Example 14
Senior Trial Manager

Job purpose

· Lead a team of Trial Managers, Assistant Trial Managers and Trial Administrators to ensure GCP compliance and to manage the responsibilities of non-commercial trials in compliance with the Clinical Trials Regulations and sponsor requirements

· Set up and manage clinical trials and actively contribute to the research planning and development in partnership with Trial Managers, Principal Investigators, Executive and Steering Groups and Study Teams

· Be a key liaison with all university departments, relevant ethics and R&D committees, funding bodies, and sponsor monitors

· Provide support to investigators conducting the studies, and develop new initiatives to ensure they are working to the highest standards and to monitor and report on the progress of trials to the sponsor monitors

Main responsibilities

- Line manage a team of Clinical Trial Managers, ensuring systems and processes are effectively implemented to ensure the Chief Investigator is supported in conducting trials to required standards
- Independently provide trial management advice at the planning and funding application stages of new projects and ensure a consistent data management service is provided.
- Set standards and supervise the monitoring of trial sites, to problem solve and review source data.
- Monitor and coordinate intervention supplies and intervention compliance
- Assist in the education and training of trials active staff. This training to include GCP guidelines, relevant legislation and the research governance framework and to be delivered to staff conducting commercial and non-commercial trials.
- Prepare and supervise the preparation of submissions for ethics and regulatory approval, annual progress reports, contribute to reports to funders and manage communications with the Sponsor organisation. Ensure appropriate contractual arrangements are in place and documents held on file.
- Plan expenditure against multiple trial budgets and negotiate with suppliers under the guidance and approval of the study chief investigator
- Produce promotional material and dissemination plans.
- Develop trial risk assessments and trial monitoring plans
- Develop written procedures for trial processes where appropriate
- Contribute to the development of training initiatives
- Any other duties appropriate to the grade as directed by the supervisors.
- Delegate any tasks as appropriate

- Work, where applicable, with the Chief Investigators, grant co-applicants, data managers, monitors, clinicians, statisticians and external agencies on a daily basis to ensure the projects' milestones are met
- To provide expert advice to academics/clinical/non-clinical and external staff on Trial management.
- Provide expert advice on submitting amendments and relevant submissions to ethics and R&D committees in a timely manner
- Train and supervise other staff (internal and external) involved in data collection and data entry in the rules and procedures to be used, explaining the reasons/ principles behind them.
- Communicate the underlying medical and scientific rationale of the trials to a wide professional audience
- Contribute to collaborative decision-making, planning and short and long-term objective setting
- To problem solve and respond to Trial management queries both from within and external to the unit.
- Plan research area related goals including planning expenditure against trial budgets and staff needs
- Responsible for the completion, management and development of all relevant procedures for the conduct of the trials
- Coordinate workloads and ensure delivery of trial management services is conducted in a timely manner and prioritise elements where necessary
- Use initiative and creativity to resolve issues that might arise and identify issues that require onward reporting to the Chief Investigator
- Ensure the Chief Investigators and project statisticians are kept aware of all key decisions
- Ensure that the trial protocols are conducted in accordance with the applicable ethical, regulatory and quality standards and that appropriate records and audit trails are maintained
- Participate in project meetings and produce reports within the context of trial collaborations.
- Where appropriate, manage reported SAEs, checking for missing or inconsistent data and querying sites. Ensure reports are reviewed appropriately and sent to any key parties. Ensure all events are followed up to resolution.
- Set up processes for monitoring trial supplies and arranging distribution to sites, designing documents to capture accountability data.
- Be responsible for and supervise the testing of study paper CRF's, trial data entry systems and other study processes and procedures prior to recruitment.
- Strong research skills and expertise in searching medical literature and databases for clinical and technical information
- Ensure that the collection of trial data is complete, accurate and up to date for analysis according to agreed deadlines. Monitor online data entry, checking for inconsistencies, violations and adverse events.
- Keep up to date with current research literature. The publication of innovative approaches to improving trial methodology is encouraged.
- Assess training needs of Trial Managers and design appropriate training programmes or recommend external training as appropriate.
- Monitor trial manager's performance levels and give guidance and feedback where necessary.
- Create trial management policies and oversee their implementation.
- Provide Investigators with specialist advice on trial management at the grant application stages.
- Mentor staff when required