Title: Associate Director, Data Management
Hiring Manager: Vice President, Biometrics
Function: Biostatistics
Location: Waltham, MA

Position Summary:

This Associate Director, Data Management the clinical data management activities carried out by CROs and vendors in clinical programs. Collaborating closely with cross-functional teams, the role assumes a leadership position in end-to-end data acquisition planning and implementation. Additionally, it involves vigilant monitoring of risks and issues related to clinical data quality, as well as the provision of effective risk mitigations and solutions to address issues. The ideal candidate will possess up-to-date knowledge, proficient hands-on skills, and extensive experience in clinical data management.

Key Responsibilities:

- Oversee clinical data management activities within clinical programs and exercise vendor oversight of clinical data deliverables, ensuring both quality and adherence to timelines.
- Provide leadership in clinical data management aspects, including but not limited to CRF design, validation and programming of clinical database, management of data discrepancy, data extracts, and overseeing database locking and archiving.
- Identify and evaluate impact of data quality 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.
- Collaborate seamlessly with colleagues and departments, such as statistics and statistical programming, pharmacovigilance, clinical operations, regulatory affairs, medical directors, and other functions supporting clinical programs.
- Cultivate and maintain productive working relationships with CROs and vendors to ensure the successful acquisition of data for clinical programs.

Qualifications:

- Bachelor's degree preferred
- 8+ years of clinical data management experience
- In-depth knowledge of clinical data management processes, systems, technologies, and industry advancements.

- Demonstrated strategic thinking with direct experience in clinical data management functions such as CRO oversight, case report form development, database development, data validation, data reporting, database lock activities.

- Proven track record of managing CROs and vendors, with experience overseeing a trial from start up through database lock.

- Strong hands-on skills in managing essential electronic data collection platforms, including EDC, clinical laboratory, eCOA, imaging, etc. Experience with data visualization tools is a plus.

- A team player with a balance of independent and collaborative critical thinking skills. Possesses a forward-thinking mindset, capable of managing multiple projects, demonstrated ability of identifying and resolving issues.

- Excellent verbal and written communication skills, fostering open and effective dialogue throughout the company.

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