Statistical Data Analysis

Trial Close-Out Phase

Statistical Data Analysis follows the End of Trial Declaration station and precedes the Clinical Trial Summary Report station. Statistical Data Analysis is good practice and is relevant to all trials. This station is part of the 'trial close-out phase' group of stations.

Statistical Analysis

Most funders and sponsors expect early involvement of an appropriately qualified statistician, often through a UKCRC-registered Clinical Trials Unit. The statistician should support trial design, protocol development and the preparation of a Statistical Analysis Plan (SAP).

The amended Clinical Trials Regulations do not introduce specific new statutory requirements for statistics or statisticians; however, there is increased emphasis on scientific robustness, risk-proportionate design and data integrity, which reinforces the need for appropriate statistical expertise in a trial.

The SAP should be finalised before unblinding and follow established guidance, such as that of Gamble et al. JAMA consensus on SAP content, alongside CONSORT and ICH E9 Statistical Principles. It should clearly specify the analyses of the primary and key secondary outcomes, define the analysis populations, and describe methods for handling missing data, multiplicity, and any planned subgroup or sensitivity analyses.

The estimands framework in ICH E9 (R1) (.PDF) helps to ensure the planned analysis aligns with the trial's defined estimands, including how intercurrent events will be handled and how the treatment effect will be summarised.

Post hoc or exploratory analyses should be clearly identified and justified in publications. For trials using complex or innovative designs, the SAP may link to the relevant specialist guidance rather than reproduce it.

Further Reading

- NIHR Statistics Group: Supports statisticians across the country.
- UKCRC Statistics Operational Group (.PDF): Slide presentation on the group's activities.
- CONSORT Guidelines & extensions: Reporting guidelines for clinical trials.
- ICH E9 and ICH E9 (R1) (.PDF) Estimands: ICH statistical guidance.
- Stoken et al – Good Statistical Practice, the development of GCP training for statisticians.
- Australian Clinical Trials Alliance (ACTA): Guidance and webinars for statisticians, including SAPs for Adaptive and Platform Trials.