Program Lead, Data Management

Location: Waltham, MA

At Apellis, the **Program Lead, Data Management** is a key member of the clinical trial team and is responsible for ensuring the delivery of systems and data with quality. The Program Lead will partner with our external vendors and oversee all data management activities across their program, but will be hands-on when required. Therefore, the ideal candidate must be able to complete all aspects of data management independently and efficiently.

We are a small company that is rapidly growing, and our Biometrics department is in its infancy. If you are seeking an opportunity to be involved in creating processes that focus on adding value, eliminating waste and re-thinking traditional clinical data management, then we would like to meet with you!

Job Description

- Provide DM oversight of CRO and other external data vendors by developing and ensuring adherence to project timelines using metric reports and key performance indicators.
- Contribute to development of DM outsourcing strategies, long-term relationships with CRO partners / external vendors, metrics and key performance indicators
- Establish effective business relationships with external stakeholders to be able to influence process change at vendor when required
- Develops risk mitigation or action plans and oversees execution when appropriate.
- Single point of contact for the execution of data management deliverables on assigned trials/programs, providing status reports on overall study progress and communicating risks and mitigation plans to senior management and other members of the clinical trial team.
- Interpret and apply data strategy, ensuring high utilization of global/program standards (e.g. eCRFs, edit checks) across all CROs and external vendors
- Ensure the delivery of quality data by partnering with CROs and external vendors to develop and execute efficient quality data plans
- Oversee all data management activities from study initiation to database lock.
- Lead or contribute to the development, review and implementation of processes, policies, SOPs and special projects / initiatives in DM or cross-functional working groups
- Communicate and escalate of program or project level issues including processes, timelines, resourcing, performance, etc.
- Train and mentor DM staff or members of the clinical trial team form other functions on processes, projects, systems and programs
- Support study-level/program audit and inspection readiness activities as needed.
- Lead DM support of submission activities
- Perform hands-on data management responsibilities, if required

Person Specification / Qualifications

Required

- Bachelor's degree, preferably in a scientific discipline such as Physical & Life Sciences, Statistics, Mathematics, Economics, Computer Science, IT, Biology, Social Science, etc.
- 4+ years working in clinical data management, with extensive experience working as a Lead Data Manager with full accountability across study start-up, conduct and lock
- Experience leading team of data managers to ensure the timely provision of DM deliverables
- Advanced hands-on knowledge of data management processes and systems
- Knowledge of regulatory requirements (e.g. ICH, GCP, HIPAA)
- Experience overseeing outside vendors (Central labs, Imaging vendors, etc.)
- Demonstrated ability of working on multiple projects simultaneously, independently managing competing priorities, and define tracking tools to manage projects
- Excellent written and verbal communication skills, able to communicate effectively with senior management as well as with peers
- Demonstrated ability to influence without authority
- Demonstrate initiative, sound judgment and flexibility

Desirable / Preferred

- Good knowledge of clinical data management outsourcing models including functional-service providers and full-service/global CROs
- Experience overseeing outsourced clinical trials work
- SDTM, CDASH, CDISC, ADAM experience
- Strong project management skills, and ability to effectively lead and collaborate with various business functions
- Solid understanding of clinical drug development processes
- Experience with data visualization, analytics and reporting tools e.g. SAS JMP Clinical, TIBCO Spotfire etc.
- Experience programming in R, SAS, Python or other languages

Apellis is… A clinical-stage biopharmaceutical company focused on the development of novel therapeutic compounds to treat disease through the inhibition of the complement system, which is an integral component of the immune system, at the level of C3, the central protein in the complement cascade. We believe that this approach can result in broad inhibition of the principal pathways of the complement system and has the potential to effectively control a broad array of complement dependent autoimmune and inflammatory diseases.

Visit **http://apellis.com/about.html** to learn more.

EEO Statement:
Apellis is an equal opportunity employer and complies with all applicable federal, state and local fair employment practices laws. Apellis strictly prohibits and does not tolerate discrimination against employees, applicants or any other covered persons because of race, color, religion, creed, national origin or ancestry, ethnicity, sex (including pregnancy), gender (including gender nonconformity and status as a transgender or transsexual individual), age, physical or mental disability, citizenship, past, current or prospective service in the uniformed services, genetic information, marital status, AIDS/HIV

status, smoker/nonsmoker, and occupational pneumocononiosis or any other characteristic protected under applicable federal, state or local law.