Senior Manager / Manager, Clinical Data Management
Job Code 268SR

Description
Fate's Clinical Data Management group is currently seeking an experienced Clinical Data Manager to be responsible for data management activities for clinical trials from startup to closeout, as well as process improvement activities and department initiatives. This role will work with internal colleagues and external vendors to ensure delivery to time, quality, and cost expectations. Perform day-to-day data management activities according to ICH guidelines, regulatory requirements, and the company's standard operating procedures. This position reports to the Director, Clinical Data Management and is located at our corporate headquarters in San Diego, California.

Primary Responsibilities:
- Provide clinical data management support to Clinical Operations team and/or study project, Clinical Management team and Biostatistics.
- Participate in the review of Clinical research documents (eg. Protocols, Case Report Forms, Reports and Statistical analysis).
- Oversee contract research organizations (CRO) and vendors that support our studies.
- Ensures overall quality and timeliness of clinical studies from study implementation to database closure.
- Collaborate with extended team to develop and maintain Data Management Plan (DMP) throughout lifecycle of study project ensuring DMP is followed according to study design and requirements.
- Ensure clinical data within EDC is in quality to lock/unlock and freeze/unfreeze as appropriate for statistical review, interim review, and or final database lock- included but not limited to: data reconciliation and/or coding.
- With input, develop Case Report Form (CRF), electronic and/or paper.
- Develop clinical trial data specifications, including eCRF design, user requirements, edit rules/checks, query logic and data validations that are aligned with Company needs
- Lead EDC database (DB) specification process.
- Develop Data Transfer Agreement(s) (DTAs) between external data vendors and/or core labs.
- Reconcile electronic data transfers from vendor to Sponsor.
- Assist in defining and/or create data listings, summary table validation, data specifications and/or process data transfers in preparation for statistical review and/or data management audit.
- Ensure the integrity, confidentiality and security of all clinical data.
- Effectively communicate data management problems and delays to team members.

Requirements
- Bachelors or Masters in the Life Sciences with 5 or more years Clinical Data Management experience in the pharmaceutical/biotechnology industry. Exposure to Oncology therapeutic area and/or Cell Therapy is preferred but not required.
- Applicable knowledge working with clinical databases such as Oracle, SAS, or other.
- Ability to create and present PowerPoint slides from data for internal and external stakeholders.

- Proficient in MedDRA and WHO Drug coding required.
- Previous experience with EDC required.
- Experience supporting eCTD submissions through the creation of CDISC/SDTM standard datasets is highly desired.
- Detail oriented, proven ability to prioritize activities with efficiency, and multi-task across various projects at different study stages.
- Demonstrate a high level of program leadership, be self-motivated, well-organized, and be able to think strategically.
- Exceptional interpersonal skills and problem-solving capabilities.
- Flexible, team-oriented, and results driven.
- Excellent oral and written communication and presentation skills.

Working Conditions and Physical Requirements

- 100% on-site work at corporate headquarters in San Diego, CA
- Occasional evening and weekend work may be necessary

The preceding job description indicates the general nature and level of work performed by employees within this classification. Additional and incidental duties related to the primary duties may be required from time to time.

For consideration send cover letter and resume to: careers@fatetherapeutics.com and reference job code 268SR.