Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Job Description

Comp ID:	**035109**
Job Title:	Sponsorship Quality and Clinical Operations Manager
School/Department:	Medicine/Clinical Research Facility (CRF)
Job category & level:	Administrative Officer 1

The Purpose of the Role:

The Sponsorship Quality and Clinical Operations Manager will be based in the Wellcome-HRB Clinical Research Facility (CRF) at St James's Hospital (CRF) and will be responsible for leading all operations of the research sponsorship office, multiple grant funded study teams usually consisting of 2-3 people each and staff. The sponsorship office is responsible for implementing operational procedures and a quality management system for research clinical trial sponsorship services (Investigational Medicinal Products and Medical Device) within the CRF. This is a 12-month fixed term contract

Context:

The CRF is a collaboration between St James's Hospital (SJH) and Trinity College Dublin (TCD) and has been providing investigator services for clinical research trials since 2013 with many Principal Investigators from both the hospital and academic communities. It is a state of the art facility including a research pharmacy and employs 22 staff, the majority funded by research grants from HRB/IRC/EU with Trinity as the host sponsor to act as a clinical trial (Investigational Medicinal Products and Medical Device) sponsor and the CRF is the operational support for this. The Sponsorship Quality and Clinical Operations Manager will form part of the CRF operational team and will report directly to the CRF Director.

Main Responsibilities:

Compliance with protocols and pharmacovigilance and reporting to the regulator in respect of serious adverse events. The Sponsorship Quality and clinical Operations Manager is responsible for all trial sponsorship services in the CRF and will:

- Lead all clinical operations, within study scope, ensuring the performance of the sponsored clinical research portfolio including sponsorship assessments, risk management, study documentation, pharmacovigilance and monitoring.

- Define and implement work plans with the Head of Clinical sponsorship oversight (HCSO) to development and expand the sponsorship office aligning with key University strategic plans for research.
- Using their expertise and knowledge of the regulatory landscape and legislation governing clinical trials of drugs and medical devices, lead on interpreting complex legislation as it relates to trial sponsorship, identifying the implications for the CRF and initiating necessary changes to practice research trials to ensure continued compliance with ICH, GCP, ISO 14155 and all applicable regulations are addressed.
- Oversee and lead continued development of standard operating procedures (SOPs) for sponsorship services and lead by example in terms of implementation of, and compliance wit the SOPs.
- Maintain quality management systems (QMS) for sponsorship ensuring ongoing compliance with International Conference on Harmonisation Good Clinical Practice guidelines (ICH-GCP), Medical Device regulation, Clinical Trial Regulations, ISO 14155 and all applicable legislation and standards.
- Train Clinical Research Associates, sponsorship staff and upskill grant funded researchers to perform their roles as principal investigators and sub-investigators to the required ICH-GCP and regulatory standards. This includes management of investigational medicines and
- Fulfil regulatory affairs requirements pertaining to communications with competent authorities i.e. The Health Products Regulatory Agency and the National Research ethics Committee and the chief Data Protection Officer for sponsored programmes.
- Act as a partner with key clinical research stakeholders at all levels within the University, providing consultancy and professional advice for investigator-led studies, campus companies and spinouts.
- Line manage assigned sponsorship staff such as a core team of research assistants, A02 and post doc researchers and administrative staff in line with CRF SOPs and Trinity College guidelines, taking accountability for delivering sponsorship goals and objectives with grant funded study teams.
- Identify opportunities for process improvements and creative solutions in pursuit of service excellent and shares lessors learned.
- Develop Key Performance Indicators (KPIs) and report against these for sponsored research.
- Monitors own team's deliverables against milestones and acts promptly to manage deviations.
- Develop, implement and maintain corrective action preventative action (CAPA) plans for protocol deviations in collaboration with colleagues.
- Develop and manage study budgets in terms of ensuring clinical research studies are appropriately costed at the grant application stage.
- Develop study work and project plans (e.g. sponsorship monitoring, data management, pharmacovigilance and safety monitoring plans) that align with sponsorship team responsibilities.
- Represent Trinity College in local, national and international forums as a subject matter expert in sponsored clinical research.
- Perform vendor and internal audits and selection for sub-contracted sponsorship services.
- Perform additional tasks related to sponsorship by mutual agreement on behalf of the CRF director that arise to fulfil the aims of this role.

Person Requirements

The role-holder will require the following knowledge, skills and attributes for successful performance in the role

Qualifications:
Bachelor's Degree (or equivalent) in a Clinical or life sciences related discipline.

Knowledge:
Deep knowledge of the regulatory landscape and legislation governing clinical trials of drugs and medical devices.
Knowledge of sponsorship responsibilities as defined by Good Clinical Practice guidelines.
Familiarity with clinical trail management software and Pharmacovigilance systems.

Experience:
Minimum of 5 years experience as a Clinical Project Manager or Clinical Trial Lead, working in a clinical research organisation or sponsor environment.
Experience of resourcing and leading cross-functional teams.
Experience liaising with competent authorities and research ethics committees.
Prior experience in conducting site audits or monitoring.
Experience of quality management systems.
Prior experience in managing medical device clinical Investigations (desirable).
Experience in oversight of third party vendors. (desirable).
Experience of financial project management (desirable)

Skills:
Excellent written and verbal communication skills.
High standard of accuracy in both written and numerical work.

Personal attributes:
Works co-operatively with others, helping to successfully implement strategic change initiatives
Assesses and reviews work and identifies continuous improvement with a focus on quality delivery
Implement processes, systems, and ways of working in order to facilitate and support the achievement of strategic goals
Clearly defines roles and responsibilities for individuals in team
Enables an positive work environment which supports employees wellbeing
Rigorously monitors service quality standards and takes immediate corrective action when deviations occur
Checks understanding and can communicate rationale for decisions
Listens to, understands, respects and accepts the value of different views, ideas and ways of working
Builds networks and partnerships across the University.

Collates information from diverse sources, analysing the situation in a thorough manner
Has confidence to defend decisions
Focuses on the goals that matter
Works collaboratively across function to ensure seamless delivery of goals