Clinical Data Manager

Who we are:

Krystal Biotech (NASDAQ:KRYS) is a gene therapy company based in Pittsburgh, Pennsylvania. We are developing innovative and transformative gene therapy medicines to dramatically improve patient lives affected by debilitating skin diseases. We work to accomplish this goal through scientific innovation, operational excellence, and the belief that "nature operates in the shortest way possible" (Aristotle). You can learn more about Krystal Biotech at www.krystalbio.com

Our vision:

We strive to be the leader in the development of novel and proprietary "off the shelf" gene therapy products to fight some of the world's most serious skin diseases.

Our mission:

To develop transformative, innovative, and science-based HSV gene therapy products and processes to dramatically improve people lives.

Clinical Data Manager (DM) Position Description:

The Clinical Data Manager will report to the Chief Operating Officer and will be responsible for leading internal and outsourced Data Management activities in support of our clinical trials. This includes managing Case Report Form (CRF) requirements, contributing to establishing defined company data standards and conventions, coordination of centralized data review activities, and is accountable for data integrity, quality, and consistency at database lock. The successful candidate will be a key interface with internal stakeholders and outside contract research organizations (CROs) for any data management-related activities. Knowledge of Industry and regulatory standards (CDISC, SDTM) with an ability to translate clinical team objectives into operational actions and maximizing the current technical platforms will be a heavily leveraged skill set.

Specific Responsibilities will include:

- Provide leadership and content expertise for Clinical Data Management activities from start-up through statistical analysis stage of clinical studies to effectively manage data capture, review, and database lock activities.
- Participate in protocol review and ensure all protocol elements are accurately captured in the database
- Manage data activities for all clinical trials as well as the design, review, and validation of the clinical database
- Oversee or lead the design of electronic case report forms (eCRFs) as well as data management plans, data edit checks and aggregate check specifications with CROs, data transfer agreements and specifications, SDTM mapping, eCRF completion guidelines, Manual Review Guidelines, or Data Entry guidelines

- Oversee external data vendors with respect to key performance indicators, metrics, and program level deliverables and timelines. Assess metrics for vendor quality and efficiencies, and escalate issues as needed
- Oversee the development of any clinical database by the eDC/CRO vendor and manage the Sponsor user acceptance testing of the clinical database
- Review or perform external data reconciliation (i.e. laboratory data), and SAE reconciliation
- Proactively organize and perform on-going data review throughout the conduct of the study to ensure timely and appropriate identification of errors, trends, discrepancies, completeness, content, and quality issues
- Ensure proper closeout and archiving of data management study related materials, i.e. DMPs, database change documentation, validation documents, and final patient casebooks in paper or electronic format
- Proactively assess project and CDM issues and risks working with the Clinical Operations team
- Propose resolutions and mitigations to the Clinical Operations team and track issues and risks through to completion
- Define and monitor CDM related scope, cost, time and quality for all DM deliverables expected from CRO from project start up to close out
- Train sites at investigator meetings and data management staff on study database
- Represent Data Management as the lead contact and liaison on the clinical research team

Requirements:

- 5+ years of Clinical Data Management experience in biotech/pharma or CRO industry; BS in scientific/healthcare discipline
- EDC experience on multiple platforms such as Medidata RAVE, IBM experience, Medrio, etc.
- Excellent verbal, written, interpersonal and presentation skills are required
- Working knowledge and experience with Word, PowerPoint and Excel
- Working knowledge of FDA and/or EMEA Regulations, ICH Guidelines, and GCPs governing the conduct of routine clinical trials
- Must be able to prioritize multiple tasks, plan proactively, and accomplish goals using well-defined instructions and procedures
- Ability to develop tools and processes that increase measured efficiencies of the project
- Must be able to anticipate obstacles and proactively develop solutions to achieve project goals

- Must have a general understanding of functional issues and routine project goals from an organizational perspective

- A successful candidate will have clinical experience with rare/Orphan disease products and/or gene therapy clinical trials

All interested applicants are required to submit their CV/Resume and Cover Letter to svinzant@krystalbio.com. Please note, applications submitted without resumes and cover letter will not be accepted.

Krystal Biotech, Inc. is an Equal Employment Opportunity and Affirmative Action Employers. Qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender perception or identity, national origin, age, marital status, protected veteran status, or disability status. Headhunters and recruitment agencies may not submit resumes/CVs through this Web site or directly to managers. Krystal Biotech, Inc. does not accept unsolicited headhunter and agency resumes. Krystal Biotech, Inc. will not pay fees to any third-party agency or company that does not have a signed agreement with Krystal Biotech, Inc.