Example 12
Trial Manager

Main responsibilities

- Take specific responsibility for the overall coordination of individual studies as assigned by the senior trial managers, developing strategies to optimise the smooth running of allocated studies and ensuring that milestones are achieved on time.
- Have line management responsibilities for assistant trial managers. Guide and support other staff members contributing to trials activity, including members of the data team, administrative staff and members of investigator teams as appropriate.
- Communicate effectively with all members of the local coordinating team, Chief Investigator, Principal Investigators and their teams, representatives of the Sponsor organisation and other agencies to facilitate the smooth running of the trial.
- Support trials teams to ensure that necessary approvals are in place at the start of studies, negotiating with relevant agencies (e.g. research ethics committees, MHRA, funding bodies and Sponsor organisations) and helping with preparation of essential documents.
- Identify the financial and contractual agreements required for individual studies and liaise with the relevant parties to ensure that these are put in place and kept up to date.
- Advise investigator teams about the suitable composition of trial oversight committees where appropriate and ensure that these committees are set up and meet as required.
- Develop clear documentation to enable accurate and timely data collection and resolution of data queries.
- Work with the CTU data and programming teams to develop suitable document control systems and bespoke study websites as required.
- Develop and update study-specific standard operating procedures or work instructions.
- Ensure that Trial Master Files and Study Site Files are set up and maintained in accordance with regulatory requirements.
- Ensure that investigators and study site staff are conversant with study processes, assisting with set-up/initiation visits and training where appropriate.
- Liaise with central and study site pharmacies to ensure adequate provision and correct storage of study medication. Maintain clear drug accountability processes.
- Ensure that an appropriate level of pharmacovigilance is undertaken for individual trials, ensuring that adverse event reporting mechanisms are in place
- Monitor participant retention, protocol compliance and general progress of each study, producing data reports as necessary in conjunction with the data management team.
- Identify potential problems regarding the day-to-day running of trials, liaising with CTU colleagues and the relevant team regarding appropriate remedial action.
- Monitor quality assurance including adherence to the protocol and ICH GCP. Ensure that each study has a risk-based monitoring plan. Assist with monitoring visits as required.
- Develop procedures for closing study sites and archiving study data in accordance with regulations and local site policies; conduct site close-out visits where required.
- Write regular progress reports for funding and regulatory bodies as required, and prepare relevant information and data for presentation at meetings or conferences.