CI	Chief Investigator
CTU	Clinical Trials Unit
CTA	Clinical Trials Agreement
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 running a study, please contact:
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Contracting Study Management Services to the CTU

Brighton and Sussex Clinical Trials Unit

Version 2
22nd September 2014

Within the CTU researchers requiring study management would have access to study managers with experience and expertise to:

- Set up and support high quality clinical trials
- Establish and maintain effective management systems for the study
- Act as the central trials unit contact for the study
- Liaise with all collaborating organisations and individuals as required ensuring the smooth running of the study;
- Uphold the quality of the study and compliance with the protocol, GCP and applicable standards and regulations.

Study management services within the CTU deliver projects on time and on budget, while ensuring that the safety of patients and the credibility of data are paramount.

Study management service:

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

- Assist with protocol development for the study
- Provide ethical advice on running clinical studies
- Advise on sponsorship of study arrangements
- Manage version control on all study documents
- Assist in the preparation and submission of the main ethics application, plus amendments and annual reports
- Prepare and submit CTA application, if appropriate, plus amendments and annual reports
- Ensure R&D approval is in place for all sites
- Conduct site initiation visits where appropriate
- Undertake study specific training, as required
- Train site staff in systems use (with data manager)
- Prepare and maintain Trial Master File
- Provide sites with Investigator Site Files and Pharmacy Files, as needed
- Undertake regular site monitoring visits (frequency to be agreed with CI)
- Review of adverse events and con meds as appropriate
- Monitor data for the study, including randomisation system data
- Raise any issues in the database design with the database management team for resolution
- Submit monitoring documents to the CI for review
- Liaise with CI/research team to ensure reports to funders are submitted
- Ensure TSC, DMC and TMG meetings are scheduled and liaise with study statistician to ensure appropriate documents are circulated and minutes taken

The Investigator would be expected to:

- Meet regularly with the trial manager to review conduct of the study
- Take overall responsibility for the study finances.
- Review all monitoring reports or delegate an appropriate person to do so
- Review all SAE's reported in the study or delegate an appropriate person to do so

Costs:

Discuss with CTU operational manager as soon as possible:

As a guide, for trial management fully within the CTU, the % wte of a trial manager to be included would be agreed with the Investigator at the grant application stage, in addition to 0.05wte CTU Senior Trial manage to supervise the post.

For a typical multicentre trial, it would be expected that a full time trial manager would be appointed.

For smaller trials, a single trial manager could potentially work across two or more studies.

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

Administrative support and data management support must also be included where appropriate.

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