

Medical Data Review Specialist

Job ID: 00413941

Job Function

Clinical Development

Schedule

Full-time

Location

United 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

Manages the implementation of Medical Data Review, both processes and application of the tools by Clinical Scientists, by providing on-site training, development of best practices, and dedicated support. The person in this position optimizes the implementation of Medical Data Review by being an integral member of the MDR support network.

Main Responsibilities:

Provides training for medical data review tools

- Owns the scheduled training program and ad hoc on-the-job training
- Provides class room training/ one on one training as required
- Assists with the access process to medical data review tools and provides guidance
- Ensures tool users understand the data source(s) used for report generation, and assists with identification of questionable or discrepant content (includes some UAT)
- Contributes to the co-ownership of the standard training materials for MDR tools (e.g. J-Review)

- Co-develops applied job aids to support end users in use of the tools (e.g. tips and tricks sheets)
- Maintains real-time training attendance records
- Updates materials as systems undergo changes and alerts end users of changes as they occur

Provides support for medical data review

- Acts as a main point of contact for Clinical Scientists with questions on Medical Data Review processes and documentation
- Acts as the main point of contact for CDM report developers and Informatics (e.g. for specification set up and UAT)
- Acts as a main point of contact for teams engaging with CROs for MDR of external data and champions the standards used with vendors
- Provides guidance and actually develops ad hoc report objects to support ongoing MDR
- Actively solicits input from users to identify areas requiring additional support
- Delivers desk-side first level system support to end users, and understands when resolution requires escalation
- Participates in meetings with tools' owners to ensure end users requirements are met
- Co-maintains an on-line PDC communication/document repository

Tracks system compliance

- Monitors tracking reports for tool compliance and performance of reports
- Reviews and provides the Informatics team with regular updates on status and metrics using standard/automated reports

Provides input into the global development of best practice for MDR

- Promotes knowledge sharing across the Function and within Therapeutic Areas to improve MDR best practice
- Provides input into the development of best practices of MDR Tool use and advises on the optimal use of standard tools and templates
- Proactively gathers change requests for new/different report objects or changes in processes or standard templates
- Supports the set up and maintenance of report objects built per study for medical data review
- Encourages and champions standard report objects wherever possible (cross program/TA)
- Proactively incorporates learning and recommendations from users
- Contributes to activities for improving and maintaining the quality and effectiveness of tools within Clinical Science.
- Participates in local and/or global initiatives that focus on the tools
- Makes recommendations for improvements to Informatics and Developers
- Partners with end users in proposing creation/revision of report objects
- Uses Informatics, Developers of tools for information and knowledge based resource
- Shares information across the MDR Specialist team and MDR Network

- Maintains oversight of external available tools and functionality

System support management

- Reviews and approves relevant System Development Life Cycle documents
- Contributes to future upgrades and assessment for improvements, new releases, replacement software
- Provides proactive support in terms of communication regarding updates and best practice

Who You Are

Working knowledge of relational databases, electronic data capture, SQL and SAS

Evidence of ability to collate and interpret clinical science information and general knowledge of the drug development process

- University/College degree
- Evidence of sound computer skills
- Evidence of being able to deliver effective training
- Demonstrable critical thinking and problem solving skills
- Evidence of excellent communication, interpersonal skills
- Evidence of ability to multi task, organize and prioritize assignments efficiently
- Evidence of ability to work independently as well as part of a team
- Demonstrable understanding of clinical trials conduct preferred
- Preferably shows a working knowledge and experience of a data review tool

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