<table>
<thead>
<tr>
<th>CI</th>
<th>Chief Investigator</th>
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<tr>
<td>CRFs</td>
<td>Case Report Forms</td>
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<tr>
<td>CTU</td>
<td>Clinical Trials Unit</td>
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<tr>
<td>DMC</td>
<td>Data Monitoring Committee</td>
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<tr>
<td>MHRA</td>
<td>Medicines and Healthcare Products Regulatory Agency</td>
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<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
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<tr>
<td>SAE</td>
<td>Serious Adverse Event</td>
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<tr>
<td>TMG</td>
<td>Trial Management Group</td>
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<tr>
<td>TSC</td>
<td>Trial Steering Committee</td>
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<tr>
<td>UKCRC</td>
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For further information on this or other aspects of Conducting clinical research, please contact:
Nicky Perry
Operational Manager
Brighton and Sussex CTU
Bevendean House, University of Brighton
BN1 9PH

Tel: 01273 641440
Email: bsctu@bsms.ac.uk

Version 2
July 2015
**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.ukrc-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

**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

**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