

Clinovo, Inc

1208 E Arques Avenue, Suite 114
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Job Description: **Clinical Data Manager**

I. General Information

Created by: Manager, Clinical Data Management

Department name:

Status: Full-time

II. Position Summary / Primary Responsibilities

- Provide Clinical data management support to Clinical Operations team and/or study project, Clinical Data Management team and Biostatistics team.
- Participates in the review of Clinical research documents (eg. Protocols, Case Report Forms, Reports and Statistical analysis).
- Develops Data Management Plan (DMP), maintains DMP throughout lifecycle of study project and ensures DMP is followed according to study design and requirements.
- Develop Case Report Form (CRF), electronic and/or paper.
- Develop database (DB) clinical trial data specifications, including eCRF design, user requirements, edit rules/checks, query logic and data validations.
- Lead EDC database (DB) specification process
- Develops Data Transfer Agreement(s) (DTAs) between external data vendors and/or core labs.
- Reconcile electronic data transfers from vendor to Sponsor.
- Develop test scripts and execution logs for User Acceptance Testing (UAT).
- Coordination of UAT of eCRF build and validation documents, included but not limited to: edit check document, issue logs, UAT summary report.
- Maintenance/tracking of EDC user management and other Clinical databases across allocated Clinical trials, including but not limited to, compiling master user lists and activating/deactivating user accounts.
- Perform training on study trial for EDC and create user guides.
- 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

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coding.

- 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.
- Coordinate the archiving of study databases and related documents.
- Perform close-out audit, as specified, for closing of study trial in EDC or other clinical data management DBs.
- Assist in reconciling AE/SAE data in Safety DB and/or other Data Management DB, including but not limited to, performing MedDRA and/or WHO coding.
- Assist and provide input into study and project level data analysis plan.
- Coordinate and communicate with DB vendors on consistent basis to address Clinical teams requests, project plans, and/or eCRF development activities.
- Collaborate with IT and implementation team(s) to address Clinical application requests and/or changes to Clinical database systems.
- Participates in the preparation and presentation of data, when applicable.
- Ensures data system compliance by following the established guidelines of national and international regulatory authorities.
- Participate in conference calls and/or meetings with vendors.

III. Qualifications

Required Skills/Experience/Education:

- Bachelor's degree in a science related field.
- At least two (2) years data management and/or related work experience in a medical device or pharmaceutical industry/company.
- Working knowledge of Good Clinical Practices, Good Manufacturing Practices, Clinical research, Clinical trial process and related regulatory requirements and terminology.
- Working knowledge of Clinical database applications such as EDC and CTMS.
- Project coordination\

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- Excellent verbal and written skills, good organizational, interpersonal, and team skills.

Desired Skills/Experience:

- Applicable knowledge working with other clinical databases such as Oracle Clinical, SAS, other.
- Experience with working on Phase I- IV study trials within the medical device and/or pharmaceutical industry.
- AE Coding, if applicable.