ICOSAVAX

Job Announcement

Clinical / Sr. Clinical Operations Manager

SUMMARY:

Icosavax, Inc. is a publicly traded (NASDAQ: ICVX) biopharmaceutical company leveraging its innovative VLP platform technology to develop vaccines against infectious diseases, with an initial focus on life-threatening respiratory diseases. Icosavax's VLP platform technology is designed to enable multivalent, particle-based display of complex viral antigens, which it believes will induce broad, robust, and durable protection against the specific viruses targeted. Icosavax's pipeline includes vaccine candidates targeting respiratory syncytial virus (RSV), human metapneumovirus (hMPV), and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Icosavax was formed in 2017 to advance the breakthrough VLP technology from the Institute for Protein Design at the University of Washington with the goal to discover, develop, and commercialize vaccines against infectious diseases. Icosavax has an experienced management team, has raised over $350M to date, and is in Seattle, Washington. Icosavax is based in Seattle.

Icosavax seeks an experienced Clinical Operations Manager (COM) to lead and manage specified clinical projects while adhering to budget, scope, and timeline requirements and applicable regulations.

RESPONSIBILITIES:

- Manages Sponsor's day-to-day study-related activities to meet defined study timelines; works closely with internal and external team members to ensure IVX compliance with applicable regulations and FDA/EMA/ICH guidelines
- Responsible for the set-up and oversight of a specified clinical project from study planning, execution, data analysis through close-out
- Actively participates in CRO meetings, including regular CRO study team meetings and protocol training, and provides Sponsor oversight
- Responsible for reviewing the content and adhering to CRO study operational plans (e.g., project management plans, communication plans, quality plans, safety plans, risk management plan, monitoring plan, communication plan, etc.)
- Responsible for the oversight of the development of study-related documents such as informed consent, case report forms, etc.
- Contributes to the development of RFPs and participates in selection of CROs/vendors; manages CROs/vendors activities to ensure adherence to budget, deliverables, performance/quality, and timelines; may train CROs/vendors and study sites on study requirements
- Tracks study progress and proactively escalates project-related issues to key internal stakeholders as needed, including those related to time, budget, and quality. Ensures timely resolution of these issues and provides feedback to management.

- Ensures the ongoing compilation and reconciliation of the Trial Master File is "audit ready" at all times. Ensures that any audit observations are addressed appropriately and in a timely manner
- Acts as a liaison between functional areas for project-related matters

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EDUCATION, EXPERIENCE, KNOWLEDGE AND SKILLS:

- Bachelor's degree in a scientific/healthcare or business/finance discipline is required. An advanced degree (Master's degree or above) is preferred
- Minimum of 4 years of industry experience (biotech/pharma) with at least 2 years as the lead clinical project manager (at least 5 years to be considered for the Sr. COM position); and at least 2 years monitoring experience strongly preferred
- Proven experience in managing and executing US and/or global trials from start-up to database-lock, as well as solid experience in management of CROs/vendors to quality, timelines, and budget
- Prior direct experience managing vaccine trials strongly preferred
- Strong understanding of ICH, GCP and relevant regulatory requirements, guidance, and guidelines. Understanding of inspection readiness, audit preparation and clinical quality assurance strongly preferred.
- Strong operational and management skills with attention to detail; solid problem solving and analytical skills; identifies issues and problems and suggests solutions
- Proficiency in verbal and written presentations (including Microsoft Outlook, Word, Excel, and PowerPoint)
- Demonstrated ability to deal with competing priorities, work independently in a fast paced, cross functional, start-up environment

Travel demands: 10-20% expected to various meetings or clinical sites. International travel may be required.

Preferred location for this role is at the Icosavax headquarters in Seattle, Washington, USA.

Please send cover letter and resume to careers@icosavax.com