STANDARD OPERATING PROCEDURE FOR THE IMPLEMENTATION OF STATISTICAL ANALYSIS IN CLINICAL RESEARCH

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1. PURPOSE

This Standard Operating Procedure (SOP) describes the process for the statistical analysis of clinical research in compliance with the principles of Good Clinical Practice.

2. SCOPE

This document applies to Clinical Trials of Investigational Medicinal Products (CTIMP) and clinical research sponsored or co-sponsored by the University of Dundee (UoD) or NHS Tayside (NHST).

This SOP applies to UoD and NHST members of staff responsible for the statistical planning and analysis associated with clinical research. Responsibility for the statistical analysis may be transferred to a group or individuals outside UoD or NHST but this must be done using a formal clinical trial service agreement or collaboration agreement as appropriate.

3. RESPONSIBILITIES

The role of statistics in clinical trial design and analysis is acknowledged as essential in ICH Good Clinical Practice. This SOP is intended to give direction to the Study Statistician and Chief Investigator (CI) on the statistical principles relating to the design, conduct, analysis, and evaluation of clinical studies. The CI may also be the Study Statistician.

This SOP should be used in conjunction with other relevant TASC SOPs relating to Data Management and Statistics.

4. PROCEDURE

4.1 A Statistical Analysis Plan (SAP) must be written and finalised as per the TASC SOP on Statistical Analysis Plans for clinical research prior to any analysis in a study. This applies to both interim and final analysis.

4.2 The SAP should detail exactly the analysis populations proposed for each analysis.

4.3 The SAP should also detail the analysis program and version to be used, *e.g.* SAS, R, SPSS. The statistical analysis itself may be undertaken by menu-driven options in the software, using previously created programs/macros/systems, or by writing new

code in the statistical software. If programming is required, programming activities may be undertaken by programmers rather than qualified statisticians, but it is recommended that there is demonstrable oversight of the analysis by a statistician.

4.4 Programming should follow good practice on programming standards.

4.5 All programs used for analysis should be validated. Macros can be validated in advance, custom-written programs should be validated during the analysis. The level of validation for each analysis should be defined in the SAP and outlined below.

4.6 At the lowest level of validation, the program should run free from errors and warnings. Where warnings are unavoidable, a comment should be inserted into the program to show the WARNING has been acknowledged by the programmer.

4.7 At the second level, an independent statistician should check the program for consistency and correctness. Any errors in the program should be resolved by the Study Statistician. The check should be documented by both statisticians, signed, and dated (Doc Ref 115).

4.8 The primary analysis will be checked by independent programming by a second ideally independent statistician. The results should be compared to the primary analysis and any discrepancies discussed and resolved. The check and its results will be documented, signed and dated by both statisticians (Doc Ref 115).

4.9 All output from the analysis should contain date and time stamps to ensure an audit trail can be maintained. The stamps should be applied to both the document itself and the document names.

4.10 End of Trial - all programs and outputs, electronic and paper documentation created in association with the analysis is part of the Trial Master File and should be archived as per the relevant sponsor SOPs. The Study Statistician and any independent statistician(s) must provide all paper and electronic data programs and listings to the trial team to be archived.

5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
ICH	International Council for Harmonisation
NHST	NHS Tayside
SAP	Statistical Analysis Plan
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre
UoD	University of Dundee

6. ASSOCIATED DOCUMENTS & REFERENCES

Doc Ref 115: Signature Sheet Template

7. DOCUMENT HISTORY

History prior to 2021 is in the archived SOPs available from TASC Quality Assurance Dept.

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
3	Tracy Petrie (Quality Assurance Support Officer)	01/02/2021	Uploaded to new TASC SOP template which shows the new TASC website in the footer. Physical scan converted to electronic pdf as a requirement for upload to new TASC website.
4	Petra Rauchhaus (Clinical Trials Statistician)	05/04/2021	Scheduled review date. No changes made.
5	Petra Rauchhaus (Clinical Trials Statistician)	05/04/2023	Scheduled review date. No changes made.
6	Petra Rauchhaus (Clinical Trials Statistician)	07/04/2025	Scheduled review date. No changes made.

8. APPROVALS

Approved by:	Date:
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	03 Apr 2025