a CTIMP study is about to undergo a study closure visit during regular Sponsorship meetings.

5.1.2 The QA Manager or QA Coordinator will contact the CI of this study, after close out, reminding them to send a draft copy of the CSR or summary report to QA@accord.scot for review.

5.2 If delegated this task by the Sponsor, the QA Manager or QA Coordinator will also remind the CI that end of trial summary results must be uploaded to the EudraCT database within 12 months of the 'end of the trial' for adult trials or within 6 months of the 'end of trial' for paediatric studies.

5.3 Report Review

5.3.1 On receipt, the QA Manager, or designee, will review the CSR or summary report using QA004-T01 (Report Review Checklist).

5.3.2 The QA Manager, or designee, will send findings and comments to the CI within 10 working days from receipt of the report.

5.4 Report Finalisation

5.4.1 If the CI, or designee, has not sent the Sponsor the final signed CSR or summary report or confirmation that study data has been uploaded to the EudraCT database (if applicable), the QA Manager or QA Coordinator, or designee, will contact the CI reminding them to send the final CSR or summary report to QA@accord.scot and/or to upload the study data to EudraCT.

5.4.2 Reminders will be sent to the CI until completion of this task.

5.4.3 On receipt of a final CRS/summary report, the QA Manager or QA Coordinator will file these in the appropriate study folder.

6 REFERENCES AND RELATED DOCUMENTS

- ICH-GCP E6(R2) Guidelines
- QA004-T01 Report Review Checklist
- CR011 Clinical Study Report Preparation - CTIMPs
- CR011-T01 Clinical Study Report template
- CM001 Site Initiation Visit and Sponsor Authorisation
- CM003 Close Out Visits

7 DOCUMENT HISTORY

Version Number	Effective Date	Reason for Change
1.0	22 MAR 2011	New procedure.
2.0	17 SEP 2013	Removed reference to Protocol, Information Sheet, Consent Form and Labs work plan review.
3.0	29 AUG 2016	New SOP template, including responsibilities section (4). Introduction reworded. New QA e-mail address added. Text amended throughout to detail requirements for CSR and summary report review and finalisation, including follow up with the CI and uploading data to the EudraCT database. Purpose of SOP amended to reflect that QA will review only, and all references to sampling of data removed from SOP and also from QA004-T01.
4.0	02 OCT 2018	Change of author and update to references.

8 APPROVALS

Sign	Date
SIGNATURE KEPT ON FILE AUTHOR: [redacted] QA Manager, NHS Lothian, ACCORD	
SIGNATURE KEPT ON FILE APPROVED: [redacted] Head of Research Governance, NHS Lothian, ACCORD	
SIGNATURE KEPT ON FILE AUTHORISED: [redacted] , QA Coordinator, NHS Lothian, ACCORD	