York Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S27

End of Study Reports and Publications

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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	Date:	17th June 2019
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	Signature:	Signed copy held by R&D Unit
	Date:	17th June 2019

This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	6th September 2010	
2.0	17th March 2014	Change of SOP Controller. Removal of references to the North and East Yorkshire Alliance. Addition of requirement to review publications and posters. Inclusion on Non-CTIMP studies.
3.0	22nd August 2017	
4.0	15th July 2019	Change of author. Change of link to R&D website. Paediatric CTIMP update.

Contents

1 Introduction, Background and Purpose

This SOP is intended to assist with the development of an end of study report and/or publication that is complete, free from ambiguity, well organised, easy to review and is an accurate representation of the study undertaken and the results obtained. It is an expectation that all Trust funded research studies will result in an appropriate output.

It is a requirement of the Clinical Trial Regulations that end of study reports are submitted to the regulatory authorities within 12 months of the end date of a CTIMP study or 6 months for a paediatric CTIMP study. Sponsors are obliged to post results in EudraCT for any interventional trials registered in EudraCT and that have ended within a certain period of time:

- For any interventional clinical trials that ended on or after 21 July 2014, sponsors will have to post results within six or twelve months following the end of the trial, depending on the type of trial concerned;
- For trials that ended before that date, sponsors will need to submit the results retrospectively, in accordance with the specific timeframe laid out in the above-mentioned European Commission guideline on the posting and publication of result-related information on clinical trials.

In addition, for non-CTIMP studies, an end of study report is required to be submitted to the Research Ethics Committee within 12 months of the study end date.

It is expected that Trust sponsored research studies will also result in a Publication and/or Conference Presentation.

Additionally, the Health Research Authority website offers guidance on providing information to participants at the end of a study. This is good practice and a process for this should be considered at an early stage with clear plans detailed in the IRAS application.

2 Who Should Use This SOP

Section 4 of this SOP should be used by Chief Investigators for CTIMP studies sponsored or co-sponsored by the Trust. It may be used by investigators on hosted studies although this is not a requirement and a sponsor SOP may take precedence.

Section 5 is relevant to Chief Investigators for non-CTIMP studies.

3 When this SOP Should be Used

This SOP should be followed when compiling the end of trial report, publication or conference presentation for a study sponsored by York Teaching Hospital NHS Foundation Trust.

4 CTIMP studies Sponsored by the Trust

4.1 End of Trial Reports

Where the Trust is acting as Sponsor for a CTIMP study, the CI is required to submit a draft end of trial report to the R&D Unit within 10 months of the date of the end of trial (as notified to the MHRA and REC). This Report will be reviewed by a Research Adviser before submission to the York Teaching Hospital NHS Foundation Trust R&D Group for additional review. The R&D Unit will subsequently be responsible for submitting the approved end of study report to the MHRA and Ethics Committee on behalf of the Sponsor, to arrive within 12 months of the date of the end of the trial. The Sponsor may delegate submission of the final approved report to the CI.

4.1.1 Content of Report

The end of study report should provide a clear explanation of how the critical design features of the study were chosen and enough information on the plan, methods and conduct of the study so that there is no ambiguity in how the study was carried out. The report, with its appendices, should also provide enough individual patient data, including the demographic and baseline data, and details of analytical methods, to allow replication of the critical analyses when the R&D Group or authorities wish to do so. All analyses, tables and figures should carry, in text or as part of the table, clear identification of the set of patients from which they were generated.

It is important to clarify features of the study that were not well described in the protocol and identify ways in which the study was conducted differed from the protocol, and to discuss the statistical methods and analyses used to account for these deviations from the planned protocol.

It is essential that the report contains a listing of all the non-compliances that occurred during the trial and a statement describing how these have been accounted for in the analysis. All non-compliances should be clearly documented during the course of the study (refer to R&D/S04). When making any statement of non-compliance in the report there should be careful assessment as to whether this statement requires quantification based on the conduct of the trial and any departures from the protocol and GCP non-compliance that occurred.

A full description of safety aspects should be included. This must include a detailed discussion of individual adverse events or laboratory anomalies.

Where appropriate, the report should describe demographic and other potentially predictive characteristics of the study population and, where the study is large enough to permit this, present data for demographic (e.g. age, sex, race, weight) and other (e.g., renal or hepatic function) subgroups so that possible differences in efficacy or safety can be identified.

4.1.2 Format of Trial Report

The results from clinical trials are reported with text and data with a level of detail ranging from informal to highly structured and comprehensive, depending on individual trial requirements and intended audience for the report. For some smaller studies a report of the study published in a peer reviewed journal may suffice while other studies may require a more formal report as described below.

Randomised studies should be reported in compliance with the CONSORT statement[1].

At the very minimum reports should inform the reader whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research, including any feedback to participants.

For more detailed guidance refer to International Conference on Harmonisation (ICH) Topic E3 (Structure and Content of Clinical Study Reports)[2].

A template (R&D/T24) is adapted from ICH Topic E3 and is available at www.northyorksresearch.nhs.uk/sops.html

4.1.3 Review and Approval of Report

For all CTIMPs sponsored or co-sponsored by the Trust an end of study report should be submitted to the York Teaching Hospital NHS Foundation Trust R&D Group within 10 months of the date of the end of trial.

The CI should organise for draft study reports to undergo review by involved parties prior to submission to the R&D Unit.

On receipt by the R&D Unit, the Research Adviser will review the end of trial report and will seek review by an independent statistician where this is considered appropriate. The study data will be made available if necessary. Comments may be fed back to the Chief Investigator at this stage. Draft documents should be version controlled during this process.

The draft report will then be submitted to the R&D Group for review, along with any comments from the Research Adviser and external statistician.

Following Group review the R&D Unit will be responsible for ensuring any suggested changes are incorporated and for submitting the report to the Main REC and the MHRA in line with current submission procedures. The Sponsor may delegate submission of the final approved report to the CI.

N.B. All timeframes refer to non-paediatric trials, for paediatric trials submission is required within 6 months of the end of the trial. Whilst the process remains the same for paediatric trials advice on timelines should be sought from the Research Advisor on a case-by-case basis to ensure timely submission.

4.2 Publications, Posters and Conference Presentations

For CTIMP studies sponsored by the Trust the CI must discuss, in advance, any plans to present the trial results with the Research Adviser. Under no circumstances should any results be presented without the prior written approval of the Sponsor. The Research Adviser will review the proposed publication, poster or presentation to ensure that it is an accurate representation of the trial undertaken. Where considered appropriate the Research Adviser may seek advice from the R&D Group and/or trial statistician. The submitted presentation or publication must be also be forwarded to the R&D Unit for information.

[1] CONSORT statement. http://www.consort-statement.org/
[2] ICH Topic E3. Structure and Content of Clinical Study Reports. (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002832.pdf)

5 Non-CTIMP Studies Sponsored by the Trust

5.1 End of Study Reports for the Research Ethics Committee

The CI should send a summary of the final research report to the main REC within 12 months of the end of the study.

There is no standard format for final REC reports. As a minimum, it is a requirement to inform the main REC whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research, including any feedback to participants.

Before submitting to the REC, a copy of the draft report should be forwarded to the R&D Unit for review by a Research Adviser. Following submission, a copy of the final REC report should be provided to the R&D Unit for information.

5.2 Publications and Posters

A copy of any draft publication resulting from a Trust sponsored research study should be forwarded to the R&D Unit for review by the Research Adviser prior to submission. The CI must allow adequate time for this review to take place prior to the planned submission as the RA may request input from the Trust's R&D Group. No formal submission may be made until the RA has confirmed this in writing.

It is important to note that:

- Randomised studies should be reported in compliance with the CONSORT statement[1].
- Observational studies (e.g. cohort or case-control studies) should be reported in compliance with the STROBE statement[2].

Following submission, a copy of the final approved publication or presentation must be forwarded to the R&D Unit for information.

The R&D Unit would also like to receive copies of conference or meeting Posters for display.

6 Related SOPs and Documents

R&D/S04 Breaches of GCP or the Study Protocol

R&D/S06 Reporting Requirements during Studies

R&D/T24 End of Study Report Template

[1] CONSORT statement. http://www.consort-statement.org/
[2] STROBE statement http://www.strobe-statement.org