Title: Director, Data Management
Hiring Manager: Vice President, Head of Biometrics
Function: Biometrics
Location: Waltham, MA

Position Summary:

The Director of Data Management will lead end-to-end data acquisition planning and implementation. The Director will lead a small team of professionals, overseeing the data management activities carried out by CROs and vendors in clinical programs. Collaborating closely with cross-functional teams, the Director will vigilantly monitor risks and resolve issues related to clinical data quality. This role is ideal for a data management professional looking to balance strategic oversight with a significant hands-on contribution.

Key Responsibilities:

- Ensure compliance and quality of data acquisition planning and implementation in clinical programs. Drive innovation in data management, including data standards, electronic data capture (EDC) tools, and integration of emerging data technologies.

- Oversee clinical data management activities carried out by CROs and exercise vendor oversight of clinical data deliverables, ensuring both quality and adherence to timelines. Conduct regular reviews, including metric tracking, to assess CRO performance, quality, and adherence to contractual obligations

- Identify and evaluate impact of data quality risks and issues through examination of the clinical database, vendor database, and Central Monitoring. Collaborate closely with cross functional teams to pinpoint and implement solutions, demonstrating leadership and oversight throughout the resolution process.

- Lead the Data Management team, working alongside the team in executing key data management tasks, fostering an environment of collaboration and continuous improvement.

- Ensure all processes are compliant with industry regulations, company standards, and audit requirements. Maintain accurate records of data management activities and ensure audit-readiness at all times.

Qualifications:

- A bachelor's degree and minimal of 10 years of clinical data management experience.
- In-depth knowledge of clinical data management processes, systems, technologies, and industry advancements; proven CDM leadership role in late phase clinical trials with experience overseeing trials from start up through database lock.

- Demonstrated strategic thinking with substantial experience in CRO oversight throughout clinical trials, including case report form development, database development, data validation, data reporting, database lock activities.
- Strong hands-on skills in managing essential electronic data collection platforms, including EDC, clinical laboratory, eCOA, imaging, etc. Experience in risk-based central monitoring is essential.
- Excellent analytical skills with attention to detail, combined with effective communication and problem-solving abilities.

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