CI	Chief Investigator
CRFs	Case Report Forms
CTU	Clinical Trials Unit
DMC	Data Monitoring Committee
MHRA	Medicines and Healthcare Products Regulatory Agency
R&D	Research and Development
SAE	Serious Adverse Event
TMG	Trial Management Group
TSC	Trial Steering Committee
UKCRC	UK Clinical Research Collaboration

For further information on this or other aspects of
Conducting clinical research, please contact:
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Statistics Services within the CTU

Brighton and Sussex Clinical Trials Unit

Brighton and Sussex University Hospitals NHS Trust

University of Sussex

brighton and sussex medical school

Services offered:

The Brighton and Sussex Clinical Trials Unit offers a full trial statistician service to randomised controlled trials and other well designed studies in line with the role of a CTU http://www.ukcrc-ctu.org.uk/

Consultancy or advisory support is available from The Kent, Surrey and Sussex Research Design Service (RDS) http://www.rds-se.nihr.ac.uk/

You may wish to refer to ICH GCP E9 - Statistical Principles for Clinical Trials.

Access to expertise:

Trial statistician involvement via the CTU ensures that the study benefits from methodological expertise locally, from the design stage through to analysis and publication.

Trial statisticians within the CTU are committed to full collaborative involvement in trials to ensure meaningful reports are produced for oversight committees, to protect the safety of patients and the credibility of the trial data and that analyses are completed in a timely manner.

Trial statistician service:

When contracted to provide trial statistical input to a study, the following tasks are undertaken as appropriate:

- Perform sample size calculations
- Advise on study design
- Contribute to statistician sections of grant application
- Respond to reviewers' comments
- Contribute to statistical aspects of protocol writing
- Liaise closely with the data manager and trial team to devise the CRFs.
- Advise on randomisation method
- Prepare DMC reports
- Attend DMC meetings
- Attend TSC meetings
- Prepare a statistical analysis plan in collaboration with the CI
- Prepare code for primary analysis (typically using STATA)
- Communicate data queries back to the study team at the analysis stage
- Conduct primary analysis
- Contribute to primary paper
- Quality checking, by an independent statistician, at each of the above stages, as appropriate
- Maintaining a Statistics Master File of all related documents

How to get the best from statistical services:

- Approach the CTU early
- Provide relevant papers and information to inform the sample size calculations
- Develop a comprehensive trial protocol
- Work closely with the trial statistician in the production of the analysis plan, providing information on scoring algorithms and clinical Interpretation where needed
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- Identify appropriate independent TSC and DMC members
- Organise DMC and TSC meetings, scheduled well in advance
- Ensure the data set is appropriately collected and entered
- Ensure all data checking is complete and a clean data set is ready for analysis at study end
- Respond promptly to data issues raised by the statistician at the analysis stage
- Make alternative arrangements for statistician input into secondary analysis and production of secondary papers

Costs:

For trial statistician services, typically a minimum of 10% and up to 30% of total statistician time must be included, for the duration of the grant

Computer, telephone and stationery costs must also be included where appropriate.

For more information on the CTU please go to www.bsms.ac.uk/ctu