Section 1

Project Management, Project Communication/Process Design, Mgmt, Documentation, Definition & Scope /CRO-Sponsor Partnership

PROJECT MANAGEMENT - SCOPE DEFINITION AND MANAGEMENT

Understands the scope of work and notifies Project Lead and management of scope changes.

Contributes to definition of the project scope of work.

PROJECT MANAGEMENT - PROCESS DESIGN, MANAGEMENT AND DOCUMENTATION

Plan and prioritize daily/routines DM Team work.

Coordinates with cross-functional team to develop and manage project timelines.

Design, maintain and monitor work flow process within CDM.

Oversees production and delivery of weekly data status reports to internal & external team.

Tracks progress on deliverables and production. Proactively identifies and communicates problems/backlogs to project team & management along with proposed solutions.

Identifies risks to project deliverables and timelines and notifies the appropriate personnel.

Independently manages portions of a project once in production.

Prepare for internal and external process audits.

Facilitate understanding of data management processes across the organization, and educates cross-functional teams on data management best practices.

Calculates and monitors project specific productivity standards.

Clearly defines project specific expectations, roles and responsibilities for all data management team members.

Analyze best practices for implementing and conducting project activities.

PROJECT MANAGEMENT -PROJECT COMMUNICATIONS

Proposes or provides agenda items for data management or cross-functional meetings.

Clearly and appropriately communicates issues to cross-functional team members.

Provides content for project communications such as alert letters, project newsletters, etc.

Prepares and delivers presentations.

Clearly and appropriately communicates across all levels of the organization.

Contribute to the development of and adherence to a project communication plan.

CRO-SPONSOR PARTNERSHIP

Reviews Vendor data management plan. Alternatively, develop the Vendor data management plan.

Requests, reviews and comments on regular status reports from CRO. Alternatively, creates and explains the study status to the sponsor.

Provides oversight and QC of CRO activities. Alternatively, coordinates the CRO activities with those of the sponsor.

EDC

EDC

Executes validation & Users Acceptance Testing plans

Understands how EDC technology can impact data entry.

Knows how to design electronic Case Report Forms to minimize data entry errors.

Knows how to use the system to keep data clean and manage the data.

Ability to articulate how the EDC process and the paper data collection process differ and overlap.

Overall Clinical Trials Process, Roles & Responsibilities

Overall

Understands the drug development or clinical trial process and those roles, tasks and activities for which Clinical Data Managers assume responsibility.

Develops and maintains familiarity with applicable regulations and guidance.

Monitor work productivity or quality to ensure compliance with SOPs.

Read and Understand SOPs

Protocol Review

Protocol Review

Understands the protocol content.

Identifies critical data elements used for analysis and reporting.

Understands and interprets primary and secondary hypotheses.

Is able to suggest changes that will ensure good study design.
Assures consistency internal to the protocol and the goals of the study/program.
Identifies gaps in protocol details that are necessary for successful CRF design, database design, data cleaning and evaluation of study results and safety data reporting.
Challenges unnecessary data collection and contribution to study objectives.
Documents the process, procedures and standards for protocol review.
Data Management Plans
DATA MANAGEMENT PLANS
Documents the process, SOPs and standards for creating, approving, and maintaining Data Management Plans.
Understands the key elements of a data management plan.
Defines elements required in a data management plan.
Builds new plans based on templates and plans from similar protocol types.
Gathers input from specialists in various areas to build the details of the data management plan.
Defines the flow of CRFs and DCRs (DM Process).
Outlines all other data flow including external data sources
Identifies problem areas for a study - works through defining resolutions, checks, etc.
Relates disease area under study to data management requirements to outlines all areas of data management plan.
Defines all in-process data quality control steps and procedures and metrics.
Clinical Database Design/Relational Databases
Prepare appropriate formatting to datasets as requested.
Develop technical specifications for data management programming and communicate needs to appropriate staff.
Creates annotated CRF.
Designs clinical database structures for data acquisition and data entry.
Implements, per design, clinical database structures for data acquisition and data entry.
Designs clinical database structures for data validation.
Implements, per design, clinical database structures for data validation.
Implements, per design, clinical database structures for data extraction, analysis and reporting.
Write specifications for database screens and tables.
Writes test plans and test data for data entry screens and data tables to ensure proper data storage.
RELATIONAL DATABASES
Understands the fundamental need for and uses of relational databases and communicate these concepts to others when discussing tasks, assignments or projects.
Executes basic data manipulations and data definition functions following specific oral or written instructions.
Demonstrates working knowledge and efficient use of the Relational DataBase Management System and common data models.
Understands the concepts of referential integrity including rules of cardinality of one to many, many to many, and many to one relationships.
CRF Design
CRF DESIGN
Relates protocol to CRF design and ensure that design supports data analysis and reporting requirements.
Understands and applies widely accepted good CRF design techniques.
Collaborates with team members to assure all needs are met by the CRF design.
Documents CRF completion guidelines, instructions and eHelp for EDC systems.
Understands the relationship between the CRF and database.
Creates effective/efficient new CRF designs from new data types defined by protocol.
Identifies data collection that will require non standard programming.
Is able to explain why a particular collection method may not be appropriate.
Defines content, structure and procedures for using a library of CRF design modules.
Ensures CRF design consistency across number of studies in a program.
Identifies and requests additions to standard metadata.
Presents CRF completion instructions at investigator meetings.
Develops or maintains a working knowledge of health care and research data that is collected in the therapeutic area.
Consults with external and internal parties to recommend the optimal modes of data collection for trials.
Understands the impact of international sites on the CRF design.

Section 2

Processing Local Lab Data (CRF collection)/Maintenance of Lab Normal Range Information

PROCESSING LAB DATA

Understands the fundamentals of management of local laboratory data including the specification and checking of normal ranges and units and QC of ranges and units against listings from the patient database.
Generates standard reports of missing local laboratory data from the patient database.
Defines the types of edit checks against the data.
Runs edit checks against the standardized data.
Develops data base specifications, collecting, processing and reporting for lab data.
Able to apply appropriate sequencing conventions to lab data.

MAINTENANCE OF LAB NORMAL RANGE INFORMATION

Understands when normal range should be updated.
Understands different types of lab tests and units appropriate to those tests.
Performs lab unit conversions.
Identifies and follows appropriate process to obtain missing lab range data

Processing External Data (loading/merging) Central Lab Data or Other Electronic Data

LOADING AND PROCESSING OF ELECTRONIC DATA

Understands the fundamentals of management of central laboratory data and other types of electronic data.
Understands and utilizes metafiles or control files, vendor data files and loading software to load electronic data routinely.
Communicates with vendors to define schedule and process for transfers of data.
Communicate with sponsor or other functional groups to perform data base reconciliation where data is maintained or managed by more than one entity.
Performs test transfers to validate/verify electronic data processing.
Work with external parties to agree on data transfer format, contents and schedule.

(Metrics) CRF Tracking & Inventory/Communication of Data Trends

CRF TRACKING

Applies protocol/CRF schedules to populate CRF tracking tools, if they exist.
Notifies data entry group of priorities.
Determines and reports anticipated vs. actual CRF receipts.
Routinely maintains tracking/inventory and identifies missing CRFs.
Tracks down and retrieves missing CRFs.
Identifies CRF flow issues and initiates steps to resolve.
Resolves issues with data flow in collaboration with the project team.
Creates tools to track and inventory CRFs.
Defines user requirements for integrated electronic tools to perform CRF tracking tasks.
Develops and maintains process, SOPs and standards for CRF Tracking and Inventory control.

COMMUNICATION OF DATA TRENDS

Uses established guidelines to identify and communicate trends to date.
Reviews data for safety or efficacy at aggregate and site levels and identifies clear trends or outlier values and summarizes results.
Executes standard reports of trends in clinical data.
Develops ad hoc reports for clinical team as required.
Documents and maintains process, SOPs and standards for identifying signals and trends in data.
Oversees testing of project specific reports.
Utilize appropriate software or programming language to create and verify ad hoc reports for clinical data and status reports when necessary.
Oversee design and specification of project specific clinical data and status reports.

Data Query Processing & Tracking

QUERY RESOLUTION

Clearly understands the data problem identified.
Identifies, clarifies and processes mis-answered query responses.
Applies corrections to database using appropriate processes.

Understands basic principles of communication and escalation with regard to query resolution.
Applies sound judgment and decision making to evaluating responses and applying to database updates, documentation, etc.
QUERY TRACKING
Maintains tracking/inventory and identify outstanding queries.
Categorizes queries by age/site and regenerates if necessary.
Tracks down and retrieves outstanding queries.
Generates and interprets standard reports of query status, in support of standardized metrics.
Relates queries per site to additional training requirements at site to attempt to reduce query needs.
Develops and maintains process SOPs and standards for query tracking.
Creates tools to track and inventory queries.
Creates standard reports to efficiently identify outstanding queries, query types per site, etc.
Relate queries to processes and activities (e.g. CRF design) requiring process improvements.
CRF DATA ENTRY PROCESS- DISCREPANCY RESOLUTION
Develops guidelines for data entry.
Resolves discrepancies and issues that arise during data entry that are not readily resolved by data entry staff, e.g. medical abbreviations and terminology, marginalia.
Understands the discrepancy resolution process (includes AE-subject data)
Compares the entered data to the original to arrive at proper verification.
Reviews and oversees routine verification activities to assure consistency and judgment.
Creates reports to track data entry process.
CRF DATA VALIDATION (e.g. data review, cleaning, query generation, applying data handling conventions)
Understands the data validation process and its importance.
Understands the principles behind single field, multi-field and cross table data items.
Understands the interaction of data types across CRFs and visits to perform review when automated checking is inefficient.
Identifies area of manual review where electronic checks are not effective.
Is able to apply thorough detailed review of CRF data routinely
Initiates automated methods to minimize manual review
Writes discrepancy management work instructions.
Relates elements of protocol to defining data validation checks.
Applies standard data validation techniques, software and guidelines to routine data cleaning activities.
Defines data handling conventions.
Uses appropriate problem solving techniques to ensure that the precise data problem is identified and queried.
Writes clear, concise queries.
Generates queries based on standard data cleaning practices.
Identifies tools and methods to improve or facilitate manual review process.
Evaluates and improves efficiency of the data validation, query, query resolution process.
Defines content, structure and procedures for using a library of standard data validation procedures and queries.
Defines new requirements for data validation techniques, procedures, etc.
Defines standards for written queries and query process.
Develops standard query language.
Documents and maintains data validation process, SOPs and standards.
Database Updates
Top number is the count of respondents selecting the option. Bottom % is percent of the total respondents selecting the option.
Follows up on query responses, errors identified in data cleaning by performing accurate database updates.
Documents database changes in the automated system audit trails and paper/electronic documentation.
Develops and maintains process, standards and SOPs for performing database updates.
Reviews audit trails, database change rates to assure staff expertise, extraordinary problems with CRF design, investigator site training, database screen design, etc.
Section 3
SAE Reconciliation/Safety Review
SAE RECONCILIATION
Understands the definition of serious adverse events.

Is able to identify SAEs in clinical data.
Understands the SAE reconciliation process.
Reconciles clinical databases' adverse events with serious adverse event reporting databases according to guidelines.
Documents the outcome of the reconciliation process clearly and consistently.
Relates different or similar medical terms/conditions in order to reconcile information presented in different text/coding terms from different systems.
Understands the data that SAEs are reconciled against and make decisions on what to query.
Understands the elements of clinical and safety systems that handle automated safety data exchange.
SAFETY REVIEW
Understands severity levels in AE data.
Identifies safety issues/trends for the study based on clearly defined guidelines and a review of all clinical trial data.
Understands safety profile of the drug under study and disease state of patients.
Communicates safety trends to project team.
Coding (Aes: Signs and Symptoms) Medication
CODING (AEs: SIGNS AND SYMPTOMS)
Understands medical terminology.
Understands what medical auto encoding is and how it works.
Utilizes available tools, systems and processes in support of the coding of medical terms.
Understands the structure of an electronic medical dictionary.
Can manually code adverse events, when/if required.
Familiar with all standard adverse event dictionaries, e.g. MedDRA.
Familiar with company-specific dictionaries and code lists.
Creates an ad hoc listing of coded adverse events for clinical review of pointing/mapping.
CODING MEDICATIONS
Understands what medication coding is and why it is important.
Understands drugs dictionary drug classes and what they mean.
Creates an ad hoc listing of medications.
Can manually encode medication data, when/if required.
Identifies all standard drug dictionaries, e.g. WHODRUG.
Creates ad hoc listings of medications for clinical review of pointings/mappings.
Understands the structure of the medication dictionary.
Database Quality Control Audits
DATABASE QUALITY CONTROL AUDITS
Understands and applies quality acceptance criteria.
Distinguishes critical from non-critical errors.
Performs database audit and generates report per guidelines.
Documents database QC performed
Established quality criteria and quality error rates acceptance limits.
Evaluates data points that should be audited.
Establishes timelines to perform an audit and oversees activities of audit teams.
Identifies root cause of errors in order to recommend change in process/technology to assure the error doesn't occur again (continuous improvement).
Ensures adequate preparation for internal and external database and data management audits, can respond knowledgeably and confidently to issues or questions that arise during audits.
Ensures scope of audits include all potential sources of data errors.
Applies sound judgment on handling audit findings.
Database Lock Procedures
DATABASE LOCK PROCEDURES
Ensures that all steps preparatory to locking are accomplished, e.g.: patients are received, unverified records resolved, all edit checks are resolved, all lab data loaded, all data clarification queries have been returned from sites, all coding complete
Understands the steps in locking databases.
Understands the concept of "frozen" data.
Responsible for initiating removal of all unauthorized access and informs users.

Documents the locking procedure followed and any deviations from it.
Establishes and coordinates the timely completion of the database lock procedures.
Understands and follows the process if the database needs to be unlocked.
Informs team of database locking timelines/issues.
Develops and maintains process and SOPs standards relevant to database locking and unlocking.
Application of Randomization Schemes (Breaking the Blind)
APPLICATION OF RANDOMIZATION SCHEMES (BREAKING THE BLIND)
Understands what randomization schemes are and their importance.
Understands when randomization codes get applied.
Understands issues related to access to unblinded data.
Adhere and maintains process SOPs and standards relevant to randomization and break blind process.
Understands how randomization codes may be applied to the database (e.g. Batch loaded, entered manually).
ARCHIVING DATABASE AND ASSOCIATED INFORMATION
Understands procedures related to archiving
Understands and applies the processes and standards relevant to database archiving as defined by the SOPs.
Performs archiving of case report forms that follow study or company procedures or any FDA regulations.
Performs archiving of data management study file that rolls up into the trial master file.
Communicates timelines, retention requirements, archiving process, and access rights to DBA.