Title: Senior Manager, Clinical Trial Management
Hiring Manager: Director, Clinical Operations Lead
Function: Clinical Operations & Medical Writing
Location: Waltham, MA

Position Summary:

Upstream Bio seeks a resourceful, data-driven and integrative thinker for an important role overseeing clinical vendors supporting one or more of our clinical trials. This key role will plan, oversee and drive high quality end-to-end clinical trial vendor delivery in a fully outsourced model to ensure data integration across clinical trial vendor types (such as eDC, eCOA, Lab, Imaging). Additionally, this individual will provide guidance and shared learning throughout planning and implementation, as well as ensure clinical trial vendor deliverables and timelines are met across assigned clinical trials. This position will report to the Head of Clinical Operations.

This position requires a strong ability to synthesize scientific, clinical and business considerations into a cohesive clinical vendor operational and data delivery strategy. This individual will use outstanding cross-functional skills to achieve study and program goals and will develop a solid understanding of the clinical indications being pursued including knowledge of the patient needs, development plan, applicable regulatory guidance as well as the competitive landscape in the therapeutic space. The ideal candidate has clinical trial operations experience and strong project management skills combined with a critical eye for important details.

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

Key Responsibilities:

- Plan and oversee key third-party vendor-related aspects of single and multi-center global clinical trials in compliance with GCPs / SOPs and applicable regulations, within approved budgets and timelines and in close collaborations with key stakeholders and Clinical Research Organizations (CROs)
- Contribute to CRO/vendors identification, qualification and selection processes as applicable.
- Provide oversight for relevant vendors-related activities, including contracting, budgeting and documentation
- Partner with the Clinical Operations Lead and CRO Study Management Team lead to ensure effective third-party vendor risks identification & mitigation strategies as well as proactively identify & resolve issues
- Drive effective integration of clinical trial data derived from key vendors via vendor strategy setting, implementation within vendor specifications / requirements and ongoing oversight
- Develop and implement clinical oversight plans and perform ongoing risk-based data-driven review pertinent to clinical oversight activities

- Collect and analyze qualitative and quantitative results from quality oversight activities and develop reporting that highlights areas of concern and outlines investigations, action plans, and resolution
- Provide expertise to oversee the end-to-end data delivery integration activities across clinical vendor types (may include eDC, eCOA, Labs, Imaging). This includes providing oversight of operational input into vendor specifications and requirements, as well as data transfer agreements and/or transfer specifications for third party vendors
- Secure agreement with appropriate stakeholders (clinical operations, clinical development, clinical supplies, translational research, quality) to develop strategies across studies
- As applicable, act as Subject Matter Expect for oversight of the electronic trial master file (eTMF) (provided by third party vendor) across trials and vendors
- May be required to perform other activities, as assigned, in support of successful study execution, such as overseeing other areas of clinical trial management, participating in onboarding study team members.

Qualifications:

- Bachelor's Degree or international equivalent required; Life Sciences preferred. Advanced degree highly desirable.
- 6+ years of relevant clinical operations experience, in trial management and/or vendor oversight roles
- Strong knowledge of ICH GCP and global regulatory and compliance requirements for clinical research. Experience with regulatory inspections a plus.
- Strong critical thinking, with 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.

About Upstream Bio:

Upstream Bio is a public company based in Waltham, MA. We are developing verekitug, the only known antagonist currently in development that targets the receptor for Thymic Stromal Lymphopoietin (TSLP). We have advanced this highly potent monoclonal antibody into separate Phase 2 trials for the treatment of severe asthma and chronic rhinosinusitis with nasal polyps (CRSwNP) and plan to initiate development in chronic obstructive pulmonary disease (COPD). Our experienced team is committed to maximizing verekitug's unique attributes to address the substantial unmet needs for patients underserved by today's standard of care. Learn more about us at upstreambio.com.

Interested candidates, please contact:
Recruiting@upstreambio.com