

SOP-QA-23 V5

Title: Statistical Analysis Plans for clinical trials

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Document History

Version	Description of update	Date Effective
3	Scheduled review at three years; no changes identified.	01-08-20
4	Withdrawals updated to read participant change of status at 3.12	09-08-23
5	Modernise statistical terminology, improve clarity and align with current clinical trial statistical guidance (including ICH E9(R1) where applicable).	15-09-26

1. Scope

- 1.1 This SOP applies to all clinical trials sponsored by University of Aberdeen (UoA) and/or NHS Grampian (NHSG) and applies to the statistician(s) commissioned to conduct statistical analysis and the Chief Investigator (CI).
- 1.2 All clinical trials must have a Statistical Analysis Plan (SAP) which is a comprehensive description of the methods and presentation of data analysis proposed.

2. Responsibilities

Chief Investigator (CI) Preparing the SAP (delegated by the Sponsor)

3. Procedure

- 3.1  The overall responsibility for preparing the SAP is delegated to the CI or Clinical Trials Unit (CTU) by Sponsor. This delegation of duty shall be agreed before the study begins and shall be documented in the sponsorship/site agreements.
- 3.2  The CI, acting on behalf of the Sponsor, may delegate the responsibility for preparing the SAP to the lead statistician but the responsibility for the final SAP remains the CIs. Any such delegation shall be documented. At least one author of the SAP shall be a professional statistician.
- 3.3 The SAP must be drafted, finalised and agreed before commencing the final statistical analysis of clinical trial data. Where possible, statistical programming and validation should be complete before unblinding (revealing the treatment allocation).
- 3.4 Any changes to the SAP during the course of the clinical trial must be documented in the SAP and reasons for the change noted.
- 3.5 The SAP shall document authorship, including the statistician responsible for preparation of the SAP, approval from the lead statistician overseeing preparation of the SAP (if required), approval from the Chief Investigator and be version controlled.

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Key to symbols  = Important point to note  = Warning

- 3.6 The SAP shall define the estimands (where applicable), the hypotheses to be tested and/or any parameters that are to be estimated in order to meet trial objectives stated in protocol.
- 3.7 The SAP shall provide details of the sample size calculation specified in the trial protocol, explicitly stating all assumptions made and the sources of supporting evidence used and expert opinion sought.
- 3.8 The SAP shall list details of tables, figures and other data to be presented in the statistical report(s) and shall include the set of dummy data tables reflecting the contents of the final report.
- 3.9 The SAP shall clearly define populations within the clinical trial, for example, intention-to-treat, per-protocol and safety populations.,
- 3.10 The SAP shall list and define all primary and secondary outcomes, and also describe in detail any algorithms required to derive outcomes.
- 3.11 The SAP shall state whether interim analyses are planned and, if so, their timing and purpose.
- 3.12 The SAP shall include a description of the methods for analysis and presentation of the data, including, where applicable:
- Definition of the estimand(s) for the primary and secondary outcomes, where applicable
 - Methods for point and interval estimation.
 - Levels of statistical significance to be used, one-tailed or two-tailed tests to be performed.
 - Methods for adjustment for multiplicity, where applicable..
 - Use of baseline and covariate data.
 - Methods for handling multi-centre data.
 - Methods for handling missing data.
 - Methods for handling participant change of status and protocol deviations.
 - Specification of the statistical models to be used, including fixed and random effects where applicable.
 - Planned interim analysis and statistical stopping rules.
 - Methods for assessing model assumptions and planned sensitivity analyses.
 - Specification of computer systems and statistical software packages to be used for statistical analysis.

4. Abbreviations and definitions

CTU	Clinical Trials Unit
SAP	Statistical Analysis Plan

5. Related documentation and references

SOP-QA-3	Protocol guidance for high risk trials and CTIMPs
SOP-QA-17	Project committees
SOP-QA-18	Randomisation and blinding for controlled trials
SOP-QA-20	Data management for clinical trials
SOP-QA-21	APRs and DSURs

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