

Example 7

Clinical Trial Coordinator

Job purpose

To provide management and operational support for the Trial Manager in day-to-day running of the trial in order to ensure effective and efficient trial conduct

Main responsibilities

- Supporting the CI and Trial Manager to write and prepare applications for submissions to the Health Research Authority (HRA), Research Ethics Committee (REC) and Regulatory Authorities (Medicines and Healthcare products Regulatory Agency – MHRA)
- Co-ordinating the implementation of all necessary trial approvals
- Assisting with development and writing of study related documents, reports and processes (e.g. protocol, participant information sheets, informed consent forms, case report forms etc.) in accordance with relevant Standard Operating Procedures (SOPs)
- Working with the Trial Manager to deliver trial-related training
- Working with the Trial Manager to monitor centre recruitment, data completeness and quality, and retention of participants in follow up; and to identify problems, and implement strategies to overcome any identified problems
- Assisting the Trial Manager in performing site monitoring according to the monitoring plan
- Preparing trial correspondence and communications e.g. newsletters, flyers, posters and other updates for centres
- Providing support to the Trial Manager for preparing documentation and contributing to Investigator, Trial Steering Committee, Data Monitoring Committee, and Trial Management Group meetings
- Working in accordance with Good Clinical Practice and undertaking regular training to keep up to date with all relevant research regulations and research methodology
- Contributing to unit-wide activities and process improvements, for example sitting on working groups, reviewing SOPs and sharing best practice
- Printing, sending and tracking of trial materials to trial sites and / or participants
- Preparing and maintaining trial files and documentation
- Arranging and coordinating trial-related meetings and documentation including taking and writing of meeting minutes
- Assisting with monitoring of trial budgets and performing financial reconciliation activities
- Ensuring timely entry and management of trial data and ensuring quality of trial data
- Working collaboratively with other members of the trial team to identify and resolve data issues in a timely manner in accordance with trial documents
- Tracking/monitoring of project progress in accordance to project plan and needs of the trial escalating issues to the Trial Manager as appropriate