ROLES AND RESPONSIBILITIES OF KEY TEAM

TOPICS COVERED

- Role and responsibilities of the CDM team members

✓ Data manager
✓ Database programmer or designer
✓ Medical coder
✓ Clinical data coordinator
✓ Quality control associate
✓ Data entry associate

DATA MANAGER

- The data manager is responsible for supervising the entire CDM process.
- The data manager prepares the DMP, approves the CDM procedures and all internal documents related to CDM activities.
- Controlling and allocating the database access to team members is also the responsibility of the data manager.
- A clinical data manager ensures that statistical information and results from clinical trials are recorded accurately.

- A professional is usually involved in every aspect of a trial, from selecting qualified participants to publishing final scientific papers.
- Clinical data managers record information about the effects of medication on patients, daily experimental data, and ongoing issues with a study.
- Most clinical data manager jobs are found in government organizations, pharmaceutical companies, and biotechnology firms.
- Clinical data managers develop and execute data testing and analysis plans, ensuring robust data quality and identifying ways to improve processes.

DATABASE PROGRAMMER

- To liaise with relevant staff to determine the allocation of tasks, to establish timelines, to report progress and any issues outstanding.
- To assist in training and mentoring Clinical Database Programmers in the configuration of databases and development, testing and running of SAS programs.
- To assist in training and mentoring Data Management staff in the specification of databases and SAS programs.
- To review specifications for the set-up and modification of project specific data entry software (including edit check specifications).

- Review validation plan for edit check and reconciliation check specifications.
- Develop, test and run SAS programs for clinical data management. This includes programs for data validation and reconciliation checks, data listings and data transfers.
- To configure database/EDC software (both internal and 3 rd party) for the use of DM, sponsor and sites.

- To perform testing of databases and related applications according to IT and Data Management departmental SOPs, both for initial set-up and maintenance.
- To run database upload programs and to process any error reports.
- To liaise with 3 rd party vendors to resolve issues, implement changes to software.
- To liaise with Sponsors or their designates on matters associated with the transfer of electronic data to or from the company, as defined by the Director, Data Management.
- To support Data Management in the production and maintenance of system procedures and documentation in accordance with applicable SOPs.
- Assist with Quality Assurance and Audit requirements.

MEDICAL CODER

- The medical coder will do the coding for adverse events, medical history, co-illnesses, and concomitant medication administered during the study.
- Oversight of medical coding activities performed by partner resources.
- Oversight of SAE reconciliation activities ensuring regulatory requirements are met by CRO partners.
- Developing and maintaining efficient and flexible best-in-class medical coding processes and procedures.
- Managing the up-versioning of coding dictionaries and performs dictionary upgrade impact analysis.

CLINICAL DATA COORDINATOR

- The clinical data coordinator designs the CRF, prepares the CRF filling instructions, and is responsible for developing the DVP and discrepancy management.
- All other CDM-related documents, checklists, and guideline documents are prepared by the clinical data coordinator.
- Reads and follows the Data Management Plan (DMP) for ongoing projects.
- Assists in development of Clinical Data Management Database Systems including QC or testing activities required for database finalization.

- Performs testing on custom reports and listings.
- Assists with development of supporting Data Management documentation as required, including but not limited to: CRF Completion Guidelines, Test Subject Cases and Data Entry Guidelines.
- May perform data entry and/or verification tasks as necessary for assigned projects.
- Conducts Data Management tasks for data review, including production of reports, listing, or other outputs required, authoring/ issuing queries, data reconciliation and query updates.
- Assists the Clinical Data Manager with data review metrics and reporting

- Conducts database maintenance activities, including permissions activities, end user training, and maintenance activities of training records.
- May act as back up support to the Clinical Data Manager for sponsor facing communications as required.
- Exports data from the clinical database to provide either internally or externally.
- Conducts all activities and files documentation in accordance with SOP requirements and TMF filing guidelines.
- Performs final Quality Control check of profiled clinical data against paper CRFs for paper studies.

QUALITY CONTROL ASSOCIATE

- The quality control associate checks the accuracy of data entry and conducts data audits.
- Sometimes, there is a separate quality assurance person to conduct the audit on the data entered.
- Additionally, the quality control associate verifies the documentation pertaining to the procedures being followed.
- Provision of training, coaching and mentoring of junior scientists and contribution to an ethos of excellence and high achievement.
- Working with Analytical development, ensure creation and delivery of optimal QC strategies for clinical Programmes, covering product/process development, batch release, stability and provision of data for regulatory submissions.

- Accountable to support and manage outsourced programmes of work, providing scientific scrutiny and interpretation, ensuring commercially viable outcomes.
- Development of laboratory capacity/facilities and expertise in GMP QC labs ensuring best practice and technical excellence.
- Oversee QC laboratory operations compliance with GMP standards.
- Develop specifications and testing protocols commensurate with stage of product development.
- Oversee technology transfer of GMP QC tests between labs.
- Set implement of strategies for the continued development of QC testing capability including building and gaining approval for the GMP QC function business plan.
- Manage analytical methods transfer, development and validation at partner contract research organisations, ensuring compliance with relevant specifications, standards and processes, ensuring data integrity.
- Support Quality Assurance auditing of service providers from a Technical perspective.

DATA ENTRY ASSOCIATE

- The data entry personnel will be tracking the receipt of CRF pages and performs the data entry into the database.
- Have strong Clinical research knowledge and not necessarily DM experience required for this task- Can focus on screening PV experience, CRA,CRC or CTM etc.
- Rave database knowledge is an added advantage, DB-Inform and OC is fine too.
- Good understanding of DM process.
- Ability to work in a team environment and independently as needed
- Ability to work productively with support and minimal supervision.

REFRENCES

- Database Management and Design. By Gary W. Hansen, James V. Hansen, Prentice Hall, 2nd edition, 2002.
- Fundamentals of Database Systems. By Ramez Elmasri, Shamkant B. Navathe, T. Benjamin. 2nd edition, 2002.
- Database System Concepts By Henry F. Korth, Abrabam Silberchatz, Mc Graw Hill. 4th edition, 2002.
-