icnarc intensive care national audit & research centre

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Trial Manager

Job description

Purpose	Takes primary responsibility for the set-up and day-to-day management of allocated Trial(s).
Responsible to	Senior Researcher
Direct reports	Dependent on experience
Internal relationships	The Trial Manager will work in the Research department within the ICNARC Clinical Trials Unit (CTU) and will work closely with other CTU staff within the wider ICNARC team.
External relationships	The Trial Manager will represent either the Trial Team(s): - when dealing with enquiries from participating trial sites (hospitals and critical care units) and other relevant individuals, bodies (i.e., funder) or groups (i.e. patient representatives); - at meetings (i.e. Trial Management Group, Trial Steering Committees) and conferences when required.

Principal duties and responsibilities

Lead the Trial Team to ensure effective start-up, ongoing management and close-down of allocated Trial(s):

- Develop the project management plan and monitor progress against this to ensure trial deliverables are met throughout the trial,
- Work with the Trial Chief Investigator and the Lead Trial Clinical Investigators to develop essential documentation (e.g. protocol, participant materials, Standard Operating Procedures (SOPs), etc.),
- Develop the research applications to the regulatory authorities such as the Health Research Authority (HRA) and NHS Research Ethics Committee and obtain all relevant registrations and approvals,
- Work with the Data Management team to develop the dataset to meet trial objectives,
- Liaise and work with the Local Clinical Research Networks and Research and Development offices to initiate research at sites including assessing site feasibility, progressing site approvals,
- Ensure efficient site set-up and undertaking training,
- Work with the data management team in the development of data collection (trial database and Case Report Form) and validation systems,
- Responsible for quality control, including visiting trial sites to ensure adequate record keeping and source data verification in accordance with the standards of Good Clinical

Practice (GCP) and other relevant legislation
[Note: regular travel will be required, including occasional travel outside normal working hours and overnight stays],

- Lead participating site teleconferences to discuss implementation of the trial,
- Oversee the implementation and maintenance of computerised systems to efficiently monitor recruitment, follow-up and data collection, to ensure that trial data needs are being met,
- Prepare any substantial amendments and liaise with Research Ethics Committees and HRA (as required),
- Maintain effective regular communications with all collaborating sites and encourage their continuing enthusiastic involvement in the trial; dealing promptly and efficiently with any queries, acknowledging all communication and ensuring efficient flow of information,
- Maintain essential documentation ensuring it is up to date and disseminated across participating sites as required,
- Monitoring recruitment and compliance with the trial protocol at all sites,
- Identify potential problems with regard to recruitment, data collection and adherence to the trial protocol, and liaise with Trial Management Group with regard to the appropriate action,
- Monitor and report to the Trial Management Group, Trial Steering Committee and Data Monitoring and Ethics Committee on the progress of trial objectives, including monitoring recruitment and compliance with the trial protocol at all sites,
- Produce regular newsletters and updates for collaborators and other relevant stakeholders,
- Prepare progress reports for the Trial Steering Committee, Data Monitoring and Ethics Committee, funding body, Research Ethics Committee, and UK Clinical Research Network,
- Close down sites in compliance with SOPs on completion or early withdrawal.

General duties will include

- Maintain an up-to-date knowledge of the regulatory and governance requirements,
- Facilitate any audit, inspection or progress visit processes required by regulatory bodies, funding body or Sponsor,
- Read, develop and review relevant policies and SOPs across the CTU,
- Undertake any other relevant duties.

As a member of the ICNARC team, you will be expected to play a part in its general activities.

The above list of duties and responsibilities is not exhaustive and you may be required to undertake other responsibilities and training as requested and as appropriate to your role level.

Changes

This is a description of the job as it is presently constituted. It is the practice of ICNARC to examine job descriptions from time to time and to update them to ensure they relate to the job as then being performed, or to incorporate whatever changes are being proposed. This will be conducted in consultation with you.

This job description is supported by annual objectives and performance standards to provide an indication of the level of performance expected from the role.

By signing this job description I confirm as follows:

- I have read and understood the requirements of this position
- I am competent to hold and perform all the responsibilities listed
- I agree to perform fully, effectively and to the best of my abilities the tasks, responsibilities and duties listed.

Signed by Job holder — Date

Signed by Line Manager — Date

Person specification

Essential

- **Qualifications***:* Minimum of an undergraduate degree in health services research, biomedical science (or allied subject), or equivalent experience.

- **Experience***:*
  - previous experience managing multicentre, randomised clinical trials, including quality control and adherence to standards of Good Clinical Practice (GCP);
  - understanding of regulatory and governance environment for Clinical Trials of Investigational Medicinal Products;
  - familiarity with database software used for managing clinical trial data.

- **Knowledge:**
  - understanding of the scientific principles of randomised controlled trials;
  - understanding of clinical trial methodology
  - knowledge of essential clinical trial documentation including protocol, CRFs and reports

- **Achievement orientation***:* Demonstrates motivation to achieve results by agreed deadlines; perseveres with plans.

- **Organised**: Experience of managing projects with the ability to plan ahead and deal with any issues as they arise. Ability to prioritise workloads within timescales and meet deadlines.

- **Proactive***:* Demonstrates ability to identify potential problems and acts to avoid them or to ensure a positive outcome. Seeks opportunities to improve work procedures.

- **Conscientious***:* Ensures work is completed carefully and correctly with detailed checking and examination of the output produced.

- **Flexible***:* Adapts approach to fit with changing conditions, tasks, responsibilities or people. Willing and able to travel to participating sites.

- **Communication***:* A high level of persuasive communication and presentation skills with highly developed report writing skills. Has the ability to explain complex information in simple terms both verbally and in writing.

- **Customer service orientation***:* Is courteous and helpful to both internal and external stakeholders. Shows understanding for stakeholders concerns and takes actions to accommodate their needs where possible.

- **Relations with others***:* Is cooperative and gets along well with others. Keeps manager informed, reports problems promptly and seeks guidance when needed.

- **Data compliance and discretion***:* Has an understanding of data security and confidentiality issues.

Desirable

- **Qualifications***:* Post-graduate university degree in health services research, biomedical sciences or an allied subject.

- **Experience***:* Evidence of previous publications.

- **People management***:* enlists support, cooperation and participation when influencing and guiding others toward the accomplishment of tasks. Monitors performance on an ongoing basis, providing positive feedback for effective performance and coaching to resolve performance difficulties.

- **Delegation***:* considers job responsibilities, workloads, skills and developmental needs in effectively allocating work to staff. Communicates specific work expectations while delegating tasks, discusses ways of accomplishing tasks and follows up to ensure successful completion.