

Example 13

Clinical Trial Manager

Job purpose

The role holder will be a key member of a multidisciplinary team undertaking high quality clinical trials, working closely with the Chief Investigators, other researchers and clinicians. They will be responsible for all trial management activities required to ensure efficient and successful completion of trials.

Main responsibilities

- Working with the Chief Investigator (CI) and the trial team to develop the research protocol
- Contributing to developing trial documents for Research Ethics Committees and Regulatory Authorities approval (e.g. participant information sheet, and informed consent form) including co-ordinating input from the trial team. Similarly, managing any amendments and ensuring accurate version control
- Contributing to the Trial Steering Committee and Data Monitoring Committee
- Implement proven new strategies for trial management and participate in methodological research to improve trial efficiency
- Work with the Chief Investigator and other members of the research team to ensure dissemination of the trial results, for example contributing to writing the trial report, preparing results for publication, and presenting at relevant conferences and other meetings.
- Ensure project(s) milestones are met and the trial is delivered on time and within budget
- Developing and maintaining risk assessment for the duration of the project, ensuring risks are identified and minimised, and escalated to the appropriate member of the research team when necessary
- Monitoring recruitment against targets to identify problems and their potential solutions, and work with sites to implement corrective actions if required
- Design, undertake and deliver training to the research team both locally and nationally and, where appropriate, internationally.
- Contributing to the multidisciplinary teams developing the Case Report Forms, and designing and testing the trial database(s)
- Working with the data team and site staff to ensure timely and accurate data collection, monitoring data quality and completeness
- Developing and implementing a trial monitoring plan to ensure high quality trial conduct, using a mixture of central monitoring and site visits, appropriate to the trial.
- Line management and or supervision of trial management staff including conducting annual and interim performance reviews and dealing with pastoral issues. Supervision to include allocating work and monitoring against deadlines and identifying areas for staff development/training and providing such training where appropriate.