ECTU Central Office SOP ECTU_ST_05: Statistical Analysis and Reporting

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Authorship and Approval			
Name and Designation	Author/Reviewer/ Approval/ Authorisation	Date	Signature
Catriona Keerie, Senior Statistician	Author	18 Mar 2024	Catriona Keerie
Sharon Tuck, Senior Statistician	Reviewer	18 Mar 2024	Sharon Tuck
Steff Lewis, Statistics Team Lead	Approver	19 Mar 2024	Steff Lewis
Tanya Tharakan, QA Manager	QA Authorisation	19 Mar 2024	Tanya Tharakan Tanya Tharakan (Mar 19, 2024 15:50 GMT)

Document Revision History		
Version No	Effective Date	Summary of Revisions
1.0	6 Aug 2012	New document
2.0	19 Apr 2015	Removed sentence that suggested hard coding was acceptable. Validation now applies to all studies, not just CTIMPs.
3.0	26 Jun 2017	Updates after scheduled review. Section 3.4 (on DMC report validation) removed (sections renumbered as a result). Reference to ECTU_WPD_ST_W5 added to Section 4.
4.0	26 Aug 2019	Updated at scheduled review. Document moved to new SOP template.
5.0	21 Apr 2021	Revision ahead of two year review period in order to align with review timings for ECTU_WPD_ST_W5.
6.0	03 Apr 2024	SOP has been transferred to new ECTU SOP template. Additional updates incorporated to better reflect current processes.

The user of this document is responsible for ensuring it is the current version.

1.0 PURPOSE

The purpose of this SOP is to outline the procedures for statistical analysis and reporting in Edinburgh Clinical Trials Unit (ECTU).

2.0 SCOPE

This SOP applies to all randomised trials with statistical support provided through ECTU.

3.0 RESPONSIBILITIES

It applies to the ECTU statisticians performing the trial analyses and producing statistical reports.

4.0 PROCEDURE

All analyses must be repeatable, and processes must be in place to ensure that the final report is accurate and to minimise bias.

4.1 The final analysis should follow the pre-specified Statistical Analysis Plan, this should be stored in the study specific Statistics Master File, in a statistical analysis plan sub-folder.

4.2 The final analysis, and any formal interim analysis, , should be documented in enough detail so that it is repeatable. This includes indicating which statistical software was used (including version number), keeping copies of computer programs that create any datasets used for analyses, keeping the analysis datasets, and keeping computer programs that run statistical analyses. Electronic SAS log files (or equivalent for other software) and output files (or their equivalents) for these programs should also be kept in a clearly labelled separate folder to the analysis programs. It should be clear precisely which programs were used to produce each report.

4.3 The primary outcome and other key results should be independently validated before the report is finalised and either it, or the results within it, are made public. Further details are provided in ECTU_WPD_ST_W5: Statistical Analysis and Reporting

4.4 If data errors are found during the course of the final analysis, then either:

Option 1 – Unlock the trial database, amend the data and relock the database, ensuring that all the steps are documented. When re-locked, the new final database should not overwrite any analysis datasets that were created at the time of the original database lock. Analysis can then recommence. Further information on unlocking a database is detailed in ECTU_SOP_OP_20: Requests to Lock and Unlock a Study Database

Option 2 – Do not amend or correct the data on the database but include a footnote in the report to highlight the data error.

It is generally not acceptable to amend data in statistical programs (hard coding) and this is specifically not acceptable in CTIMP trials.

5.0. RELEVANT DOCUMENTS AND REFERENCES

On ECTU website

- ECTU_SOP_ST_03 Data Monitoring Committee
- ECTU_SOP_ST_04 Statistical Analysis Plans
- ECTU_WPD_ST_W5: Statistical Analysis and Reporting
- ECTU_SOP_OP_20: Requests to Lock and Unlock a Study Database

Adobe Approval: SOP_ST_05 Statistical Analysis and Reporting v6.0 and WPD_ST_W5 Statistical Analysis and Reporting v5.0

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