Apellis

Position: Senior Clinical Data Manager

Reports to: Senior Director, Clinical Operations

Description:
Primary objective of the Senior Clinical Data Manager is to manage all aspects of the clinical data management process from study initiation forward for all Apellis clinical trials.

Job Responsibilities:

- Oversee the establishment and maintenance of Data Management plans and study-specific data management and related documents.
- Manage CRF Development process and EDC validation including edit specification development and validation.
- Provide oversight of external partners (e.g., CDM, CRO's, central laboratories, ECG core labs, dictionary coding service providers etc.) to ensure consistency and quality are maintained across projects.
- Ensure clinical data management activities for clinical trials and regulatory submission projects are completed on time in line with applicable SOP's.
- Ensure delivery of clinical trial databases of the highest quality by establishing procedures for ongoing and final data review.
- Ensure that CDM study files are organized and accessible during study, and archives are completed after study closeout.
- Collaborate with cross-functional study team members.
- Contribute to the development and review process for DM SOP's.
- Manage clinical data management staff as required.
- Participate in the review of clinical data, analysis tables, for consistency and accuracy.
- Other duties and responsibilities as required.

Experience and Background:

- Bachelor's degree in scientific, medical, or related field, Master's preferred.
- 8-10 years experience in clinical data management, in pharmaceutical research environment, with progressively increasing responsibility.
- Thorough understanding of clinical trials process and regulatory requirements.
- Thorough understanding of core CDM processes and procedures generally adopted as best practices within the industry, including knowledge of CDM processes with safety laboratory data management and dictionary coding for adverse events and medications.
- Adept at mechanics of conducting all phases of clinical trial data management with electronic data capture databases.
- Electronic data capture experience required.
- Experience in rare disease and/or ophthalmology preferred.
- Excellent verbal and written communication skills.
- Experience in a start-up environment preferred.
- Must be pro-active team player, flexible, and open to change.