

# Clinical Study Manager

Office based, fulltime (37.5 hours per week), permanent contract

## Key responsibilities:

- 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 Affairs Manager (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 3<sup>rd</sup> 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.

## 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
- Working with GMO experience
- CRA/monitoring experience
- Experience of EDC and eTMF; comfortable with electronic systems e.g. CTMS
- Infectious Diseases and Oncology experience

The successful candidate will report to the Head of Clinical Operations.

Please use the cover letter to highlight how you meet the competencies for the role which will be used along with your CV to assess your application. Please also confirm your current salary and salary expectations.

With your application could you please quote job reference CSM003