Statistical Analysis Plan

Introduction to Statistical Analysis Plans

- ▶ Statistical Analysis Plan (SAP) describes the planned statistical analysis of a studies objectives.
- ▶ In other words, it describes what variables and outcomes will be collected and which statistical methods will be used to analyse them.
- ▶ In clinical trials a SAP is an essential document because very often the individuals collecting the data will not be those who conduct the analyses.
- ▶ Regulatory bodies all over the world expect that the SAP will meet requirements in pre-specifying inferential analyses and other important statistical techniques.
- ▶ It is expected that the Analysis Plan will provide explicit guidance to be followed by the statistician.

Why is a SAP needed?

- ▶ A SAP is used to help with reproducibility of studies results.
- ▶ Therefore, it is an important document for all types of statistical analyses, not just clinical trials
- ▶ An individual not involved in a study should be able to reproduce the results in a study when given the final data, study protocol, documentation of the data collection procedures, and the SAP.
- ▶ A SAP also help prevent cherry-picking results and,
- ▶ it eliminates investigator (or statistician) bias.

Main elements of a SAP

- ▶ The SAP should be written prior to any data analysis being conducted.
- ▶ The SAP defines the statistical analysis that will be performed and all of the output required to be included in the final report. It should contain,
    - ▶ I statistical methods to be used
    - ▶ how subject data will be summarised
    - ▶ the statistical tests and models to be used,
    - ▶ data-handling rules for reporting purposes e.g. when and how to impute missing/partial data
    - ▶ a complete table of contents with all Tables/Lists/Figures (TLFs) to be produced and representations of what each TLF will look like but without the actual numbers.

Detailed below (and on moodle) is an example of the generic headings used in a SAP.

- ▶ Population
- ▶ Primary Objective
- ▶ Secondary Objectives
- ▶ Data Collection methods
- ▶ Variables under consideration
- ▶ Missing data procedures
- ▶ Numerical and graphical summaries to be presented
- ▶ Models to be fitted

Example SAPs

▶ On Moodle there is an example research question and example SAP on a study investigating the growth of Dungeness Crabs.

▶ Read through this example, then have a go at producing a SAP for the second research question on snakes