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Project Management for Clinical Data Managers: Empowering CDMs

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Project management skills are critical for clinical data managers because high quality clinical data must be delivered in compliance with the International Council for Harmonisation (ICH) E6(R3) and ICH E8(R1) while coordinating complex, decentralized, and technology-enabled clinical trial environments. These skills enable effective planning, risk management, stakeholder communication, and oversight of timelines, budget, and resources across clinical portfolios and programs. Clinical data managers are accountable for data integrity and end-to-end clinical data strategy; understanding how core Project Management Book of Knowledge, 5th Edition (2013)[1] domains apply to clinical data management activities is therefore essential. A data manager equipped with strong project management capabilities can seamlessly navigate overlapping milestones, integrate diverse functional inputs, and drive efficient, high-quality trial execution.

Keywords: Project Management; Clinical Data Management; PMBOK

1) Learning Objectives

After reading this chapter, the reader should be able to:

- **Understand** the project management framework from the Project Management Book of Knowledge (PMBOK Guide), fifth Edition (2013).[1]
- **Recognize** the five process groups and ten knowledge areas of project management:
  - Process Groups: initiating, planning, executing, monitoring, and closing.
  - Knowledge Areas: integration, scope, cost, time, quality, human resources, communication, risk, procurement, and stakeholder.
- **Apply** this framework to clinical data management activities.
- **Appreciate** that while the PMBOK framework provides structure, the categorization of activities is tailored to the operational realities and regulatory requirements of clinical data management.

Note: While the PMBOK seventh Edition (2021) advances a principles-driven, adaptive model, the structured framework of the fifth Edition (2013)—with its five process groups and ten knowledge areas—remains the most operationally relevant for clinical data management. This chapter adopts the PMBOK framework to ensure rigor and discipline, however the interpretation and categorization of activities are intentionally aligned to the realities of clinical data management. In practice, the fifth edition's process groups and knowledge areas serve as the structural backbone, while the content reflects the specific operational demands and regulatory requirements of data management.

2) Introduction

Project management is a unique discipline that can be described as "...the application of knowledge, skills, tools, and techniques to project activities to meet the project requirements."[1] Project management skills to many people only equate to being organized and being able to communicate. Traditionally, the project management scope of clinical data managers (CDMs) has been limited to building and testing the clinical database, reviewing clinical data, and ensuring a quality electronic data capture (EDC) lock.

Clinical trials are becoming more complex, with increases in the use of data sources outside of what is collected in EDC. In today's environment what defines clinical data has broadened to include electronic Clinical Outcome Assessments (eCOAs), such as electronic Patient Reported Outcome (ePRO), eDiaries; real-world data; and direct data capture of electronic source data with Electronic Health Records (EHRs), wearables, and others. Additionally, COVID-19 expedited the use of decentralized clinical trial methodologies and other new solutions for enrolling (e.g., Interactive Response Technologies (IRTs), electronic informed consent (eConsent)), monitoring, and collecting clinical data much faster than previously anticipated. Adopting a risk-based strategy for data management is becoming a standard part of clinical studies.[2,3]

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This significant expansion of clinical data's 5 Vs (Volume, Variety, Velocity, Veracity, and Value)[4] has led to an increase in trial complexity. As CDMs, our responsibilities have evolved beyond traditional roles to include project management and the integration of new technologies and research strategies. This shift enhances our leadership in clinical trials and offers new opportunities for career development. Successful project execution often depends on broader understanding of processes and roles across regulatory requirements, clinical operations, and other related functions.

3) Scope

This chapter is focused on applying project management skills in the preparation of clinical data while ensuring data integrity. This chapter describes the process groups and knowledge areas from the fifth edition of the PMBOK Guide, from a clinical data management perspective.[1]

This chapter explains how project management principles are applied to CDMs. It addresses both traditional clinical data management activities such as case report form (CRF) development, data cleaning, and database lock and the broader project management responsibilities required in today's complex research environment including timeline planning, cost management, and data integration across diverse data sources such as real-world data and EHRs. Vendor management processes are addressed separately in *Vendor Selection and Management* and are therefore outside the scope of this chapter.[5] Likewise, project management considerations specific to eCOA development and implementation are covered in *Guidance for eCOA Development in Clinical Trials*.[6]

4) Minimum Standards

The ICH E6(R3) Guideline for Good Clinical Practice contains the following instructions related to project management:

- *Section 3.4 Qualification and Training* states, "The sponsor should utilize appropriately qualified individuals for the activities to which they are assigned (e.g., biostatisticians, clinical pharmacologists, physicians, data scientists/data managers, auditors and monitors) throughout the trial process."
- *Section 1 Introduction* explains, "The term "trial conduct" in this document includes processes from planning to reporting, including planning, initiating, performing, recording, oversight, evaluation, analysis and reporting activities as appropriate."
- *Section 3.10 Quality Management* states, "The sponsor should adopt a proportionate and risk-based approach to quality management, which involves incorporating quality into the design of the clinical trial (i.e., quality by design) and identifying those factors that are likely to have a meaningful impact on participants' rights, safety and well-being and the reliability of the results (i.e., critical to quality factors as described in ICH E8(R1))."
- *Section 3.11.4.5.1 Communication with Parties Conducting the Trial* states, "Establishing and maintaining a line of communication between the sponsor and the investigator and other parties and individuals involved in the trial conduct (e.g., centrally performed activities)."
- *Section 4.3.1 Procedures for the Use of Computerized Systems* states, "Documented procedures should be in place to ensure the appropriate use of computerized systems in clinical trials for essential activities related to data collection, handling and management."[2]

Additionally, ICH E8(R1) General Considerations for Clinical Studies *Section 6.1.3 Data Management* states:

> "The manner and timelines in which study data are collected and managed are critical contributors to overall study data quality. Operational checks, centralized data monitoring, and statistical surveillance can identify important data quality issues for corrective action. Data management procedures should account for the diversity of data sources in use for clinical studies (section V.G (5.7)). For interventional clinical studies, further guidance on data management is available in ICH E6(R2)."[7]

With these requirements in mind, in **Table 1** we state the following minimum standards.

Table 1: Minimum Standards.

1.	Ensure clinical trial activities are performed by appropriately qualified and trained individuals.[2]
2.	Ensure data integrity principles are followed throughout clinical trials including study planning, execution, oversight, data management, analysis, and reporting.[2]
3.	Ensure quality is built into the design of databases and utilizes a risk-based approach that prioritizes participant safety, data integrity, and reliable study results while considering user-friendly system interfaces.[2]
4.	Ensure clear and effective communication is maintained among sponsors, vendors, cross-functional team members, investigators, and all other parties involved in trial conduct.[2]
5.	Ensure documented procedures are established and followed for all computerized systems used to support clinical trial activities and data management.[2]
6.	Ensure data management processes support timely and accurate data collection, review, oversight, and issue resolution to ensure data quality throughout the trial.[2]
7.	Ensure data management procedures are designed to accommodate all study data sources and include appropriate quality control and monitoring activities.[7]

5) Best Practices

- Create a RACI (Responsible, Accountable, Consulted, Informed) matrix that describes activities to be conducted during the study (see Appendix B). [VI]
- Participate in protocol development to ensure it is clear what, where, how and when data points are collected. [VI]
- Conduct regular internal and sponsor–clinical research organization (CRO) meetings with the study team (virtual and/or in-person). During these meetings, track progress and upcoming milestones, and discuss corrective actions if needed. [VI]
- Continually assess project processes and modify processes as needed to function more efficiently. Ensure all process changes are communicated, documented, and version controlled. [VI]
- File this documentation within the study master file in effort to establish a clear audit trail. [VI]
- Familiarize team members with the Statistical Analysis Plan to understand how data will be used in terms of endpoint derivation, analysis windows, treatment discontinuations. [VI]
- Assess whether the design of all data capture systems within a study (e.g., Interactive Response Technology (IRT), EDC, eCOA, labs, devices, etc.) themselves create risks. [VI]
- Ensure CRF completion guidelines also capture any other system-related task or risk that may be dependent or impact on EDC. For example, IRT or eCOA integration. [VI]
- Review and approve all clinical data systems budget, change orders, and invoices. [VI]

6) Key Project Management Concepts

Portfolio, program, and project management in clinical data management

In the context of clinical data management, portfolio management ensures that all clinical programs and projects align with strategic clinical development goals. A portfolio may encompass multiple therapeutic areas or indications. Each clinical program focuses on a specific compound or product; individual projects typically refer to distinct clinical trials (e.g., Phase 1, 2, or 3 studies) within that program.

For instance, a weight loss portfolio may include multiple investigational compounds. Each compound would represent a separate program, and within each program, multiple projects (such as individual Phase 1 or Phase 3 trials) are conducted. Clinical data management activities must scale accordingly to ensure consistent data strategy, standardization, quality control, and system integration across all levels.

PMBOK framework

The PMBOK (2013) framework organizes projects into Initiating, Planning, Executing, Monitoring and Controlling, and Closing phases. Success in each phase requires balancing key knowledge areas:

- Project Integration Management: Coordinating project elements for seamless execution.
- Project Scope Management: Ensures all required work is included.
- Project Time Management: Defines and manages project schedules.
- Project Cost Management: Controls budgets to avoid overruns.
- Project Quality Management: Aligns deliverables with organizational standards.
- Project HR/Resource Management: Optimizes team roles and resource allocation.
- Project Communication Management: Ensures effective information flow.
- Project Risk Management: Identifies and mitigates potential project risks.
- Project Procurement Management: Oversees acquiring necessary external resources.
- Project Stakeholder Management: Engages stakeholders for alignment and support.[1]

Example application:

- *Project Initiating*: Obtain project authorization (e.g., CRO engagement).
- *Project Planning*: Develop study start-up timelines and resource plans.
- *Project Executing*: Launch databases for First Patient First Visit (FPFV).
- *Project Monitoring*: Track timelines, cost, and data quality indicators to ensure targets are met.
- *Project Closing*: Complete database lock and post-lock deliverables.

Table 2: Grading Criteria for Best Practices.

Evidence Level	Criteria
I	Large, controlled experiments; meta, or pooled analysis of controlled experiments; regulation or regulatory guidance
II	Small, controlled experiments with unclear results
III	Reviews or synthesis of the empirical literature
IV	Observational studies with a comparison group
V	Observational studies including demonstration projects and case studies with no control
VI	Consensus of the writing group including GCDMP Editorial Board and public comment process
VII	Opinion papers

Table 3 summarizes the PMBOK framework application for CDMs with activities tailored specifically to clinical data management practices. Note that this table includes common examples and is not an exhaustive chart of activities. Not all of these items may be the responsibility of data management in all organizations, but data managers should be familiar with these tasks or concepts.

Agile approaches

Project management approaches used in technology, such as the development of clinical databases, have traditionally used the "waterfall" method with linear, well-defined stages and planning the entire scope and formal handoffs upfront.[8] Any new or change implementation with budget and timeline impact is unfavorable. However, in today's environment of adaptive clinical protocols, CDMs might also take advantage of some project management approaches using the "agile" method of managing projects. The "agile" project management approach is flexible and involves frequent stakeholder collaborations, adaptive documentation, and continuous improvement to result in optimal design that meets protocol needs and is user-friendly.

A full discussion of "waterfall versus agile" project management methods is not in scope of this chapter. However, the reader is encouraged to be familiar with both approaches and to employ processes from each as applicable within the organization's standard operating procedures (SOPs). Please refer to PMBOK seventh edition (2021).[8]

Table 3: PMBOK Framework – Process Groups and Knowledge Areas[1].

Knowledge Area	Initiating	Planning	Executing	Monitoring & Controlling	Closing
Integration	Define unified data workflows across vendors, sites, and devices.	Integrate decentralized platforms (e.g., EDC, wearable devices).	Coordinate data collection from diverse sources.	Continuously optimize workflows based on interim data.	Finalize integrated datasets and analytics.
Scope	Align data management tasks with study objectives (e.g., eCOA/ePRO setup).	Design workflows for seamless data integration.	Ensure that all planned workflows are operational.	Confirm data completeness and protocol compliance.	Ensure all deliverables are complete per scope.
Time	Estimate study start-up timelines.	Develop a detailed data collection and cleaning timeline.	Track data entry and cleaning progress in real time.	Adjust timelines for delayed site or participant responses.	Validate that final timelines were met.
Cost	Define initial budgets for decentralized data tools.	Plan budgets for DCT tools and resources.	Monitor resource allocation vs. budgets.	Track expenditures against budgets.	Evaluate cost effectiveness of tools used.
Quality	Identify QA benchmarks (e.g., what, when, and how data to be checked).	Implement risk-based quality management plans.	Conduct mid-study quality checks.	Verify data integrity and adherence to quality standards.	Perform final quality reviews on datasets.
HR/Resources	Assign key DM leads for oversight.	Train teams on decentralized tools.	Manage workload across DM teams.	Optimize resource deployment.	Release resources and conduct team debriefs.
Communication	Communicate project goals to stakeholders and vendors.	Ensure communication pathways for distributed teams.	Provide frequent updates to sites, sponsors, and teams.	Communicate updates on progress and issues.	Summarize communication outcomes and lessons learned.
Risk	Identify DCT- specific risks (e.g., participant compliance).	Establish mitigation plans for data inconsistencies.	Address emerging issues in wearable or app-based data.	Address issues/ identified risks promptly.	Document risk resolutions for future studies.
Procurement	Choose eSource, eCOA, and telehealth platforms.	Secure long-term contracts for required tools.	Manage ongoing vendor relationships.	Evaluate vendor performance and reliability.	Close vendor contracts and review partnerships.
Stakeholder	Engage site and participant stakeholders early.	Align with patient-centric goals.	Ensure stakeholder expectations are met.	Maintain alignment with sponsor and site expectations.	Obtain stakeholder sign-off on deliverables.

Note: QA: Quality Assurance; DM: Data Manager/Management; DCT: Decentralized Clinical Trial.

Soft skills and other considerations

One important aspect of project management is the set of soft skills of the CDM. Effective project management requires a great deal of application of soft skills: negotiation, clear communication, assertive advocacy, and the ability to present complex data in both business and lay terms to engage different stakeholders.[8]

Organizational influence

Projects are influenced by organizational culture, communication, and structure. Effective management requires alignment with established practices to ensure that resources are optimized, timelines are realistic, and quality objectives are met.[1]

7) Project Initiating Phase

Integration management

- Once the protocol is approved, process initiation is the first step under which the project is created and defined. Performing this properly ensures a strong foundation and sets the tone for the project team. It is important that the CDM takes the time to execute the initiation phase thoughtfully by considering the key components.
- Identify all data sources, vendors, and respective systems and any data analytic tools that will be used for reviewing data. Best practice is to only collect data identified in the protocol. If the reason is justifiable to collect data that is not in the protocol, it is important to amend the protocol first, if possible, or to document this for the next protocol amendment before it is implemented.
- Identify the critical data (primary and secondary endpoints), in collaboration with the medical and biostatistics teams, especially if the nature of the data is complex and ambiguous. For example, in phase 1 trials there may be a lack of clarity as to these endpoints because of the exploratory nature of the trial and the volume of tests being conducted.
- Develop a high-level process flow that encompasses data movement across vendors, sites, and systems.
- Identify any data analytic tools that will be used for cross-functional data review.

Scope management

- Review the contract assumptions regularly rather than relying on memory. Identify strategies for data collection and data review, considering technologies such as EHR, eSource, decentralized monitoring, eCOA, IRT, imaging vendors, risk-based monitoring, visualization, AI driven data review, etc.
- Review the scope of third-party vendors to ensure clarity of responsibilities and ownership of tasks.

Schedule/Timeline management

- Participate in the development of the high-level cross-functional timeline from project award to final clinical study report (CSR).
- Discuss the timelines of other functional groups and the impact on data management e.g., Regulatory, Clinical Monitoring, Contracts, etc.
- Understand interdependencies between external vendors and data capture systems i.e., integration, single login, etc. The greater the number of vendors the more complex the planning. A flow chart can clarify interdependence.
- Collaborate with regulatory and clinical operations on any country specific translations that may impact study timeline e.g., EDC impact, patient reported outcome (PRO) licensing, and development impact, eConsent impact, training/eLearning impact, etc.

Cost management

- Resource Planning: Identify the cost to qualify data managers (DM) and data vendor(s) managed by them. Some sponsor companies may have a list of identified and qualified vendors. If these vendors are capable of the current project/program, then no additional cost is needed for this step. This step can take a long time, so it is critical it starts as early as possible.
- Please refer to GCDMP chapter *Vendor Selection and Management, section 8 Vendor Qualification, Initial Evaluation and Selection*.[5] A startup work order could be developed to expedite a faster project initiation. This is useful for a complex project with multiple functional areas and vendors which typically could take several months to finalize. If this is the case, the DM should ensure DM activities and costs during that period are covered by the startup work agreement. The scope of work (SOW) should include assumptions to provide sufficient detail to explain what is covered or not covered.
- Even if the data technology vendor is not being directly managed by the DM, it is recommended that they review vendors' SOWs to ensure any data collection and review impact is incorporated. This may require approaching the related functional lead if the DM is not the business owner of that process step.
- Review the SOWs carefully before signing contracts. Find out the company policy for its authorized signatories and approved contract amount. Ensure that the contract is fully executed before commencing work. Store and share contracts with stakeholders if you are the contract holder unless the company's contract manager manages this task.
- Discuss and identify tolerance for out-of-scope activity that may come up during the start-up phase to allow continuity of work without delay.

Quality management

- Identify quality assurance lead/representative for the study.
- Determine whether CRO SOPs or sponsor SOPs will be utilized for the study.
- If the decision is to utilize CRO SOPs, the sponsor is still accountable and therefore should maintain oversight according to their vendor oversight SOP.
- It is critical that Data Management lead participants in all data vendor qualification and audit. The lead clinical data manager (LCDM) should be encouraged to be involved and/or lead in all data collection modalities (EDC, eConsent, IRT, telehealth, eCOA, etc.).

- Conduct a gap analysis of CRO SOPs versus sponsor SOPs.
- Determine if any planned SOP deviations are needed and how this will be documented.
- Review protocol through a data management lens.
- Look for inconsistencies that could impact the sponsor clinical program level standards and endpoints.

Resource management

- Determine the scope of the project, the high-level timeline, and assess the demand and complexity of the project to determine the right skillset. Typically, a senior level DM is involved in this phase while strategy is being discussed and decided. A junior level DM may be introduced at the implementation level.
- Estimate activity with the current resources. Determine whether the skillset is currently available or if the hiring process needs to start.
- Compare budget to resource needs. Determine if full-time-equivalent (FTE) and organizational structure need adjustment.
- Share CVs of key personnel with the study team as permitted and if required.
- In addition to determining human resource related activities, other resources also need proper planning and preparations. Some of the examples are deciding the DM vendor, EDC vendor, other data collection tool vendors, data analytics tools vendor, electronic trial master file (eTMF) site, secured data transfer site, SharePoint or other document sharing systems, etc.

Communication management

- Obtain the team list and vendor lists noting the time zone for each participant.
- Setup DM meetings with internal and external team members according to the timing agreed upon in the budget and the time zones for the study team and who will be setting agendas and taking minutes.
- Ensure DM is included in study communications(s) and meeting(s) organized by other functional areas.
- Determine method of communication outside of meetings.
- Identify a communication strategy (Please refer to Appendix A, PMP communication sections).

Risk management

- Conduct protocol and study risk assessment from a data management perspective. Typically, the clinical operations team member takes the lead on the overall risk management plan and the DM will be asked to contribute the DM perspective for risk planning. Risk assessment must inform the design of EDC, eCOA (ePRO), and other systems. The goal is to minimize risks wherever it is possible with a good design (Quality by Design) and facilitate the creation of key risk indicators/quality tolerance limits by providing adequate data points.
- Consider the various data streams and any challenges especially considering any technologies or vendors that are new to the project.
- Remember any critical data points would be crucial to success and should be reflected in the risk management plan.
- Perform data classification (critical, supportive, and minimal) for all data items being collected. It is recommended to collaborate with lead clinician and lead biostatistician to classify integrated data points and/or unique pages as critical, supportive, and minimal to assist with data cleaning activities. Identify all data points that need to remain blinded:
  - Critical data: Includes primary and secondary endpoints as well as safety related data. It may also include data essential for calculations or derived data.
  - Supportive data: Includes data that contributes to understanding or supports critical data e.g., secondary endpoints, data required to join datasets.
  - Minimal data: Includes items that are not reported in summary tables and figures but appear in the CSR listings.

Procurement management

Procurement management involves vetting out quality products, services, and vendors from a set budget within a specific timeframe. Having an effective procurement strategy helps the business keep costs in control, helps the business identify suppliers, ensures all goods and services are properly acquired, and that the procurement process is transparent and fair. The Journal of the Society for Clinical Data Management (JSCDM) chapter *Vendor Selection and Management* covers this topic in depth.[5]

Stakeholder management

Identifying who the stakeholders are for data management and how they will affect the project from the start is particularly important to ensure proper processes and documentation are established.[9]

Major stakeholders of a project for data managers are sponsors, CROs, third-party vendors in addition to one's internal and external project team. Often two or more sets of project managers, clinical operations, medical, biostatisticians, clinical science, statistical programmers, safety, quality, regulatory, and IT departments are stakeholders when work is outsourced. Investigative sites and patients are also key stakeholders.

8) Project Planning Phase

Project Planning ensues after project initiation is completed and consists of those processes required to establish the scope of the project, refine the objectives, and define the course of action required to attain the objectives that the project was undertaken to achieve. At this stage, the clinical team develops study start up timelines and initiates study start-up activities.

Careful consideration should be given to the specific aspects of the entire project. In this section we will delve into the ten knowledge areas as they relate to the planning phase of a trial.[1]

Integration management

- Design the Data Management Plan (DMP) ensuring that all data sources are recorded and adhere to CDISC SDTM/ADaM standards for regulatory submission compliance.
- Develop a holistic data review plan for the entire process from protocol design to CSR integrating EDC, eCOA, IRT, and external data sources, ensuring regular reconciliation to avoid discrepancies before the CSR.
- Ensure that the primary, secondary and safety endpoints have reviews identified to confirm the data is complete, logical, and ready for analysis.
- Develop a data handling plan for each data deliverable, considering interdependencies from all data sources and contributing functional areas.
- Tools like the Risk Assessment and Categorization Tool (RACT) help assess the impact, probability, and detectability of identified risks, ensuring that critical processes like informed consent and adverse event reporting are handled appropriately.[10]

Scope management

The scope outlines the activities for the project and should be detailed in management plans. These plans will document how the project will collect the requirements, as well as define, validate, and control the scope. The following considerations should be made:

- Attend and present data management activities at the project kick-off meeting.
- Develop or contribute to the project timeline.
- Develop or contribute to the RACI matrix.
- Create the DMP and seek cross-functional feedback.
- Review and provide feedback on other functional area study plans such as Clinical Monitoring, Protocol Deviation, Project Management.
- Create the Data Review Plan and seek cross-functional feedback.
- Attend meetings with vendors, clinical operations, biostatistics, pharmacovigilance, etc.

Schedule/Timeline management

When planning timelines, it is good to start with the end date in mind and allow for the unexpected—such as a principal investigator (PI) not being available—by allowing a margin around each task. The timeline management includes the processes required to manage the timely completion of the project. Milestone dates may be recorded in the DMP; detailed timelines should be kept in a separate and easy to manage format and document; use of tools such as Microsoft Excel, Microsoft Project or Smartsheet work well. These basic principles must be considered in all the steps below.

- Outline activities required for timeline development. Include a contingency plan in case Go Live of EDC or other systems are not available for the FPFV.
- Identify key study milestones:
  - Site initiation visit (SIV), first person in (FPI), FPFV, last patient last visit (LPLV), database lock dates.
  - Key deliverable dates (Data Monitoring Committee, Safety Review, interim analysis (IA)).
  - Detail EDC system integrations (ePRO, IRT, eConsent).
  - Detail DM documents and the finalization dates per relevant SOPs.
- Detail downstream activities required:
  - Coding Report Set-up and Generation.
  - Data Review Listing Development and Generation.
  - Vendor Reconciliation Set-up and Generation.
  - Serious Adverse Event (SAE) reconciliation cycles.
  - Data Review Meetings.
- Estimate duration for each activity, allowing for issue resolution from user acceptance testing (UAT) and participation from other parties e.g., EDC review meetings.
- Ensure assignments are made and include participation from the project team (clinical research associate (CRA)/clinical monitor, statistician, and clinician) throughout the timeline as needed. It is important that the team develop an integrated, cross-functional timeline with all departments and tasks included so that dependencies between the tasks and impact on critical tasks are documented.

Cost management

- Assign resources to the right location according to the budget.
- Identify financial key performance indicators (KPIs) and key metrics targets and communicate financial penalties that may apply if data management KPIs are not met.
- Identify award systems to motivate high performing employees at sponsors, CROs, etc.

Quality management

- Develop a quality definition for the study. e.g., Conduct query review on a stated sample size and specific tolerance limits to ensure the query quality (query is worded or/and closed correctly).
- Develop processes and plans for ensuring data quality.
- Define quality metrics for each data vendor.
- Vendor performance:
  - Determine if Standard KPIs are in place or develop KPIs. e.g., requested updates are done in a timely manner.
  - Determine level of data cleaning required for study milestones (e.g., Data Monitoring Committee, publications).
- Define testing plans and identify testers for all sources of data.
- Determine frequency of review of eTMF.

Resource management

Project resource management is the process to organize, manage, and lead the project team. The project team is composed of people with assigned roles and responsibilities for completing the project. Important considerations should be made for the following:

- Understand resource requirements of the project (basis of the projected estimate).
- Request resources and ensure experience, location, job description, bill rate to match budget and expectations.
- Create a study team member list to track the start and end date of an individual involvement.
- Ensure study team member transition plan process and templates are in place in the event a transition of staff is required.

Communication management

This includes the ability to communicate with team members and other stakeholders, whether they are internal or external to the organization. PMBOK 5th edition states that "effective communication creates a bridge between diverse stakeholders who may have different cultural and organizational backgrounds, different levels of expertise, and different perspectives and interests, which impact to have an influence upon the project execution or outcome."[1]

During the project planning phase, the lead data manager determines the communication requirements of the stakeholders and documents the specifics in various plans accordingly, e.g., DMP, Data Transfer Plan/ Agreement, or equivalent document by including a communication management section that is relevant to data management activities and covers all data sources for a given study. Depending on the nature of the project or task, the mode of communication may differ.

Here are some of the factors that may impact the decision:

- Urgency
- Technology need
- Ease of use
- Environment/Company culture
- Type of information, confidentiality, etc.

The method and type of communication will be different as well depending on the situation. It is important for a data manager to understand when to use formal and informal communications in their daily work. Some factors that may define whether formal versus informal communications are needed are situationally based on the table of examples above.

Risk management

"Project Risk Management includes the process of conducting risk management planning, identification, analysis, response planning, and controlling risk on a project. The objectives of project risk management are to increase the likelihood and impact of positive events and decrease the likelihood and impact of negative events in the projects."[1] It is critical for DMs to be involved in the planning phase to determine how data related risk will be managed and documented in the risk plan (or equivalent) at the study level.

Per *ICH E6 R3*, section 3.10 on Quality Management states that "Quality management includes the design and implementation of efficient clinical trial protocols, including tools and procedures for trial conduct (including for data collection and management), in order to ensure the protection of participants' rights, safety and well-being and the reliability of trial results."[2]

For this chapter's purposes, project risk is categorized below:

1. Technical: Requirements, Technology, Complexity, Performance, Reliability, and Quality.
   - New or unfamiliar system risk.
   - System integration risk (one way vs. two ways, the number of critical fields).
   - System related limitations (firewall, connectivity, training, language issues).
   - Reliability of the system.
   - Protocol endpoints if external technology.
2. External: Vendors, Regulatory, Market, Customer, Weather.
   - Vendors – New or unfamiliar.
   - Regulatory – country level regulatory requirements can impact data collection, especially regarding data privacy or system access to EHR.
   - Market – Competitive landscape of therapeutic area can impact the timelines.
   - Weather, political, local emergencies can impact the timeline.
3. Organizational: Project Dependencies, Resources, Funding, Prioritization.
   - Project Dependencies – projects may need results from another trial to move forward.
   - Funding – funds might be reallocated or reduced.
   - Prioritization – Project may get deprioritized.
4. Project Management: Estimating, Planning, Controlling, Communication risk.
   - Time zone – Identify the team members, time zones, holidays vs. study timelines.
   - Resource Management – turnover, promotions.
   - Procurement Management.
   - Ensure product, services and results which were identified for the project are secure and align with the budget and contract.

Stakeholder management

Ensuring stakeholder engagement is an important aspect of overall management of a clinical trial. The project manager or Data Manager determines what methods are needed to keep the stakeholders engaged in the project. In absence of the stakeholder engagement plan, the project may not be able to meet its requirements as stakeholders are alienated from the project. The Project Management Plan (PMP), either at study level or CDM level in the DMP, should document expectations for stakeholder engagement. (e.g., reviewers of the CRF, user acceptance testers).

9) Project Executing Phase

Executing is the phase during which the planned processes and decisions become operational. It is possible that what has been planned requires some modification while being executed. At this stage the database goes live towards FPFV.

Integrations management

- Direct and manage project from a CDM perspective.
- Be an active participant in cross functional team meetings.
- Active participant means presenting and questioning.
- Anticipate and coordinate all data deliverables for life of study.

Scope management

- Ensure data managers are aware of the plans and actions required to avoid duplication or out of scope work.
- Identify out of scope requests and negotiate resolutions prior to acting unless urgent, e.g., safety concern.
- When attending meetings, be aware of the contracted budget.
- Utilize the "3-times rule" – if the issue cannot be resolved in three rounds of email exchanges, have a phone call or meeting to resolve.
- Utilize good meeting practices – have an agenda, take minutes, record action items, allow all participants to contribute.

Schedule/Timeline management

- Ensure database build timeline is adhered to as each component will have a ripple effect. Activities such as CRF specification review and finalization, User Acceptance Testing (UAT(s), Edit Check Specification review and finalization, programming, IRT (and other system integration and related testing), CRF Completion Guidelines, training materials for each system, system access for both UAT and production environments, and coding dictionary implementation should be monitored and any risks mitigated on an ongoing basis.
- If there are different systems, they will require defining both their own timelines and then inclusion in the overall timeline (e.g. EDC, IRT, eCOA).
- eConsent setup related considerations may fall under the scope of data management and are time-critical activities.
- EHR setup implementation related: Deciding mapping strategy and timeline in collaboration with the core team.
- Medical device setup related: Deciding strategy and timeline in collaboration with the core team.
- External vendor data related timeline considerations: Data transfer agreement (DTA) review and finalization for each external data.
- eCOA/ePRO setup related schedule considerations: Licensing (in collaborations with clinical operations and regulatory) and translations (and linguistic validation) related timeline impact can be significant.
- Other clinical systems could fall within CDM considering the experience of the LCDM with system design, build, testing, and the rest of the study team (e.g., IRT, eCOA).
- Risk assessment specific to each data vendor to be determined in collaboration with the core team.
- Determine the criticality of data prior to edit check programming during the study start up timeline, e.g., adding prefix in Query wording "c" for critical, "s" for supportive and "m" for minimal data to determine the level of follow up based on query response.
- Implement programming of metrics and gain acceptance by all parties. This will reduce the potential for out-of-scope programming during study conduct.
- Decide KPI for each study, e.g., number of days from query answered to query closed or number of days from data entered to query raised. It is important that the production of these KPIs is consistent throughout the study for the efficiency of any process change to be measured.
- Confirm that the metrics discussed in the planning stage are clearly defined and relevant e.g., number of open queries, missing visits, number of completed visits, etc. These metrics should be useful for the running of the study and not be created just because they can. How these numbers are generated, how they should be reviewed, and any limitations must be clear to all reviewers. The use of visualization may enable non 'data experts' greater understanding. The running and delivery of metrics has to be understood, e.g., it may take a day to run the metrics so may reflect 'old' data when reviewed. For timelines created during the study, the same level of communication with other functional groups, review of interdependence and communication is required.

Cost management

- Ensure change orders have sufficient detail to document out of scope activities and the adjustments being made to the budget.
- The updated budget should have an identification number in the description to link it to the change order for clarity.
- Execute any change orders in a timely manner.
- Maintain a tracker of out-of-scope changes and driving factors (sponsor led or CRO led) to ensure the costing is handled properly after the fact without compromising the timeline.

Quality management

- Participate in investigator meetings to orient sites to data collection processes.
- Consider the need for additional information or support for sites or CRAs.
- Schedule review meetings to review any trends or issues that have been outlined in the Quality Control Plan and Data Review Plan.
- Review deliverables in a timely manner to identify issues early.
- Identify variables and cleanliness level required to meet deliverables.
- Ensure awareness of timelines.
- Review metrics to ensure alignment of activities.

Resource management

- Train team on protocol and applicable systems.

- Ensure access to applicable systems.
- Communicate each team member's role and responsibilities.
- Consider using a RACI matrix for roles and responsibilities.
- Communicate expectations on monthly hours allocated to the project.
- Hold applicable kick-off meetings, store minutes in a shared location.
- Set up project team file structure in shared location.

Communication management

- Monitor flow of communication throughout the study, including meeting agenda and minutes, delivery of metrics and reports, transitions to new team members, and the continued use of appropriate forms of communication (email, phone, shared sites) to mitigate escalations.
- Ensure information is delivered to all team members effectively, e.g., decisions made in a high- level meeting are communicated to the data cleaning team.
- Adjust meetings and other communications as the study progresses and situations vary, e.g., an interim safety snapshot requiring a cut off for data.
- Educate team on the data management good practices and persuade team's involvement to ensure optimal data capturing and cleaning, e.g., a data manager cleaning the SAE data should attend any SAE reconciliation meeting.
- Store minutes and metrics in a location accessible by all members of the team.
- Ensure relevant communications are filed on an ongoing basis into the TMF.
- Risk Management:
  - Monitor for the triggers defined in the Risk Management Plan and ensure mitigation actions are taken.
  - Maintain the Risk Management Plan with regard to data management issues that may arise during the study, e.g., holidays when a deadline is approaching.

Stakeholder management

To maintain stakeholder engagement, it is advisable to use a tracking log available for all stakeholders to track issues and their resolution. This reduces the need to go back over previously discussed issues if there is a change of personnel during the study.

10) Project Monitoring and Controlling Phase

Effective monitoring and controlling in clinical data management is essential to ensure integrity, accuracy, and timely delivery of data throughout a clinical trial. This stage involves applying robust project management processes to track progress, ensure compliance, and mitigate risks across various domains of the project. Below, the key actions for monitoring and controlling are outlined within each project management area, integrating considerations from project data management, scope, schedule, cost, quality, communication, and risk management.

Integration management

- Continuously monitor and evaluate the study execution to ensure it aligns with the predefined objectives.
- Modify plans as necessary based on ongoing results to ensure the study progresses efficiently.[11] This includes ensuring smooth integration of third-party vendors, IT systems, and data collection tools to maintain data consistency and reliability across platforms.
- Evaluate and adjust project deliverables and timelines based on real-time data feedback, ensuring seamless integration with other trial management activities.

Scope management

- Consistently review and track the clinical data management budget versus actual expenditure to prevent overspending. Regular budget reviews are essential to identify overspending areas and implement corrective actions.[12]
- This includes reviewing protocol amendments for their impact on the budget and aligning the study's scope with these adjustments.
- Ensure periodic reviews of TMF and updates by functional leads to guarantee all changes are captured, and scope remains aligned with the study's goals.

Schedule/Timeline management

- Regularly review the project's schedule to ensure milestones are met.
- Use methodologies like agile or critical path to identify and mitigate delays proactively.[8,12] For example, schedule regular data review meetings where key metrics such as site performance, data quality, and source data verification (SDV) completion are discussed.
- Establish a mitigation plan to proactively address delays by ensuring that key milestone dates are tracked against actual dates and integrating IA plans, especially for studies with significant data-dependent decisions.

Cost management

- Regularly assess the study's financial health by comparing the budget to actual expenditures.
- This involves reviewing invoices from third-party vendors for accuracy and ensuring the timely processing of payments to avoid disruptions. Engage in budget reconciliation to track remaining funds and prevent potential overspending.[12]
- Perform cost reviews on a quarterly basis, identify out-of-scope spending, and engage with vendors to negotiate changes as necessary, ensuring that the overall financial resources are aligned with project goals.

Quality management

- Quality management in clinical trials involves continuously evaluating data accuracy, completeness, and consistency. This includes reviewing data for discrepancies and implementing corrective actions based on quality audits and feedback from cross-functional teams.[11]
- Focus on continuous improvements in data collection processes, incorporating lessons learned from previ-

ous trials into the current study. Ensure that corrective actions are implemented promptly for any identified issues in CRF or data review protocols.

Resource management

- Monitor the allocation and efficiency of resources (e.g., personnel, software tools) to ensure optimal performance.
- Regular performance assessments based on time sheets, invoices, and resource utilization help identify inefficiencies and performance gaps.[12]
- A proactive approach to resource management includes anticipating staffing needs and adjusting team roles, as necessary.
- Regularly review team member timesheets to detect discrepancies or out-of-scope tasks.
- Implement performance gap assessments and training to ensure that resources are optimally aligned with project needs.

Communication management

- Ensure that the project's communication plan is executed effectively, with regular meetings (e.g., core team meetings, data management meetings, data review meetings (DRMs), ad-hoc meetings). Communication plays a crucial role in ensuring all stakeholders are aligned with the project's status, issues, and changes.[13] For example, conducting core team meetings and data review sessions with both internal teams and external stakeholders (e.g., CROs and sponsors) ensures that any potential risks or delays are promptly addressed.
- Maintain detailed agendas/minutes, and clear documentation.
- Foster clear, concise, and frequent communication across all levels of the study team, sharing important metrics, issue logs, and risk assessments to prevent delays and improve decision-making.

Risk management

- Regularly review the risk register to identify new risks and update mitigation plans.
- Implement a continuous review process for risk management, updating risk assessments and mitigation strategies regularly. This includes adjusting project plans and activities based on risk evaluations and feedback from the clinical trial team.

Procurement management

- Regularly review contracts with CRO/sponsor and third-party vendors to ensure that services are delivered on time and within budget.
- Managing procurement processes involves frequent communication with vendors to resolve any issues related to deliverables and ensuring vendor performance aligns with the project's goals.[5]
- Vendor performance should be tracked, and any issues must be addressed quickly to avoid delays.

Stakeholder management

- Managing stakeholder expectations and communication is critical to ensuring the success of a clinical trial. Regularly engage with stakeholders to assess their needs, update them on the progress of the trial and address any concerns.[14] The key is to maintain an open line of communication and promptly respond to any stakeholder inquiries to keep the trial on track.
- Adjust the stakeholder engagement plan as needed, ensuring that each stakeholder's requirements are met, and they are kept informed of progress, risks, and mitigation strategies. This fosters a collaborative environment that supports the trial's objectives.

11) Project Closing Phase

The end of a study is not just the locking of the database but requires skills in other areas, such as budget reconciliation and quality control (QC) of the TMF to ensure all data management documents have been filed.

Integration management

- Perform study close-out activities including reconciling all sources of integration where applicable.
- Participate in cross functional lessons learned meetings by presenting integration problems encountered and solutions implemented from the data management perspective.

Scope management

- Perform database lock.
- Revoke access to database, SharePoint, Secure File Transfer Protocol (SFTP) as applicable.
- Transfer data to the study statistician.
- Provide subject data PDFs to respective sites.
- Decommission databases as applicable. Note, databases will need to be decommissioned, if a unique URL is used; however, if there are other ongoing studies in the same URL, this step will not be required post database lock.
- Archive study data.
- Review data management sections of the TMF and report any gaps to each data vendor for remediation.
- Finalize "Lessons Learned" documentation.

Schedule/Timeline management

- Review and adjust timeline for database lock and study closure with cross-functional input. It is crucial to incorporate early site closure as a key deliverable so that all data cleaning activities can occur before the sites are closed.
- Activities to be considered include, but are not limited to, final data entry, data review and reconciliation, medical coding, query resolution, SDV, and PI signatures.
- Discuss database lock timeline with biostatistics and medical writing colleagues to align on provisioning of raw data to biostatistics and writing the CSR.

Cost management

- Action invoices and change orders as applicable.
- Reconcile or participate in budget reconciliation for data management related deliverables and activities for each vendor.

Quality management

- Ensure all the data management study plans are fully executed and represented by actual activity performed.
- Ensure all the corrective and preventive actions (CAPAs) are closed out.
- Ensure all data management related documents are filed in the study TMF and QC is performed.
- Ensure all electronic data systems are properly closed out or access removed.
- Ensure patient data are provided to respective sites and sponsors depending on the regulatory requirement about media and IT capability.

Resource management

- Anticipate team member assignment to next studies and the impact of closing the current study.
- Anticipate the post database activities including TMF review, final data transfer to sponsor and sites, submissions-related questions, vendor close-outs, final budget/change order reconciliations, etc. and plan resourcing accordingly to ensure these tasks are supported.

Communication management

- Share lessons learned with team members and upper management.
- Share and celebrate the successful completion of each data management milestone of the study.

Risk management

- Review final Risk Management Plan and update as applicable.

Procurement management

- Notify all the study vendors about close-out and ensure all the close-out activities are complete.

Stakeholder management

- Notify all stakeholders of the end of the study.
- Continue to be available as some stakeholders may require information at a later stage, e.g. medical writer.

12) Recommended SOPs

The following SOPs are recommended to support the project management activities described in this chapter; however, these SOPs should be adapted to each organization's processes, tools, outsourcing model, and quality system.

- Vendor Management
- Contract Management
- Vendor Oversight
- Document Management Control
- Data Management Start-up
- Data Collection and Review
- Query Management
- Data Integration
- Risk and Escalation
- Compliance and Security
- Database Lock/post-Lock
- Archiving and Transfer

13) Literature Review

The conduct of a formal systematic literature review was outside the scope of this update, as agreed with GCDMP Editorial Board. Pertinent literature was reviewed where relevant and is appropriately cited in this chapter.

14) Version History

Version No.	Finalized Date
V1	June 2010
V2	August 2026

Appendix A: PMP for CDM Template (eClinical Focus)

Project Title:	**Version:**
Sponsor/Protocol ID:	**Date:**
Program ID:	
Therapeutic Area:	
Clinical Study Phase:	

1. Introduction

- Purpose:

To establish a data management framework that ensures data integrity, regulatory compliance (ICH GCP, FDA 21 CFR Part 11, ALCOA+), operational efficiency in a decentralized clinical trial.

- Scope:

Covers all data management processes and tools, including EDC and external data sources e.g., IRT, eCOA, Central laboratory, Specialty Laboratory (Pharmacokinetics, Anti-drug Antibody), etc. and associated integrations.

2. Objectives

- Seamless integration of eClinical systems (e.g., EDC, IRT, eCOA, central labs, specialty labs, wearable devices).
- Maintain blinded/unblinded data segregation.
- Ensure data integrity, security, and regulatory compliance.
- Ensure cross-functional collaboration, timely risk identification, and issue resolution.
- Proactively manage decentralized trial risks and vendor oversight.

3. Data systems/Service vendors

System/Service	System Version	Purpose	Vendor	Contact Name/email	URL Location
EDC: <SYSTEM NAME>		Electronic data capture	[Insert vendor Name]		
IRT: <SYSTEM NAME>		Randomization and drug tracking	[Insert vendor Name]		
eCOA: <SYSTEM NAME>		COA(s) and eDiaries	[Insert vendor Name]		
Central Labs: <SYSTEM NAME>			[Insert vendor Name]		
Specialty Labs: <SYSTEM NAME>		(one per row)	[Insert vendor Name]		
Additional Data: <SYSTEM NAME>		(One per row)	[Insert vendor Name]		
Clinical Operations vendor		Clinical operations service	[Insert vendor Name]		
CDM vendor		Data management service	[Insert vendor Name]		
Biostats & Stat Prog. vendor		Analysis service	[Insert vendor Name]		
CTMS		Clinical trial management system	[Insert vendor Name]		
eTMF		Trial master file repository	[Insert vendor Name]		
Document sharing platform (Internal)		Internal collaboration and document sharing	[Insert vendor Name]		
Document sharing platform (External)		External collaboration with CROs/ sponsors, vendors, and partners	[Insert vendor Name]		
Data repository		Final storage and archival of all clinical trial data, ensuring regulatory compliance and long-term accessibility	[Insert vendor Name]		

4. Key stakeholders, roles and responsibilities

Organization	Stakeholder	Role	Name/email	Responsibilities
Sponsor/CRO/ External Vendor	Clinical Data Manager (Blinded)	Data Oversight		Blinded data review and query management; ensure data quality and compliance
Sponsor/CRO/ External Vendor	Clinical Data Manager (Unblinded)	Unblinded Data Oversight		IRT data management; unblinded data handling and reconciliation
Sponsor/CRO/ External Vendor	Project Manager for Data Manager (PM for DM)	Data strategy, oversight and coordination		Ensure timelines, cross-functional alignment, vendor management, risk tracking, issue escalation, and overall data management project governance
Sponsor/CRO/ External Vendor	EDC Programmer	EDC setup and maintenance		Build and validate EDC system; implement mid study updates; ensure system functionality
Sponsor/CRO/ External Vendor	IRT Lead	IRT setup and maintenance.		Manage patient randomization, drug inventory, and unblinded data flow; oversee IRT system changes
Sponsor/CRO/ External Vendor	eCOA Lead	eCOA setup and maintenance		Oversee system build, patient compliance tracking, and integration of eCOA data with EDC
Sponsor/ CRO/ External Vendor	Clinical Operations Lead	Site and patient operations		Oversees site performance, protocol adherence, patient engagement, issue resolution, and DCT/ home health activities
Sponsor/CRO/ External Vendor	Biostatistics Lead	Data analysis oversight		Approve database specifications, ensure data readiness for analysis, manage SDTM/ADaM delivery, and support statistical outputs

(Contd.)

Organization	Stakeholder	Role	Name/email	Responsibilities
Sponsor/CRO/ External Vendor	Medical (Blinded)	Medical oversight		Review blinded clinical data, assess CRF entries, participate in DMP and data review plan (DRP), and support safety signal detection
Sponsor/CRO/ External Vendor	Medical (Unblinded)	Safety oversight		Review SAEs, manage unblinded safety data, participate in DMP review for unblinded pathways and data flowchart(s), and support regulatory safety reporting
Sponsor/CRO/ External Vendor	Quality Assurance	Quality Assurance oversight		Conduct audits, manage CAPAs, ensure SOP compliance and support inspection readiness
Sponsor/CRO/ External Vendor	Safety Lead	Safety Management		Manage pharmacovigilance and all related aspects
Sponsor/CRO/ External Vendor	Regulatory Affairs	Regulatory compliance		Ensure adherence to regulatory requirements, support submissions, and manage interactions with health authorities
Sponsor/CRO/ External Vendor	Site Investigators	Data collection		Ensure accurate and timely data into systems; ensure protocol compliance and patient safety
Sponsor/CRO/ External Vendor	IT Support	System uptime and issue resolution.		Maintain system uptime, manage user access, and resolve technical issues across platforms
Sponsor/CRO/ External Vendor	Wearable Device Vendor	Device provider		Deliver and maintain wearable devices; ensure data capture integrity and troubleshooting device related issues
Sponsor/CRO/ External Vendor	Home Health Vendor	Remote visit provider		Conduct home visits, collect patient data per protocol, and ensure timely data upload
Sponsor/CRO/ External Vendor	Data Standard Lead (optional)	Data standardization		Ensure CDISC compliance, manage CRF annotations, and support SDTM/ADaM mapping
Sponsor/CRO/ External Vendor	Data Integration Lead (optional)	Data integration oversight		Oversee integration of data from multiple sources (e.g. EDC, eCOA, IRT, Labs); ensure consistency and traceability

5. Communication strategy list of meetings

Communication Type	Milestone/Frequency	Participants
Study Kick-off Meeting	Planning Phase	Full project team
DM Kick-off Meeting	Planning Phase	DM Lead, PM for DM Lead, Clinical Operations Lead, DM Programmers, Biostatistics Lead, Medical Lead, Safety Lead
System specific UAT Kick-off Meeting	Planning Phase	Clinical Operation, CDM, other UAT participants.
eClinical Systems Kick-off Meetings	Planning Phase	IRT/eCOA leads, DM lead, PM for DM Lead, Clinical Operation Lead, Clinical Supply Lead (IRT), Biostatistics Lead
Central and Specialty Laboratories Kick-off Meeting	Planning Phase	Lab specialist, Clinical Operations Lead, DM Lead, PM for DM Lead,
Core Team Meeting	Weekly	Full project team
Data Management Meeting	Weekly	CDM, Biostatistics, and Clinical Operations leads
Internal DM Meeting	Bi-Weekly	All DM Team (study or program level)
SAE Reconciliation Meeting	Monthly	LDM, SAE/Safety Lead, Medical Lead
Data review meeting	Monthly	DM Lead, PM for DM Lead, Clinical Operations Lead, Biostatistics Lead, Medical Lead, Safety Lead
Risk management meeting	Quarterly	PM for DM Lead, DM Lead
eClinical vendor meeting	Weekly	IRT/eCOA leads, DM lead, PM for DM Lead, Clinical Operation Lead, Clinical Supply Lead

(Contd.)

Communication Type	Milestone/Frequency	Participants
Central and Specialty Laboratories Meeting	As Needed	Lab specialist, Clinical Operations Lead, DM Lead, PM for DM Lead
Interim Analysis Kick-off Meeting	As Needed	Full Team, External Data Leads
Database Lock Kick-off Meeting	As Scheduled	Full Team, External Data Leads
Query Resolution Updates	Daily (if needed)	Site staff, CDM, and clinical ops

6. Meeting agenda and minutes

Meeting agenda is expected to be shared 24–48 hours prior to the meeting start in the agreed template.

- Meeting minutes are expected to be shared 24–48 hours after the meeting ends including action items in the agreed template.
- Meeting agenda and minutes must be filed in TMF.
- Meeting agenda and minutes recommended components:
- Meeting Details:
  - Date
  - Time
  - Location and/or meeting link
  - Facilitator/Chairperson/Note Taker
  - Invitee(s)
- Agenda items:
  - Introduction and purpose
  - Review previous meeting minutes
  - Main agenda topics:
    - ➢ Accomplishments, recognitions and appreciations, shout-outs
    - ➢ Metrics that matter
    - ➢ Data and/or system related risks and issues.
  - Open floor: Ideas and challenges, next steps
  - Out of office and any other business
  - Closing motivation
- Minutes items to be added post meeting:
  - Attendees
  - Discussions points
  - Decisions made
  - Action Items, owner, and deadline
  - Next meeting date (as applicable)

7. Study milestones

Milestone	Target Date	Owner
Protocol Finalization	[Insert Date]	Medical representative
FPI	[Insert Date]	Project manager
LPLV	[Insert Date]	Project manager
EDC System Initial Go-Live	[Insert Date]	EDC administrator
IRT System Initial Go-Live	[Insert Date]	IRT specialist
eCOA Initial Go-Live	[Insert Date]	eCOA vendor representative
Interim Analysis (as applicable)	[Insert Date]	Biostatistician
Database Lock	[Insert Date]	CDM
Protocol Amendment (as applicable up version)	[Insert Date]	Medical/Regulatory representative
EDC Modifications (as applicable up version)	[Insert Date]	CDM
IRT Modifications (as applicable up version)	[Insert Date]	IRT specialist
eCOA Modifications (as applicable up version)	[Insert Date]	eCOA vendor representative

8. Risk management RACT (Risk Assessment Categorization Tool)

Risk Category	Risk Description	Impact	Probability	Detectability	Risk Score	Mitigation Strategy	Residual Risk	Owner
Technology	System downtime	High	Medium	High	Medium	Maintain 24/7 IT support and implement disaster recovery plans.	Low	IT Lead
Data Management	Data integration issues	High	High	Medium	High	Schedule frequent system checks and vendor reviews.	Medium	Data Manager
Operations	Delayed query resolution	Medium	Medium	High	Medium	Allocate dedicated staff for query follow-ups and escalation protocols.	Low	Clinical Data Manager
Data Privacy & Security	Data privacy breaches	High	Medium	Medium	High	Enforce strict access controls, regular audits, and compliance with GDPR/HIPAA.	Medium	Compliance Officer
Data Quality	Incomplete data capture	High	Medium	Medium	Medium	Implement real-time validation and site training.	Low	Site Coordinator
Regulatory	Regulatory non-compliance	High	Low	Medium	Medium	Regularly review regulations and involve compliance experts.	Low	Regulatory Affairs
Training	User training gaps	Medium	Medium	High	Medium	Provide onboarding and continuous training.	Low	Training Coordinator
Vendor Management	Vendor performance issues	High	Medium	Medium	Medium	Establish SLAs, conduct reviews, and maintain backup vendors.	Low	Vendor Manager
Protocol Management	Change in protocol design	Medium	Medium	Medium	Medium	Set up a change control board and impact assessment process.	Low	Project Manager

8.1. RACT scoring dimension

1. Impact: How severe the consequences would be if the risk materialized.
2. Probability: How likely the risk is to occur.
3. Detectability: How easily the risk can be detected before it causes harm.

8.2. Risk score calculations

Risk Score = Impact × Probability × Detectability
High = 3, Medium = 2, Low = 1
Minimum score: 1 × 1 × 1 = 1 (low risk)
Maximum score: 3 × 3 × 3 = 27 (high risk)

8.3. Risk prioritization

Risk Score Range	Risk Level	Action Required
1–6	Low	Monitor; minimal action needed
7–14	Medium	Mitigation plan recommended
15–27	High	Immediate mitigation and close monitoring

9. Metrics

Metric	Metrics Owner	Details
EDC Missing Data		Counts, %, Durations, Identify Sites that are consistent
EDC Open Queries		Counts, %, Durations, Identify Sites that are consistent
EDC Source Data Verification		Counts, %, Durations, Identify Sites that are consistent
Reconciliation Issues (e.g., EDC vs IRT) [one row per reconciliation]		Counts, %, Durations, Identify Sites that are consistent
eCOA Missing Data		Counts, %, Durations, Identify Sites that are consistent
eCOA Data Change Request		Counts, %, Durations, Identify Sites that are consistent
eCOA Data Syncing >5 days		Counts, %, Durations, Identify Sites that are consistent
Medical Terms Coded		Counts, %

10. Escalation management

10.1. Data collection and review issues

Issue Type	Escalation Path
Critical Data Issues (e.g., affecting primary endpoints)	Site → CRA → CRO LCDM → Sponsor Data Lead
Non-Critical Data Issues	Site → CDM → Sponsor Data Lead
System Outages/Tool Malfunctions	Site → CRA → CDM → Sponsor IT/EDC Vendor Support or Programmer
Repeated Site Non-Compliance	CDM → Clinical Operations Lead → Site Management Team

10.2. Personnel issues (CDM team)

Issue Type	Escalation Path
Interpersonal or Performance Concerns	Complainant → Individual and/or Complainant→ Individual's Manager → Functional Lead (if unresolved)

10.3. Escalation triggers and timelines

Metric	Metrics Owner
Query unresolved > 5 business days	Escalate to Lead CDM or escalate Clinical Operations to work with Site
Missing critical data > 3 days post-visit	Escalate to Site and Clinical Operations
System downtime > 2 hours	Escalate to Sponsor IT/EDC vendor/programmer
Reconciliation discrepancies unresolved > 7 days	Escalate to Data Leader or escalate Clinical Operations to work with Site

11. Approval and signatures

Name	Title*	Organization	Signature	Date
	Clinical Data Manager (Blinded)			
	Clinical Data Manager (Unblinded)			
	Project Manager for Data Manager (PM for DM)			
	EDC Programmer			
	IRT Lead			
	eCOA Lead			
	Clinical Operations Lead			
	Biostatistics Lead			
	Medical (Blinded)			
	Medical (Unblinded)			
	Quality Assurance			
	Regulatory Affairs			

*List each participant required for signature (CRO, Sponsor, Vendor).

Appendix B: RACI Chart Template

Task/Activity	CDM	Clin Ops	IRT Lead	eCOA Lead	Biostatistician	Medical	Sponsor
Project Kick-off Meeting	C	R/A	I	I	I	I	C
EDC Build Kick-off Meeting	R/A	C	NA	NA	C	C	C
IRT Build Kick-off Meeting	C	A	R/A	NA	C	C	C
eCOA Build Kick-off Meeting	C	C	NA	R/A	C	C	C
Protocol Review for eClinical Requirements	R	A	C	C	C	I	C
EDC System Design and Build	R	A	I	C	C	C	C
IRT System Configuration	I	A	R	I	I	C	C
eCOA System Setup and Validation	C	A	I	R	C	C	C
User Acceptance Testing (UAT)	R	A	R	R	C	C	I
Data Collection (Sites and Patients)	I	I	I	I	I	C	I
Query Management and Resolution	R	A	C	C	I	I	I
Data Reconciliation (EDC/IRT/eCOA, SAE)	R	A	C	C	C	C	I
Ongoing Data Monitoring and Cleaning	R	A	I	C	C	I	I
Database Lock Preparation	R	A	C	C	C	C	C
Final Database Lock	R	A	C	C	C	C	C
Regulatory Submission Datasets Preparation	C	A	I	C	R	I	R
Issue Escalation and Risk Management	R	A	C	C	I	R	C
System Maintenance and Support	C	A	C	C	I	R	I

R (Responsible): The individual(s) who performs the task.
A (Accountable): The person who ensures the task is completed (one per task).
C (Consulted): The person(s) who provides input or advice.
I (Informed): The person(s) who need to be kept updated on progress or decisions.

1. **Add Tasks as Needed:** Tailor tasks to your project.
2. **Customize Roles:** Modify stakeholder roles based on your organizational structure or services provided.
3. **Assign Specific Names:** Replace general roles (e.g., CDM, PM) with the specific team members for accountability.
4. **Use with Milestones:** Combine this RACI chart with a project timeline to track progress.

Competing Interests

The authors have no competing interests to declare.

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