

Effective trial management pulls all critical elements of a trial together to ensure its successful delivery on time and within budget and to a high standard. KCTU can offer the following collaboration to support this function in your trial.

Collaboration:

KCTU collaboration enables research teams to obtain senior support for trial management activities. This offers the study teams the opportunity to buy-in expert support from senior trial 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 trial management activities throughout the duration of a trial.

Details of this collaboration:

- The trial manager will be employed by the relevant department, line managed by the Chief Investigator or other appropriate individual*.
- The trial manager will receive expert supervision from an experienced senior member of the trial management team.
- The trial manager will participate in the King's Trial Partnership and will therefore be able to attend talks relevant to the delivery of trials,
- The trial manager will participate in the Trial Managers & Data Managers Network, to gain peer support.
- The trial 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 trial 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 trial manager will work to the relevant KCTU SOPs.
- It is expected that a full time trial manager will be dedicated to the delivery of the trial. Where the trial is single-centred, it is possible for the trial manager to work on more than one trial.
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Supervision provided in the following areas:

- Provision of content for the study protocol with regards to trial management.
- Provision of support and advice to the nominated individual on how to approach trial management and draft a trial management plan.
- Review of trial management plan content and to advise on alternative approaches to trial management.
- Provision of advice on contracts, submissions for approvals, and other study documents (eg scope and content of SOPs) as necessary.
- Attendance at a proportion of Trial Management Group Meetings (as required).
- Provision of feedback on performance of trial manager to the Chief Investigator as appropriate.

Resource required:

- Minimum of 5% senior trial management supervision time must be costed into the grant application.

*In exceptional circumstances and with the agreement of King's CTU the line management of the trial 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 trial manager will be required. In these instances it is anticipated that the trial manager will be employed and located in King's CTU for the duration of the trial.