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Clinical Trial Manager at International AIDS Vaccine Initiative (IAVI)

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Job Description

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The International AIDS Vaccine Initiative is a global not-for-profit, public-private partnership working to accelerate the development of vaccines to prevent HIV infection and AIDS.

Position Summary:

Help IAVI translate science into global health impact as a Clinical Trial Manager!

IAVI is seeking an experienced and motivated Clinical Trial Manager to oversee and execute day-to-day operational activities for the conduct of clinical trials according to ICH/GCP and relevant regulatory guidelines. The CTM will lead clinical operations of early and late phase clinical trials, mentor other clinical operations staff, contributing to clinical operations process improvement.

Make an impact executing clinical trials at IAVI!

Key Responsibilities:

Act as clinical operations lead on project teams for assigned studies.

Develop the protocol management plan (PMP) and coordinate the development of operations plans for all applicable functions for inclusion in the PMP.

Develop study timelines and ensure adherence; Escalates concerns / issues related to timelines to senior management appropriately.

Lead clinical trial team meetings and contribute clinical updates to cross-functional project team meetings.

Oversee the evaluation, development, set-up, training, and monitoring of investigational sites participating in epidemiology studies and clinical trials.

With oversight from the Director, Clinical Operations, develop and control study budgets, working with other departments as appropriate, to ensure execution of studies within budget; escalate concerns / issues related to budget management to senior management appropriately.

Together with Director, Clinical Operations, determines which services will be conducted by IAVI and which will be outsourced to other vendors and assists in the identification, evaluation and selection of CROs and other vendors.

Proactively anticipate risks and plans for and implements risk mitigation strategies throughout the trial conduct.

Actively manage issues that could impact study progress and takes action or makes recommendations to solve issues to support compliance.

With oversight from the Director, Clinical Operations, coordinate and develop study protocols.

With oversight from the Director, Clinical Operations, develop Informed Consent Documents, Study Operations Manual, monitoring plan, tracking forms, and other study related documents as required.

Lead implementation of risk-based monitoring for assigned studies and liaise with sites and IAVI CRAs and data management to perform data reviews and resolve data queries.

Review and approve monitoring visit reports submitted by CRAs for assigned studies. Complete monitoring oversight visits as needed to review clinical data for accuracy and completeness and resolve discrepancies in accordance with the study monitoring plan.

Maintain good relations with IAVI collaborators and trial sites to facilitate site development and execution of clinical trials.

Mentor and train CRAs and Clinical Trial Associates as needed.

When assigned a trial with a Clinical Operations Specialist (COS), delegate clearly defined clinical trial management activities to the COS and ensure deliverables are met with appropriate timeliness and quality. Mentor and provide training to the COS as needed.

Contribute to the Clinical Development (CD) departmental Standard Operating Procedures for conduct of clinical trials based on IAVI templates and ensures adherence to regulations/guidelines for GCP. When applicable is a member of the CD SOP task force.

Perform other duties as assigned by the manager.

Requirements

Education and Work Experience:

Bachelor’s degree in a scientific or other relevant field is required; an advanced degree in relevant field is preferred.

Minimum 5 years of relevant experience in clinical trial operations, including at least 2 years in clinical trial management or equivalent experience at study sponsor or CRO is required.

Qualifications and Skills:

Expert knowledge of clinical research operations, Good Documentation Practices, ICH GCP, FDA CFR and other relevant regulations as well as Declaration of Helsinki and relevant country-specific regulations is required.

Project management skills and ability and track record of delivering on assigned tasks within deadline are required.

Experience leading multi-disciplinary clinical trial teams effectively to deliver clinical trials at high quality, on time and within budget is required.

High level of interpersonal skills and ability to work effectively with outside vendors, collaborators, subordinates and functional peer groups at various management levels is required.

Experience working on problems of high complexity and diverse scope using good judgment within defined procedures and policies to determine appropriate action is required.

Flexibility to change priorities and be comfortable with changing deadlines to meet organizational needs is required.

Being detail-orientated, with the ability to work independently on multiple projects/tasks with overlapping schedules and priorities is highly preferred.

Following all company safety practices, Standard Operating Procedures (SOP's) and policies is required.

Excellent oral and written communication skills are required, including ability to conduct presentations of technical information concerning specific projects and to be an effective trainer.

Ability to mentor other clinical operations staff is required.

Ability to work collaboratively with people of diverse educational and cultural backgrounds and maintain a high standard of professional conduct as a representative of IAVI is required.

Familiarity with electronic document management systems such as Veeva as well as electronic data capture systems is required.

Excellent computer skills with software tools needed to fulfill the responsibilities of position is required.

Familiarity with HIV, TB, emerging infectious diseases and/or global health is highly desirable

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