Role of a statistician in CTU

Stage I – Principle and Funding Set Up

Stage II – Set Up in CTU (once trial funded)

Stage III – Trial management

Stage IV – Trial close out

Help design the clinical trial (usually SS)

- Advise on trial design – attend trial development group meetings
- Undertake sample size calculations
- Advise on method of randomisation
- Write the statistics sections of the grant application
- Respond to reviewer's comments

Attend early trial management group meetings (mainly SS)

Input into protocol development (both TS and SS)

- Write statistics sections for the trial protocol
- Undertake a thorough review of other sections of the protocol

Data management (both TS and SS)

- Work with trial team to design the database/CRFs and decide what edit checks the database should be programmed to check
- Review data management documentation to ensure all data required for analysis is captured

Randomisation system development (both TS and SS)

- Advise and/or design the randomisation method
- Prepare the randomisation schedule and ensure it is checked by another statistician
- For blinded studies oversee the preparation of the concealment list
- Test the randomisation system for functionality and to ensure the schedule is followed

Data monitoring and Ethics Committee (DMEC) meetings

- Create a template DMEC report following first meeting with the CI and DMEC input – send to DMEC for their approval prior to first meeting with data (TS, SS review)
- For every DMEC meeting prepare detailed DMEC reports (usually around 60 to 80 pages long) (TS)
- Thorough review of report before sending to DMEC (SS)
- Prepare minutes and any subsequent analysis following each meeting (TS)

Produce interim analysis as final analysis (may not be pre-specified in protocol)

Statistical Analysis Plan

- Write a detailed statistical analysis plan including table shells (TS)
- Review of SAP throughout development (SS)
- Make amendments following review by TMG, DMEC and TSC this usually involves many iterations (TS)

Other tasks undertaken by the TS (and sometimes SS):

- Attend trial team meetings and TMGs
- Adhoc statistical queries from trial team
- Make protocol amendments if needed and review every protocol amendment before submission
- Regularly review the randomisation to ensure the schedule is being followed and the arms are balanced as expected
- Review all trial reports (e.g. TMG reports)
- Central statistical and data monitoring checks (trial-specific, some trials require more checks) and highlight any data queries to trial team
- Contribute to other publications as requested by CI and agreed part of CTU remit/strategy
- Responsible for statistical master file (section of trial master file)

Final trial analysis (both TS and SS and also other CTU statisticians as needed)

- Prepare STATA/SAS code for final trial analysis
- Support database freeze/ lock process
- Raise any final data queries which need resolution before final results
- Undertake final trial analysis
- Contribute to the clinical study report
- All tables and results would be reviewed by another statistician (preferably SS) before being finalised – the same checks as applied to DMEC reports would be applied
- The primary analysis results must be 100% replicated by another statistician before publication

Contribute to writing of publications with the trial results included (TS and SS)

Contribute to other publications as requested by CI and agreed part of CTU remit/ strategy (TS and SS)

