

Study Data Manager (CDC II)

Job ID: 00407696

Job Function

Biometrics / Biostatistics

Schedule

Full-time

LocationUnited States-California
South San Francisco**Job type**

Regular Employee

Company/Division

Pharmaceutical

Job Level

Experienced

Who We Are

At the Roche Group, about 80,000 people across 150 countries are pushing back the frontiers of healthcare. Working together, we've become one of the world's leading research-focused healthcare groups. A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 30 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. The headquarters for Roche pharmaceutical operations in the United States, Genentech has multiple therapies on the market for cancer and other serious illnesses. Please take this opportunity to learn about Genentech, where we believe that our employees are our most important asset and are dedicated to remaining a great place to work.

The Position

Clinical Data Management (CDM) is a department within the Biometrics function of the Product Development (PD) organization. CDM provides data management expertise to study management teams in PD and in gRED (Genentech Research & Early Development).

RESPONSIBILITIES:

The Study Data Manager (SDM) is a core member of Study Management Teams and serves as the study data management contact at the study and/or program level, providing expert guidance to program teams. The Study Data Manager leads the CDM study team and maintains oversight of all study start-up, study conduct and study close-out data management issues, activities and deliverables for one or more studies. The SDM interacts regularly with Clinical Data Management groups to ensure that project objectives are understood and met and provides technical coaching and mentoring on data management activities to colleagues. The SDM also performs the following: provides early strategic input into protocol design focused on data management issues; leads the development of eCRFs and database development and testing specifications by interacting with other functional

area representatives; responsible for the oversight of all data review and cleaning activities involving close interaction with project clinical research professionals; responsible for the implementation of standards within Study Data Management across one or more CDM study teams; develops and executes ad hoc database queries utilizing data review and query tools; manages projects resourced externally via contract research organizations or corporate partners; provides support to ensure that study conventions, processes, knowledge sharing and best practices exist across all studies within a program; participates in departmental discussion groups, formal working groups or special projects.

Who You Are

REQUIREMENTS:

Requires a B.A./B.S. or equivalent with a minimum of 5 years experience in Clinical Data Management. Knowledge of core clinical data management applications (Clinical data management systems, electronic data capture, query tools, web browser, MS Office suite). Clinical data management system experience (EDC Medidata Rave preferred).

Ability to apply advanced principles, theories and concepts for CDM as a whole. Understanding of the conceptual basis for data management conventions, standards and processes. Good understanding of the role of data management, biostatistics and statistical programming in the drug development process. Ability to develop solutions to complex problems. Ability to grasp industry trends and apply them to work within the organization. Ability to multi-task and effectively set own priorities. Strong organizational skills. Strong communication and interpersonal skills.

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