Example 15

Senior Clinical Trials Manager

Job purpose

- To provide leadership for several projects / trials within the CTU portfolio, ensuring effective trial management and good clinical practice by providing appropriate supervisory leadership for individual Trial Management Teams, working within current legislative and governance frameworks and ensuring adherence to Lancashire CTU SOPs.

- To supervise the planning, co-ordinating and completion of projects; providing strategic, tactical and operational management skills in the set-up and implementation of such projects.

- To organise and motivate others both within the CTU Trial Management Team and with external collaborators and fund-holders, demonstrating flair, enthusiasm, innovation and leadership when faced with challenges and targets.

- To provide and/or arrange support and mentorship to members of the CTU Management Team.

Main responsibilities

- Supervise a Clinical Trial Management Team responsible for the development and efficient day-to-day management of a portfolio of clinical trials. This will involve the organisation and supervision of the Clinical Trial Management Team staff (including work allocation, covering rotas, monitoring time-keeping and performance), feeding into the staff appraisal process as appropriate.
- Provide trial management advice to investigators and research team staff for new or existing clinical trials, including offering advice on regulatory requirements, assistance with writing and/or reviewing the content and feasibility of trial management/administrative sections of grant applications, protocol, forms, participant documents, correspondence and reports.
- Lead the process of identification of resource implications during set-up of trials, working with the Clinical Trial Management Team, Chief Investigator (and other members of the research team) and relevant stakeholders as appropriate (this will include such items as staffing levels, time management, travel etc. across the project timeline).
- Contribute to the management of individual trials, as appropriate. This will generally include setting-up new trials, negotiation with key external bodies and overseeing the setting-up and monitoring of clinical sites.
- Play a leading role in developing, implementing and maintaining (trial-specific as needed) administrative systems ensuring that all key trial responsibilities are met. Be responsible for ensuring that the trial master file and all site specific files are set-up and maintained appropriately by the Clinical Trial Management and Site Teams, and that a documented process is in place for these procedures.

- Support the co-ordination of data management activities for the trials in their portfolio; this will include agreeing trial-specific processes and responsibilities at the interface between trial management and data management (and information systems) functions.
- Oversee the co-ordination of oversight committees (Trial Management, Steering and Data Monitoring Committees) and the CTU on the Trial Management and input into the other committees (as required) for trials within their designated portfolio.
- Oversee the monitoring and implementation of Standard Operating Procedures (SOPs) for allocated trials, and where required, reviewing such procedures to ensure that they are fit for purpose and accurately detail all trial processes and reporting to the Principal CTM regarding potential areas of review and development in the SOPs.
- Ensure CTU compliance with Research and Clinical Governance standards: ethics, R&D and ICH Good Clinical Practice Guidelines for Research.
- Monitor Clinical Trial Manager reports of recruitment of participants into trials, confirming that all potential barriers have been identified and that suitable strategies to improve recruitment are implemented; predict and liaise with the Trial Team to plan any changes that warrant requests to changes in trial protocol, funding or time.
- Ensure that all Clinical Trial Management Team staff have the relevant training, skills and knowledge for their role. Provide effective advice to Clinical Trial Management Teams, or sites where necessary, on trial related matters including serious adverse event identification and reporting, data queries, organisation of source files, monitoring procedures and schedules.
- Contribute to the formal and on-the-job training and development on trial management activities.
- Report to senior staff, including CTU Directorate, on resource needs in response to the changing status of the trial protocols and their deadlines. Prioritise work and allocate resources in negotiation with other interested parties.
- Identify and participate in initiatives and developments relevant to the management and conduct of clinical trials.
- Undertake other duties and research-related activities relevant to the role and commensurate with the level of the post as directed by the appraiser, where appropriate.