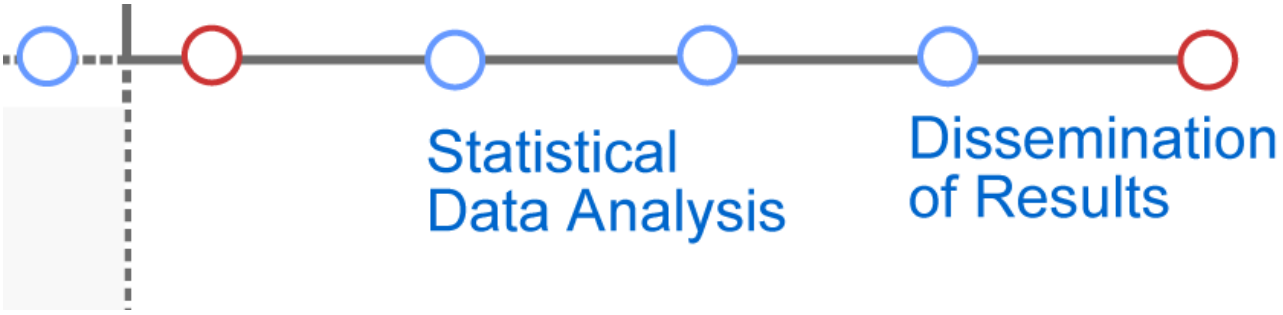
Routemap

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.

Support for trial data management and statistical analysis is available from a range of sources including UKCRC registered Clinical Trials Units. In the majority of trials, funders and sponsors will require appropriate arrangements to be specified during the trial design phase and the services of an appropriately trained statistician to be secured.

One of the main components of the analysis is the statistical analysis plan (SAP)**.** This plan ensures that the analyses to evaluate all planned study hypotheses are conducted in a scientifically valid manner and that all decisions are documented. It also provides detail on how the results will be presented and reported. The statistician should refer to The CONSORT Statement (and any extensions) and also ICH E9 Statistical Principles for Clinical Trials (PDF, 325 KB).

The following should be described and agreed in the SAP:

- Any primary and key secondary outcome measures stated in the protocol to be analysed
- Methods for handling missing data and multiplicity of data
- Justification for any non-standard statistical techniques.

In addition, any subsequent post hoc analysis should be justified and reported in any publication.

Other important considerations relating to statistical analysis include:

- Practicalities relating to the blinding of the trial statistician
- Documentation to ensure that all data manipulations and analyses performed on the original data extracted from the data entry system, can be replicated
- Procedures to ensure that all relevant documentation in the possession of the statistician is filed at trial completion, in the Trial Master File.

The trial results should be discussed by the Chief Investigator and all relevant oversight groups (such as Data Monitoring Committee and Trial Steering Committee) to assist interpretation and to discuss the implications of the findings.

Further reading:

- Trial Planning & Design station
- The EQUATOR Network - Resource centre for good reporting of health research studies.
- The CONSORT website
- Gamble et al. (2017) recommend a minimum set of items that should be addressed and included in Statistical Analysis Plans for clinical trials.