

ECTU Central Office SOP ECTU_ST_05: Statistical Analysis and Reporting

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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.

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7.0	21 Oct 2026	SOP reviewed and parts of section 4.0 have been updated to incorporate considerations for DMC reporting and data sharing.
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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, regardless of whether it is the final, interim or a Data Monitoring Committee (DMC) safety review, and processes must be in place to ensure that all statistical reporting is accurate and to minimise bias.

- 4.1 Final and interim analyses 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 or reports produced for a DMC safety review, should be documented in the Statistical Analysis Plan in enough detail so that they are repeatable. This includes indicating which statistical software was used (including version number), keeping copies of computer programs that create any datasets used for analyses, the analysis datasets, and 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(s) 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 for interim or final reporting should be independently validated (Refer to ECTU SOP ST 08 Validation for Statistical Reports) 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

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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.

- 4.5 A data sharing pack should be generated as part of the final analysis reporting. Further details are provided in ECTU_WPD_ST_W5: Statistical Analysis and Reporting.

5.0. RELEVANT DOCUMENTS AND REFERENCES

[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
- ECTU_SOP_ST_08 Validation for Statistical Reports

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ECTU_SOP_ST_05 Statistical Analysis and Reporting v7.0 and associated documents

Final Audit Report

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