Example 9

Clinical Trial Manager

Job purpose

The primary role of the post holder is to set up and support high quality clinical trials. The post holder will be responsible to the Senior Clinical Trial Manager and the Chief Investigator of the studies.

Main responsibilities

- Overall efficient, day-to-day management of one or more trials/research projects.
- Establishment of procedures to ensure adherence to trial protocol, regulatory and administrative requirements, including pharmacovigilance;
- Writing, contributing to, or reviewing trial specific documentation (e.g. protocol, CRFs, trial plans and instructions) that is compliant with the Sponsors SOPS and working practices and ensuring this is implemented and kept up to date.
- Responsible for the maintenance all trial files, including the trial master file, and oversight of site files
- Assisting in the securing of all necessary approvals for the trial and participating sites according to the UK Clinical Trials Regulations, ICH Good Clinical Practice, the European Directives on Clinical Trials and Good Clinical Practice, and the Department of Health's Research Governance Framework
- Ensuring sites have appropriate training, including conducting site initiation visits and maintaining necessary records
- Monitoring trial recruitment, providing support and motivation to recruiting staff as required. Identifying issues and feedback to Senior Trial Manager in a timely manner.
- Working with senior CTU staff and the Chief Investigator to ensure that the trial is conducted to a high standard to achieve targets and to predict and plan any changes that warrant requests to changes in protocol, ethical and regulatory approvals, funding, or time
- Ensuring that good communication is maintained between the trial team, and recruiting site staff including the provision of regular and ad hoc information, both written and verbal, to trial participants and sponsors and stakeholders, to include reports, updates, guidance, newsletters and trial website
- Providing updates on the progress of the trial at regular Trial Management Group, Data Monitoring and Trial Steering Committees as required
- Preparing the trial specifications for the database with the statistician and database managers.
- Planning and supporting meetings and work of the various groups associated with the trial and ensuring appropriate minutes are taken of all trial related meetings
- Supervising data collection from sites and entering data within the CTU, e.g. SAE forms as required
- Supervising the data cleaning and validation, including querying and chasing missing data in a timely manner
- Contributing to writing and review of trial reports and publications
- Participating in training and development initiatives