

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

Contracting Data Management Services to the CTU

Brighton and Sussex
Clinical Trials Unit

For further information on this or other aspects of running a randomised controlled trial, please contact:

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Brighton and Sussex 
University Hospitals
NHS Trust

 University
of Sussex

 brighton and sussex
medical school

Services offered:

Within the CTU researchers requiring database management would have access to a team who can design, manage and maintain database systems i.e. MACRO/OpenClinica for recording clinical trials data. They will be responsible for the on-going management of the database system for the duration of the project.

Data management services within the CTU ensure that the Investigator is kept informed of emerging problems in critical data within the study and that data are monitored centrally in the most robust way to maximise completeness and accuracy of the dataset.

Data management service:

When contracted to provide data management to the study, the following tasks would be undertaken:

- Monitor data entry into the study (excluding SDV checking as this is done by the Trial Manager)
- Produce reports on timelines to data entry, missing data, visit timelines, outliers and circulate these reports to the trial manager and CI as needed
- Inform trial manager of any issues within the database design which may need to be raised with the database design team
- Produce a data management plan for the study
- Monitor data flow through the study
Liaise with the trial statistician to plan appropriate logic checks on data
- Liaise with the trial statistician to ensure they can access appropriate data to produce consort diagrams and reports
- Attend TMG meetings
- Ensure concomitant medication and AE data is appropriately coded by site staff, linking in with CI as appropriate
- Advise the CI promptly if any concerns about data quality are identified
- Assist the trial statistician in data manipulation where appropriate
- Produce a final data set for analysis and manage the database lock process
- Training of study staff and trial managers

The Investigator would be expected to:

- Meet regularly with the data manager to discuss any issues arising in the data set
- Respond to concerns and manage process if changes to the database or conduct of study at site are needed
- Arrange for the appropriate local storage and archiving of the study data after the study has closed

Costs:

Please discuss with a member of the CTU team as soon as possible.

For data management fully within the CTU, the % wte of data manager to be included would be agreed with the Investigator at the grant application stage, in addition to 0.05wte CTU Senior Data Manager to supervise the post.

For a typical multicentre trial, it would be expected that a 0.5wte data manager would be appointed.

For smaller trials, a single data manager could potentially work across three or more studies.

Additional costs e.g. computer, telephone and stationary costs must also be included where appropriate.

If additional CTU resource is required, this must be reviewed and a funding stream agreed.