

No study is better than the quality of its data – capturing good quality data that is valid, auditable, contemporaneous, accurate, and collects the variables to both answer the research question and assess the follow of patients through the study is essential. KCTU can offer the following collaboration to support this function in your trial.

Collaboration:

KCTU collaborations enable research teams to obtain senior support for data management activities. This offers the study teams the opportunity to buy-in expert support from senior data managers within the KCTU to support and develop the individual designated to lead on these elements of the project.

Using this model those undertaking data management activities are employed directly within the department where the funding is awarded. In this way the study teams are able to build up expertise within departments with the knowledge there is sufficient support to enhance the delivery of trial and data management activities throughout the duration of a trial.

Details of this collaboration:

- The data manager will be employed by the relevant department, line managed by the Chief Investigator or other appropriate individual*
- The data manager will receive expert supervision from an experienced senior member of the data management team
- The data manager will participate in the King's Trial Partnership and will therefore be able to attend talks relevant to the delivery of trials,
- The data manager will participant in the Trial Managers & Data Managers Network, to gain peer support.
- The data manager will be part of the King's Trial Partnership and will therefore be able to attend free training on all aspects relating to the delivery of trials, including the Trial Managers & Data Managers Network.
- The data manager will have the opportunity to "hotdesk" within the King's CTU up to one day a week which facilitates networking with others in similar roles and exposure to the culture of a busy CTU.
- It is expected that the CI will fully engage with the conduct of the trial holding regular meetings with the Trial Management Group as needed.
- It is expected that a qualified statistician must be engaged with the project to deliver the trial statistics role.
- It is expected that an identified person (may be the same individual as the data manager role) will be responsible for the delivery of data management on the trial.
- It is expected that data management will utilise Informed MACRO or use another system agreed with King's CTU as appropriate at the grant application stage.
- It is expected that the data manager will work to the relevant KCTU SOPs

Supervision provided in the following areas:

- Provision of content for the study protocol with regards to data handling.
- Provision of support and advice to the nominated individual on how to approach data management and draft a data management plan.
- Review of data management plan content and to advice on different approaches to data cleaning.
- Provisions of advice on appropriate database lock procedures.
- Attendance at a proportion of Trial Management Group Meetings (as required).
- Provision of feedback on performance of data manager to the Chief Investigator as appropriate.

Resource required:

- Minimum of 5% Senior Data Manager supervision time to be costed into the grant application.

*In exceptional circumstances and with the agreement of King's CTU the line management of the data manager may be undertaken by Kings CTU in addition to the supervision outlined above. Where this is agreed in addition to the 5% Senior manager supervision required the full salary for the data manager will be required. In these instances it is anticipated that the data manager will be employed and located in King's CTU for the duration of the trial