

ECTU Central Office SOP ECTU_ST_08: Validation of Statistical Reports

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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	26 Oct 2026	Initial creation

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1.0 PURPOSE

Validation of statistical results by a second, independent statistician is critical to ensure that the analysis is accurate and to minimise bias. The purpose of this SOP is to describe the procedures for validation of formal interim analysis reports and final analysis reports of clinical trials in ECTU.

2.0 SCOPE

This SOP is applicable to all CTIMP or CIMD trials with statistical support provided through ECTU. However, it is recommended that this SOP is followed, where appropriate, for all types of studies.

3.0 RESPONSIBILITIES

This SOP applies to the ECTU trial and unblinded statisticians and the statisticians responsible for validating the statistical report of a trial.

4.0 PROCEDURE

4.1 Validation Plan

4.1.1 Before the validation starts, the validation plan should be agreed between the validating statistician and the unblinded statistician performing the interim/final analyses, using the latest version of the Validation Document (ST008). The outline plan for validation is included in the current version of the study's Statistical Analysis Plan (SAP). As a minimum, the validation plan should include reading and sense-checking of the statistical report(s). It is recommended that the validation includes the validating statistician independently replicating the primary outcome analysis from first principles. This means that the validating statistician will only use the raw data and the SAP to perform their analysis, without using any analysis code or derived variables produced by the unblinded statistician. Consideration should also be given to including additional validation of unusual or complex models. It is also good practice to validate the reporting of the minimisation/stratification variables.

4.1.2 The extent and level of complexity of the validation (e.g., programming from first principles; programming on prepared datasets; sense-checking the code/report) should take into account the complexity of the trial design, derivation of outcomes, and analyses.

4.1.3 In exceptional circumstances, the validation may involve conducting analyses on prepared analysis datasets derived by the unblinded statistician rather than using the raw trial data and/or using statistical code written by the unblinded statistician. In this case, the validation approach should be justified in the validation plan and the validating statistician should review the code used to process the raw trial data into the prepared analysis datasets. This should be evidenced in the validation document and/or statistical report (see section 4.2.9). In this situation, it is recommended that the treatment allocation and the variables included in any adjustment are considered and independently coded.

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4.1.4 Details of the database source, the analysis population(s), and any important variables used for deriving the primary outcome should be documented in the Validation Document.

4.1.5 Once the plan is finalised, the section 'Validation Plan Approval' must be completed under Part 1 of the ST008 Validation Document. In the rare circumstance where the unblinded statistician and Trial statistician are the same person (for example, in projects where there are no requirements for a separate blinded statistician), the signature section for the unblinded statistician can be marked as "Not applicable".

4.2 Validation Conduct

4.2.1 The validation analysis of the primary outcome, and any selected additional outcomes, should follow the methods described in the current version of the SAP.

4.2.2 The validating statistician should take care that the correct analysis populations are used for each validation analysis as per the SAP.

4.2.3 It is important that the validating statistician works on the analyses independently as far as possible to minimise bias.

4.2.4 Validation analyses can be performed using the same statistical software used by the unblinded statistician, or on different reliable software (e.g., SAS, R, Stata, SPSS), depending on the preference of the validating statistician.

4.2.5 It is recommended that the validating statistician starts pre-programming the analyses in advance of database lock, although this is not essential. The formal validation should always take place after database lock, although preparatory validations may also be performed before database lock.

4.2.6 Where necessary, the trial statistician will request the programmer to provide read only access to the database for the validating statistician to download the data.

4.2.7 It is important to ensure that the formal validation is conducted on the real data after database lock and on the relevant interim/final analysis report(s), rather than based on the dummy analysis report (i.e., using dummy treatment codes). 4.2.8 All validation programs including analysis datasets, outputs and log files, should be stored in a clearly labelled separate subfolder in the unblinded folder within the study's electronic folder location on DataStore.

4.2.9 It is recommended that the validating statistician prepares a brief statistical report summarising their analysis results. Any discrepancies or reasons for differences between results should be documented in the validation document.

4.2.10 Agreement on the results between the unblinded statistician and the validating statistician should be ensured before the interim/final analysis report(s) are finalised by the unblinded statistician. Once both parties are in agreement, the Final Report Authorisation form (ST005B), or the Interim Report Authorisation form (ST005C),

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whichever is applicable, should be signed off before the report is sent to the Chief Investigator (CI).

4.2.10 For final reports, there may be additional items that the unblinded statistician considers worth validating after completing the statistical analyses, which were not pre-specified in the validation plan. This is likely to occur before the release of the final statistical report. Furthermore, after the final report is issued, it is important to validate any findings the CI considers unusual or unexpected. It is also recommended to validate any results that are likely to have prominence in the abstract or final publication (e.g., significant p-values), or any additional analyses requested during peer review of a publication. In any such cases, any additional validation requested should be documented in the respective section of the Validation Document and saved within the Statistical Master File under section 4 Statistical Analysis Plan.

4.2.11 Once the validation has been conducted, the finalised date and the section 'Validation Confirmation Approval' must be completed under Part 2 of the ST008 Validation Document. See section 4.1.5 for guidance on unblinded statistician signatures.

5.0 RELEVANT DOCUMENTS AND REFERENCES

[ECTU Website:](#)

- ECTU_SOP_ST_05 Statistical Analysis and Reporting
- ECTU_WPD_ST_W5 Statistical Analysis and Reporting
- ECTU_SOP_ST_04 Statistical Analysis Plan
- ECTU_WPD_ST_W4 Additional Guidance on the Contents of a Statistical Analysis Plan
- ST008 Validation Document Template
- ST005B Final Report Authorisation Template
- ST005C Interim Report Authorisation Template

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ECTU_SOP_ST_08 Validation of Statistical Reports v1.0

Final Audit Report

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