Example 6

Senior Trials Assistant

Job purpose

The post holder will assist in managing a portfolio of clinical studies and clinical trials, contributing to the planning, coordination and completion of specified clinical trials.

Main responsibilities

- Contribute to the planning, coordination, running and completion of clinical trials.
- Under supervision, facilitate the set-up of trials managed through Lancashire CTU, including production and collation of all documentation required for compliance with legislative frameworks and applications for Clinical Trials Authorisation, Ethical Opinion and Research and Development approval.
- Support Clinical Trial Managers in ensuring that all trial procedures are developed according to Good Clinical Practice, Data Protection Guidelines, Freedom of Information Act and relevant national and international government frameworks. Maintain an up-to-date knowledge of the regulatory and governance requirements for clinical trials.
- Contribute to the preparation of clinical protocols, amendments, consent forms, study guides, monitoring plans, Case Report Forms, information sheets, reports and other relevant trial-related documentation.
- Assist the Clinical Trial Managers in creating and maintaining all trial files, including the trial master file, and oversee trial site files.
- Assist in the development and implementation of Trial Specific Operating Procedures where such procedures are encompassed within the Senior Trials Assistant job role
- Assist the Clinical Trial Managers in site set-up and monitoring of trials managed through Lancashire CTU, including the implementation of the trial protocol and procedures, central and site monitoring and study close-down
- Contribute to the preparation and conduct of workshops and investigator meetings.
- Support the Clinical Trial Managers in ensuring efficient and effective data management.
- Under supervision, provide advice and expertise to investigators and their staff regarding compliance with legislative and ethical frameworks and regarding any trial-related queries, and act as an initial point of contact for the trials within their portfolio of responsibility.
- Provide support to the Clinical Trials Managers in managing the trial budget(s) and maintaining the trial accounts.
- Under direction, liaise with key stakeholders in external agencies or partner organisations with respect to trial set-up, research governance and audit.
- Assist with the preparation of routine progress reports and ad-hoc reports to funding bodies, regulatory authorities, research ethics committees, Trust R&D departments, etc.
- Assist the Trials Team in the administrative development of grant applications for future clinical trials
- Adhere to appropriate ethical, and research governance, standards for research and protect confidentiality throughout this work.
- Undertake other duties and research related activities relevant to the role and commensurate with the level of the post as directed by the Appraiser