Title: Director, Clinical Site Management & Monitoring Oversight

Hiring Manager: Vice President, Clinical Operations

Function: Clinical Operations

Location: Waltham, MA

Position Summary:
Upstream Bio is developing innovative therapeutics in inflammation. We are a nimble company with solid financial backing that has raised $400M from high-quality investors. We are developing a monoclonal antibody targeting validated biology and are focused on our two Phase 2 studies in asthma and chronic rhinosinusitis with nasal polyps (CRSwNP) in 2024. Our offices are in Waltham, MA. We have a hybrid working model, with Tuesdays-Thursdays in the office and Mondays and Fridays flexible to work remotely if desired.

We seek a seasoned, relationship and data driven individual for an important role establishing and overseeing clinical trial site management and monitoring across global clinical trials. This role will support clinical development plan strategy across indications and provide critical contributions to study quality risks management. The individual in this key role will develop, implement and oversee capabilities and fit for purpose approaches to enable high-quality delivery of clinical sites in a fully outsourced model. This position will report to the Head of Clinical Operations.

The successful candidate will have a scientific background and will have led site monitoring, site management and/or centralized monitoring teams and associated activities. This position requires a strong ability to synthesize scientific, clinical and business considerations into cohesive site management and monitoring oversight plans, as well as a strong ability to build and develop relationship with investigational sites, clinical operations leaders and clinical vendor oversight leads. This individual will demonstrate outstanding cross-functional collaboration skills, a solid understanding of the indications being pursued, ICH GCP, regulations as well as best practices for Sponsor oversight of outsourced site management & monitoring activities.

Excellent written and oral communication skills are required, as is the desire and ability to work in a small, fast-paced, and patient-focused environment. Adaptability to changing needs and challenges and an innovative approach to problem solving will be important characteristics of the successful candidate.

Key Responsibilities:

- Plan, establish, and oversee, in a global setting, site management and monitoring oversight activities and capabilities as part of the clinical operations team.
- Partner with the clinical operations leaders and cross functional UPB team in support of effective risks identification and mitigations/resolutions, with focus on site-level and patient-level risks.
- Oversee high-quality implementation, execution and delivery of site management and monitoring activities across studies by CROs in alignment with timeline and budget plan.

- Provide leadership for and implement solutions and capabilities to support Sponsor oversight of site management and monitoring activities across indications.
- Ensure compliance with internal policies and procedures, GCPs, and applicable regulations; ensure inspection readiness

Qualifications

- Extensive (10+ years) of relevant experience in clinical development and operations.
- Site-facing experience required (as clinical coordinator, CRA/site monitor,…).
- Experience in leading implementation of oversight activities to mitigate key site-level and patient-level risks to clinical trials.
- Experience managing or overseeing site monitoring and/or central monitoring roles/contractors for global trials (direct line/functional management experience preferred).
- Data-driven professional with knowledge of best practices, tools and systems to enable efficient and risk-oriented oversight approaches
- Experience overseeing outsourced monitoring activities of respiratory clinical trials preferred.
- Bachelor's Degree or international equivalent required; Life Sciences preferred. Advanced degree highly desirable.

Skills, Knowledge & Abilities

- Strong leadership skills driving large cross functional teams.
- Deep knowledge of global regulatory and compliance requirements for clinical research, local country requirements and ICH GCP, including experience with global regulatory inspections.
- Excellent critical and strategic thinking, with strong ability to understand the big picture as well as the important details that may impact the big picture.
- Global clinical operations & development experience across therapeutic areas with demonstrated ability to rapidly learn new indications
- Excellent communicator and influencer, able to persuasively convey both ideas and data, verbally and in writing.
- Ability to travel approximately 10-15% of the time.

Interested candidates, please contact:
Recruiting@upstreambio.com