Clinical Study Manager

Reports To: Head of Clinical Operations

Location: Office based in Oxford

Main purpose of job:

To assist with the clinical activities to support the Vaccitech portfolio of research and development projects. All activities carried out with regard to time, cost and quality and in accordance with SOPs, ICH/ GCP guidelines and local regulations.

Key responsibilities include:

- Management and oversight of all aspects of allocated studies in accordance with internal SOPs, ICH GCP, relevant guidelines and all applicable laws and regulations.
- Study team coordination and leadership.
- Oversight of all aspects of the study to ensure agreed study deliverables are met to the appropriate quality.
- Responsibility for preparation of study documentation and coordination of document review, e.g. protocols, IBs, DSURs, ICFs, CSRs.
- Selection and oversight of assigned CROs, vendors or contract monitors (CRAs), as appropriate.
- Selection of suitable clinical sites in collaboration with other members of the Vaccitech study team or CROs, as appropriate.
- Periodic co-monitoring with contract CRAs or CROs as necessary for each study, to ensure high quality monitoring and site management.
- Set up and management of clinical contracts (including Clinical Site Agreements).
- Coordination of IRB/IEC and other required study submissions, and provision of essential documents to the Regulatory Head (or CRO if delegated) for regulatory submissions.
- Preparation of study budgets, forecasting and accruals.
- Thorough documentation of study team activities, decisions, actions and risk assessments.
- Active management of clinical trials supply requirements in collaboration with 3rd party storage & distribution specialist
- Oversight of Sponsor Oversight File and/or TMF creation and maintenance by Clinical Trial Administrator, to ensure 'inspection-readiness' of documentation at all times.
- Active acquisition and furthering of therapeutic area knowledge appropriate to assigned studies.
- Assist with departmental development work e.g. SOP review/writing and process improvements initiatives.
- Develop and maintain relations with sites and KOLs.

Clinical Study Manager

Personal Abilities and Traits:

- Demonstrates personal drive and goal orientation.
- Self-motivated taking personal pride in delivering on personal and corporate objectives.
- Enthusiastic and flexible to change.
- Demonstrates strong organisational and prioritisation skills to manage a diverse workload.
- Able to interact with individuals at all levels of the organisation.

Key responsibilities continued:

- A highly effective communicator, both orally and in writing with an eye for detail/ accuracy
- Reliable and trustworthy, able to work with minimal supervision.

Essential Knowledge, experience and skills:

- BSc or equivalent
- Clinical study management experience within a pharmaceutical, biotech or CRO company
- Experience in oversight of external vendors (CROs, central labs, imaging vendors, etc.)
- Excellent written and verbal communication and presentation skills
- Excellent organisational and interpersonal skills
- Ability to manage multiple priorities within one or across different projects
- Excellent working knowledge of GCP and current clinical trial legislation
- Thorough knowledge of the clinical development process, ideally from first in human through to regulatory filing for marketing
- Ability to travel in the UK and abroad periodically if needed
- Ability to work in a dynamic small team environment

Desired skills:

- Experience in early phase (I-II) studies
- Experience working with GMO
- CRA/monitoring experience
- Experience of EDC and eTMF; comfortable with electronic systems e.g. CTMS
- Infectious Diseases and Oncology experience

Reports to:

- Head of Clinical Operations