Example 5
Assistant Trial Manager

Job purpose

The role holder is responsible for supporting the delivery and continuous development of a customer focused, cost effective and efficient trial management service to ensure the successful development and conduct of high quality clinical trials and/or other well-designed studies.

Main responsibilities

- Secure all necessary approvals for research studies and participating study sites in accordance with applicable governance requirements, liaising with NHS R&D departments and Local Clinical Research Networks (LCRNs) as appropriate
- Set up and maintain Trial Master Files and/or Investigator Site Files in accordance with regulatory requirements
- Develop appropriate processes for adverse event reporting within individual studies
- Develop procedures for closing study sites and archiving study data in accordance with regulations and local site policies
- Act as a facilitator for Trial Steering Committees and Data Monitoring Committees, contributing to the writing of progress reports and collation of data prior to meetings
- Work with the CTU data managers and data programmers in the development of clear documentation to enable accurate and timely data collection and resolution of data queries
- Attend meetings and maintain regular contact with investigators and other research team members to provide feedback about study conduct; help to identify problems and suggest appropriate remedial action where applicable; ensure that communication is appropriately documented
- Monitor participant recruitment for individual studies to ensure that targets are met, identifying where additional support may be needed
- Participate in feasibility/set-up/initiation procedures, liaising with CLRN as appropriate
- In collaboration with data managers, develop and maintain procedures for centrally monitoring the progress of projects, identifying and managing issues as they arise
- Conduct site monitoring visits as required from time to time, in order to monitor adherence to the protocol and ICH GCP
- Prepare progress reports in order to update funding and regulatory bodies, including Research Ethics Committees, as required
- Work with the study team to prepare protocol amendments for submission to regulatory bodies as required, ensuring that correct regulatory approvals are obtained and all relevant parties are informed of changes
- Draft miscellaneous documents and standard letters for individual studies and help to prepare study newsletters as required
- For trials of investigational medicinal products, liaise with central and study site pharmacies regarding ordering and dispensing of trial medication and develop clear processes for documenting drug accountability and authorising drug destruction
- Contribute to the development of grant applications, study protocols and other essential study documentation
- Ensure that research teams at study sites have undertaken appropriate training and that relevant training records are kept
- Supervise junior members of the CTU team as required