



Example of Clinical Data Specialist Job Description

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Our company is looking to fill the role of clinical data specialist. We appreciate you taking the time to review the list of qualifications and to apply for the position. If you don't fill all of the qualifications, you may still be considered depending on your level of experience.

Responsibilities for clinical data specialist

- Provide training and education for stakeholders
- Identifies inclusion/exclusion criteria, reads medical charts and enters data on new subjects
- Analyze medical records, extracting clinical, pathological, therapeutic and epidemiologic data in accordance with established ICD-10 CM and CPT-4 AMA coding principles and guidelines
- Ensure that data is optimally coded for research purposes, financial reimbursement, planning, statistics and regulatory reporting
- Communicate directly with physicians to ensure that clinical documentation is coded timely, accurately and in compliance with CMS guidelines and national correct coding initiatives
- Extraction and entry of required clinical data from medical records and patient research charts/reports to Clinical Research Forms (eCRFs/CRFs)
- Maintaining and developing databases and spreadsheets used for clinical trials and research data collection and operations
- Maintaining currency of research regulations including rules concerning reporting of Serious Adverse Events (SAEs) and violations with department training and feedback
- Interact closely with regulatory and quality assurance teams to ensure data accuracy on Clinical Research Forms (eCRFs/CRFs) prior to submission for in-house, sponsored and Cooperative Group studies
- Assist in design of case report forms (CRFs) for clinical studies

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- Bachelor's Degree in Nursing, Pharmacy, Healthcare Management, Allied Health, Information Systems or related field, required
 - Current licensure as appropriate
 - Maintains current knowledge of trends and advances in clinical practice and healthcare informatics, new developments and innovations in hardware and software technology
 - Assist in the compilation of clinical data for reporting regulatory submissions
 - Ability to collaborate with entire clinical team (CRAs, Safety, Bios)
 - Excellent knowledge of clinical data concepts including knowledge of unique data collection concepts (RECIST, CDISC/CDASH, Labs, Adjudication)