

Senior Trial Manager

Job description

Purpose	To oversee and support paediatric and adult critical care clinical trials within the ICNARC Clinical Trials Unit (CTU)
Responsible to	Head of Research
Direct reports	Trial Manager(s)/Coordinator(s)
Internal relationships	The Senior Trial Manager will work closely with the managers and staff across the organisation
External relationships	Supporting and liaising with individuals, bodies or groups working with ICNARC in a research capacity and to represent ICNARC externally at meetings and events

Principal duties and responsibilities

Lead the implementation and coordination of clinical trial activities and management to ensure ICNARC delivers high quality clinical trial(s):

- Oversee the set-up, delivery of studies to time and target and completion according to Good Clinical Practice and CTU standard operating procedures (SOPs).
- Work with trial teams to ensure effective day-to-day management of clinical trials and highlighting critical issues to the senior team.
- Oversees the trial team's development and implementation of risk mitigation strategies.
- Work with the Head of Research, Senior Researcher and CTU Manager to ensure a clear infrastructure is in place for supporting clinical trials within the CTU and in the preparation and conduct internal audit of trial management procedures.
- Provide input into high quality publications in peer-reviewed clinical and methodological journals and present research findings at national and international meetings/conferences.
- Ensure international quality standards in trial management for the projects/portfolio by ensuring staff have appropriate knowledge, skills and development opportunities to fulfil their roles effectively.
- Provide regular one to one supervision and support to direct reports.
- Provide input to ensure CTU registration requirements are met and Quality Assurance procedures and processes (e.g. CTU Standard Operating Procedures) are maintained.

- Actively contribute to the development and streamlining of systems and processes through involvement in Working Groups and development or amendment of associated documentation.

Principal duties and responsibilities

- Maintain a thorough and up-to-date understanding and working knowledge of regulations, legislation, guidance and local and national initiatives relating to clinical trials and applying this knowledge through working practices.
- Support the team with external audits and inspections, where required.
- Communicate with internal and external parties.

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.

Person specification

Essential

- **Qualifications:** Minimum of an undergraduate degree in health services research, biomedical science (or allied subject), or equivalent experience.
- **Experience:**
 - Substantial experience of Trial Management (including clinical trials of an Investigational Medicinal Product) and coordinating multicentre, randomised clinical trials, including quality control and adherence to standards of GCP.
 - Working with health-related data and information systems.
 - Speaking at national and international conferences/events.
 - Collaboration within multi-disciplinary teams in research.
 - Quality control and adherence to standards of GCP.
- **Knowledge:**
 - Knowledge of the regulatory and governance environment in the UK and other relevant guidance
 - understanding of the scientific principles of randomised controlled trials and clinical trial methodology
- **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:** Ability to take initiative and work both independently and within a team. 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 with the ability to enlist support, cooperation and participation when influencing and guiding others toward the accomplishment of tasks. Highly developed presentation and 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. Ability to collaborate effectively with people from a wide range of disciplines. 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:** MSc in epidemiology, health services research or other relevant research discipline.
- **Experience:** Scientific writing, including a track record of publication in high impact, peer reviewed journals.
- **Skills/Knowledge:** Strong project management skills with knowledge of the theories of project management.
- **People management:** Previous experience supervising or line managing people. 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.