CLINICAL STUDY REPORT PREPARATION - CTIMPs

DOCUMENT NO.:	**CR011 v3.0**
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ISSUE DATE:	**18 SEP 2018**
EFFECTIVE DATE:	**02 OCT 2018**

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(s) (REC) and the Sponsor within 12 months of the 'end of the trial'.

1.3 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 describe the procedures for the preparation, review and finalisation of the CSR or summary report prior to submission to the Sponsor and the appropriate REC, and for making the Medicines and Healthcare products Regulatory Agency (MHRA) aware that clinical trial summary results have been uploaded to the EudraCT database.

3 SCOPE

3.1 This SOP applies to all research personnel involved in the preparation and review of CSRs and summary results/reports in relation to CTIMPs 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 It is the responsibility of the Chief Investigator (CI) to;

- Draft the study report using the appropriate template,
- Ensure the content of the report has been Quality Control (QC) checked for accuracy,

- Send the draft report to the Sponsor(s), and appropriate members of the study team (including the funder if required), for review,
- Address all comments raised by the report reviewer(s),
- Submit the final report to the Sponsor(s) and the appropriate REC, within the specified timeline,
- If delegated by the Sponsor, upload the end of trial summary results to the EudraCT database, and inform the MHRA and the Sponsor(s) that this has been done.

4.2 It is the responsibility of the Sponsor(s) (ACCORD QA staff), and any members of the research team delegated this task, to review the report and provide comments to the CI prior to report finalisation.

5 PROCEDURE

5.1 Report in Support of a Marketing Authorisation

5.2 If the data generated from the study are intended to be used towards a Marketing Authorisation submission, the CI, or designee, will prepare the report using the CSR template (CR011-T01).

5.2.1 Each topic in the CSR template (CR011-T01) will be addressed by the CI, or designee, except where a section is not applicable.

5.2.2 Details of issues documented in filenotes, protocol/GCP deviations and violations, considered significant by the CI, will be reported in the CSR.

5.3 Summary Report

5.3.1 For studies that will not be submitted in support of an application for Marketing Authorisation, the information required for the CSR may be captured in another medium, e.g. a summary report to the funding organisation or publication.

5.3.2 In this instance, the CI, or designee, will not be required to use CR011-T01 and will instead submit the information to the Sponsor(s) and the appropriate REC in its already captured format.

5.3.3 If required, researchers can seek guidance and clarification on this matter from ACCORD QA personnel (QA@accord.scot).

5.4 Draft Report Review

5.4.1 The CI, or designee, will ensure that the draft report (CSR or summary report) is QC checked for accuracy prior to distribution for review.

5.4.2 The CI, or designee, will send the QC'd draft report to ACCORD QA (QA@accord.scot) and to appropriate members of the study team (including,

although not necessarily exclusively: Investigators, the study manager and study statistician) for review.

5.4.3 If specified in the clinical protocol, the CI, or designee, will send the draft report to the Data Monitoring Committee (DMC) and/or funders for review.

5.4.4 If a number of drafts or the report are required, these should be version controlled as detailed in SOP QA008 (Document Version Control).

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

5.5 Final Report

5.5.1 Dependent on the contract requirements, the CI, or designee, will send the Sponsor(s) 1 unbound signed copy of the final CSR (reports can be copied double-sided, if required) and/or an electronic signed copy of the final CSR or summary report (QA@accord.scot).

5.5.2 The CI, or designee, will ensure that any report from a co-operating discipline, which is included in the final CSR, is signed and dated by the responsible scientist.

5.5.3 The CI, or designee, will distribute the final report to the Sponsor(s) and the appropriate REC within 12 months of the end of trial notification.

5.6 EudraCT Reporting

5.6.1 If delegated this task by the Sponsor(s), the CI, or designee, will upload the end of trial summary results to the EudraCT database, as per the European Commission's guidelines on posting and publication of result-related information.

5.6.2 The end of trial summary results must be uploaded to the EudraCT database within 12 months of the 'end of trial' for trials involving adults, and within 6 months of the 'end of trial' for paediatric trials.

5.6.3 The CI, or designee will submit a short confirmatory e-mail to the MHRA (CT.Submission@mhra.gsi.gov.uk) once the result-related information has been uploaded to EudraCT, with 'End of trial: result-related information: EudraCT XXXX-XXXXXX-XX' as the subject line. The Sponsor(s) will be copied in this e-mail (QA@accord.scot). It should be noted that you will not get an acknowledgment e-mail or letter from the MHRA.

6 REFERENCES AND RELATED DOCUMENTS

- The Medicines for Human Use (Clinical Trials) Regulations 2004/1031, as amended

- ICH-GCP E6(R2) Guidelines
- Commission Guideline - Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006
- CR011-T01 Clinical Study Report template
- SOP QA008 Document Version Control

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.

8 APPROVALS

Sign	Date
SIGNATURE KEPT ON FILE AUTHOR: Lorn Mackenzie, QA Manager, NHS Lothian, ACCORD	
SIGNATURE KEPT ON FILE APPROVED: Heather Charles, Head of Research Governance, NHS Lothian, ACCORD	
SIGNATURE KEPT ON FILE AUTHORISED: Gavin Robertson, QA Coordinator, NHS Lothian, ACCORD	