



TARDIS–Working Practice Document – No: 044

Statistical Programming

The purpose of this document is to describe actions the Trial Statistician at the Co-ordinating centre will take to prepare Data Monitoring Committee and Trial Steering Committee reports.

Data extract is obtained from the Trial Programmer when programmes are run for the CTU. When the STU statisticians download a new extract, this done directly from the TARDIS website.

The statistical program that is used is: SAS.

Each report will be prepared using 2 programs; SAS and Microsoft Word.

The coding for the report will be saved as a dated version alongside the Word/PDF report.

The report should include the statistician name, person checked by and the date created.

Previous versions of coding files should be saved and not over-written.

For the DMC, the CTU statistician will be sent an un-blinded data set and use the programs written by the Co-ordinating centre statistician to run the analyses.

The CTU statistician will be on the teleconference of the DMC phone call and present the un-blinded report.

The Co-ordinating Centre statistician will attend the Trial Steering Committee and present the blinded statistical report.

Each report will be checked by the Trial Statistician against the previous year's report for inconsistencies.

Each report will also be checked by another Statistician.