



# Example of Clinical Data Specialist Job Description

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Our company is looking for a clinical data specialist. If you are looking for an exciting place to work, please take a look at the list of qualifications below.

## Responsibilities for clinical data specialist

- Responsible for creation of submission-ready SDTM packages for FDA/PMDA or other regulatory authority submissions and keeping abreast in changing regulatory requirements
  - Responsible for acquiring and maintaining expertise in the various and future evolving data collection tools applied in the clinical trial space such as Medidata Rave, DTAs, Clinical Data Tools such as LSAF, Pinnacle 21, and in CDISC standards such as SDTM, CDASH, Controlled terminology and define.xml
  - Support the development of standards and drive their implementation within the organization
  - The position mentors and coaches and may delegate work
  - Analyze and provide rationale to recommend decisions, keeps specific area leaders informed of decisions
  - Interact with Data Delivery and Data Analysis clinical teams, Biostatisticians, Medical Writing and clinical solution vendors
  - Provide direction to external vendors and contractors
  - Provide guidance and expertise to the clinical business teams using data processing solutions
  - Share expertise to support internal teams and external Clinical Research Organizations (CROs) by organizing trainings, Question and Answers sessions, and organizing direct support when needed
  - Contribute to a continuous improvement and innovation culture with respect to the current and future solutions for the clinical teams
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- The ideal candidate will have 1-3 years of experience in data analytics
- Proficient in Microsoft Office (preferably within the PC operating system)
- Familiarity with formatting documents
- Ability to interact with entire clinical team (CRAs, Safety, Biostatisticians, ) and answer questions related to specific data collection concerns
- Knowledge of unique data collection concepts (RECIST, CDASH, Local Labs, Adjudication)
- Minimum 5 years experience in Clinical Data Management, database design/development or related industry experience