PROJECT MANAGEMENT FOR CLINICAL DATA MANAGERS

Empowering the CDMs

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GCDMP
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1) Abstract

Project management skills are critical for clinical data managers (CDMs) to navigate the complexities of modern clinical trials. These skills enable effective coordination of diverse teams, integration of decentralized and eClinical technologies, and adherence to regulatory requirements. CDMs are primarily accountable for the success of clinical data strategy and management. Therefore, it is important to understand the project management skills required to lead the project, the program, and the team (vertically and horizontally). A data manager with great project management skills can move seamlessly from one activity to another, and achieve overlapping milestones managing budget, timelines and resources.

2) Learning Objectives

After reading this paper, the reader should understand:

- The project management framework from the Project Management Book of Knowledge (PMBOK), 5th Edition (2013)[1]. This framework identifies five process groups and ten knowledge areas of project management (please see section 7)
- Application of this framework in the clinical data management activities:
  - Each phase of the project: initiating, planning, executing, monitoring, and closing.
  - Each knowledge area of the project as applicable: integration, scope, cost, time, quality, human resources, communication, risk, procurement, and stakeholder.

3) Introduction

Clinical data managers take on significant project management responsibilities. Traditionally it has been limited to building and testing the clinical database, reviewing clinical data, and ensuring a quality EDC lock. Although project management skills were required, it was not much emphasized. In the past, it was less complex because most of the data was collected in EDC with limited external data such as safety labs and PK data. In today's environment what defines clinical data has broadened to include eCOA (including ePRO, eDiaries, etc.), Real-world data, Electronic Health Records, Wearables, and many more. Additionally, COVID-19 expedited the use of decentralized clinical trial methodologies and other new solutions for enrolling (e.g. IRT, eConsent), monitoring, and collecting clinical data much faster than previously anticipated. Risk based data management is becoming a standard part of clinical studies (ICH E6 R2)[2] (FDA Guidance: Oversight of Clinical Investigations-A Risk-Based Approach to Monitoring (2013)[3].

This significant expansion of clinical data's 5 Vs (Volume, Variety, Velocity, Veracity, and Value) (SCDM, 2022)[4] has led to an increase in trial complexity. As clinical data managers, 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. To succeed, CDMs must develop a broader

understanding of processes and roles across regulatory, clinical operations, and other related functions.

4) Scope

The scope of this paper is focused on applying project management skills in the preparation of clinical data used for analysis in support of a clinical trial ensuring data integrity is intact. The paper describes the process groups and knowledge areas from the Guide to the Project Management Body of Knowledge fifth edition (PMBOK, 2013)[1] from a clinical data management perspective.

This paper explains how project management principles are applied to CDMs. The paper considers not only the traditional clinical data management activities such as development of the CRF, data cleaning, and database lock, but also the project management activities such as timeline development, cost management, and data integration to support today's clinical research environment with complex protocols, real-world data and electronic health records as e-source.

Vendor management processes are covered in detail in the Vendor Selection and Management paper (Amatya and Edgerton, 2021)[5] and is not within the scope of this paper.

5) Minimum Standards

- Ensure all data management study staff (including backups) are identified and assigned in the planning phase. Ensure information is documented in the study plan and updated as applicable.
- "Identify, define, and document all study-specific processes. Any planned study-specific deviations from organizational SOPs and the rationale for the deviations should be brought to the attention of quality assurance personnel and logged for discussion during future SOP review cycles." (PM for DM, GCDMP 2013)[6]
- "Ensure clear, comprehensive, and technically feasible timelines with dependencies that are created and documented such that all personnel agree and can access timelines relative to their scheduled tasks. This may take the form of Gantt charts (derived from a project plan)." (PM for DM, GCDMP 2013)[6]
- "Monitor, track and document projected costs and timelines against actual expenditures and deliveries (e.g., comparison of percentage of work completed to the percentage of budget spent)." (PM for DM, GCDMP 2013)[6]
- "Identify potential risks to the project or study. Develop early warning signals and response strategies for each identified risk (e.g., risk mitigation plan). Review and adjust study-specific contingencies in accordance with the study life cycle." (PM for DM, GCDMP 2013)[6]
- "Create and propose to the project team a communication plan, which, upon approval, shall be adhered to by all study personnel and stakeholders. The plan should be specific and easy to follow based on individual end user needs. The plan should identify a schedule for routine communications, the means by which these communications will be conducted, and how communications will be documented and archived. Common elements may include issue categories and associated severity codes, severity-based time/resource/cost impact, escalation rules, and resolution plans. For an example of what should be included in a communication plan, see Appendix B: Sample Communication Plan Template" (PM for DM, GCDMP 2013)[6]. There

may be a CDM section of the overall communication plan or an individual CDM Communication Plan depending on the study.

- "Assure a thorough assessment has been made of CDM team members' familiarity with clinical study systems, processes, disciplines, or functional lines." (PM for DM, GCDMP 2013)[6]
- "Ensure appropriate project- or study-specific training is delivered, maintained and documented for all study personnel performing CDM tasks." (PM for DM, GCDMP 2013)[6]
- "Ensure adequate and compliant electronic, virtual, and physical resources will be available for intake and archival of final accepted CDM deliverables. This may involve working with personnel from different departments, including information technology (IT), legal, and regulatory operations, as well as external vendors" (PM for DM, GCDMP 2013)[6]. The FDA does not explicitly require data flow charts for clinical trials. However, they do emphasize the importance of ensuring data integrity, quality, and traceability throughout the clinical trial process. This often involves using tools like data flow diagrams to map out the passage of data from collection to analysis.

6) Best Practices

- "Create a responsibility matrix that describes activities to be conducted during the study." (PM for DM, GCDMP 2013)[6]
- Participate in protocol development to ensure it is clear what, where, how and when data points are collected.
- "Conduct regular meetings with the study team (may be conducted via web or telephone conferences). During these meetings, track progress and upcoming milestones, and discuss corrective actions if needed." (PM for DM, GCDMP 2013)[6]
- "Continually assess project processes and modify processes as needed to function more efficiently. Ensure all process changes are communicated, documented, and version controlled. File this documentation within the study master file in effort to establish a clear audit trail." (PM for DM, GCDMP 2013)[6]
- Familiarize team members with the Statistical Analysis Plan to understand how data will be used in terms of endpoint derivation, analysis windows, treatment discontinuations.

7) Key Project Management Concepts

Portfolio, Program, and Project Management

Portfolio management aligns projects, programs, and operations with strategic goals. Clinical development programs group related projects to achieve broader objectives, while individual projects contribute to the overall portfolio. For instance, a weight loss portfolio might include multiple compounds, each as a separate program with distinct Phase 1 and later phase studies. Please refer to PMBOK 5th edition (2013)[1].

Organizational Influences

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 (PMBOK, 2013)[1].

PMBOK[1] Framework

The PMBOK (2013)[1] 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.

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 to ensure targets are met.
- *Project Closing*: Complete database lock and post-lock deliverables.

Agile Approaches

Project management approaches used in technology such as the development of clinical databases have traditionally used the Waterfall method (PMBOK 7th edition, 2021)[7] with well-defined stages and formal handoffs; however, in today's environment of adaptive clinical protocols clinical data managers might also take advantage of some project management approaches using the Agile method of managing projects. The Agile project management approach is iterative and involves frequent stakeholder engagement, adaptive documentation, and continuous improvement.

A full discussion of Waterfall vs. Agile project management methods are not in scope of this paper; however, the reader is encouraged to be familiar with both approaches and employ processes from each as applicable within the organization's standard operating procedures. Please refer to PMBOK 7th edition (2021)[7].

Soft Skills & Considerations

Not much emphasized but the project management aspect that carries a lot of weight is soft skill of the CDM. Effective project management requires great deal of application of soft skills: negotiation, clear communication, assertive advocacy, and the ability to present complex data in both business and layman's terms to engage different stakeholders (PMBOK, 2021)[7].

187 The following exhibition summarizes the PMBOK application in PM for CDM.

188 Exhibit 1: *PMBOK Framework – Process Groups and Knowledge Areas (PMBOK, 2013)*[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 quality benchmarks (e.g., real-time monitoring).	Implement risk-based quality management plans.	Conduct mid-study quality checks (e.g., central monitoring).	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 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.

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8) Initiating

Initiating Data Integration

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 for the success of the project and sets the tone for the project team. It is important that the clinical data manager 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 isn't in the protocol it is important to amend the protocol first, if possible, or document this for the next protocol amendment before it is implemented.
- Identify the critical data (primary and secondary endpoint), in collaboration with medical and biostatistics team, especially if the nature is data is complex and ambiguous.
- Develop high level process flow across data flow across vendors, sites, and systems.
- Identify any data analytic tools that will be used for integrated data review.

Initiating Project Scope Management

- Be familiar with the contract and either contracted scope of work and reference the contract and assumptions versus going by memory. Identify strategy for data collection and data review considering technologies such as EHR as eSource, decentralized monitoring, eCOA, IRT, imaging vendors, risk-based monitoring, visualization, AI driven data review, etc.
- Review scope of third-party vendors to ensure clarity of responsibilities and ownership of tasks.

Initiating Project 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.

Initiating Project Cost Management

- Resource Planning: Identify the cost to qualify DM and Data vendor(s) managed by DM. 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 this step starts as early as possible.
- Please refer to GCDMP paper Vendor selection and management (Amatya and Edgerton, 2021)[5] section 8 Vendor Qualification, Initial Evaluation and Selection. A startup of 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 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 DM, it is recommended to be a reviewer of the 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 this task is managed by the company's contract manager.
- 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.

Initiating Project Quality Management

- Identify QA 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. 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 from a Data Management lens.
- Look for inconsistencies that could impact the sponsor clinical program level standards and endpoints.

Initiating Project 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 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, eTMF site, secured data transfer site, SharePoint / other document sharing systems, etc.

Initiating Project 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 plan template [Appendix B Sample template included]

Initiating Project 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.
- 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.

Initiating Project 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 of Clinical Data Management (JSCMD) paper Vendor Selection and Management[5] covers this topic in depth.

Initiating Project Stakeholder Management

Identifying who are the stakeholders for data management and how they will affect the project from the start is very important to ensure proper processes and documentation are established (Ramdayal, 2021)[8]. 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.

9) Planning

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 (PMBOK v5 2013)[1] as they relate to the planning phase of a trial.

Data Integration Management

- Design the Data Management Plan ensuring that all data sources are recorded.
- Develop a holistic data review plan for the entire process from protocol design to 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.

Project 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 DM activities at the project kick-off meeting.
- Develop or contribute to the Project Timeline.
- Develop or contribute to the RACI matrix.
- Create the Data Management Plan 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.

Project 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 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 like Excel, MS Project or Smartsheet work well. These basic principles must be considered in all the steps below.

- Outline activities required for timeline development.

- Identify key study milestones:
  - SIV, FPI, FPFV, LPLV, DBL dates.
  - Key deliverable dates (DMC, Safety Review, 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.
  - SAE reconciliation cycles.
  - Data Review Meetings.
    - Estimate duration for each activity, allowing for issue resolution from UAT and participation from other parties e.g. EDC review meetings.
    - Ensure assignments are made and include participation from the project team (clinical monitor, statistician and clinician) throughout the timeline as needed.

Project Cost Management Planning

- Assign resources to the right location according to the budget.
- Identify financial KPIs and key metrics targets and communicate financial penalties if applicable where data management KPI is 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. sample query review to ensure the 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. 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.

Project Procurement Management

- Ensure product, services and results which were identified for the project are secured and align with the budget and contract.

Project 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 template are in place in the event a transition of staff is required.

Project 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 (2013)[1] 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."
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. Data Management Plan, 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 vs. informal communications are needed are situationally based on the table of examples above.

Project Risk Management Planning

"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. (PMBOK, 5th edition page 309, 2013)"[1]. It is critical for DMs to be involved in the risk related discussion from the beginning and the DM related risk and the mitigation plan must be documented in the risk plan (or equivalent) at the study level.
Per ICH E6 R2 [2] section 5.0 on Quality Management states that "the quality management system should use a risk-based approach." For this paper's purposes, project risk is categorized as follows:

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.

Project 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 Data Management Plan, should document expectations for stakeholder engagement. (e.g. reviewers of the CRF, user acceptance testers).

10) Executing

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.

Project Data Management - Integrations

- Direct and Manage Project from a CDM/CDS 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.

Project 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 taking action 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 or meeting to resolve.
- Utilize good meeting practices - have an agenda, take minutes, record action items, allow all participants to contribute.

Project Schedule / Timeline Management

- Ensure database build timeline is adhered to as each component activity will have a knock-on effect. Activities such as eCRF specification review and finalization, 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, coding dictionary implementation should be monitored and any risks mitigated on an ongoing basis.
- If there are different systems, they will require both their own timeline and inclusion in the overall timeline.
- eConsent set up related considerations may fall under the remit of data management and is a time critical activity.
- EHR set up 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: DTA review and finalization for each external data.
- eCOA/ePRO set up 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.
- Determining 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 in order for any process change to be measured in its efficiency.
- 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 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.

Project 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.

Project 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 deliverable.
- Ensure awareness of timelines.
- Review Metrics to ensure alignment of activities are achievable.

Project Resource Management

- Team train 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.

Project Communication Management

- Monitor flow of communication throughout the study including, meeting agenda and minutes, delivery of metrics and reports, transitions to new team members, continued use of appropriate forms of communication (email, phone, shared sites) and 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.

Project Stakeholder Management

- Maintain stakeholder engagement, it is advisable to use a tracking log available to all stakeholders in order 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.

11) Monitoring and Controlling

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 (Fleming et al. 2017)[9]. 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 (Lu & Su, 2010)[10].
- This includes reviewing protocol amendments for their impact on the budget and aligning the study's scope with these adjustments.
- Ensure periodic reviews of Trial Master Files (TMF) and quarterly 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 (Lu & Su, 2010)[10]. and (PMBOK, 2021)[7]). For example, schedule regular data review meetings

where key metrics such as site performance, data quality, and SDV (Source Data Verification) completion are discussed.

- Establish a mitigation plan to proactively address delays by ensuring that key milestone dates are tracked against actual dates and integrating interim analysis 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 (Lu & Su, 2010)[10].
- 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 (Flemming et al., 2017)[8].
- Focus on continuous improvements in data collection processes, incorporating lessons learned from previous trials into the current study. Ensure that corrective actions are implemented promptly for any identified issues in eCRF 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 (Lu & Su, 2010)[10].
- 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, DM meetings, Data Review Meetings, ad hoc meetings). Communication plays a crucial role in ensuring all stakeholders are aligned with the project's status, issues, and changes (Webber, 2015)[11] (Harvard University Information Technology, 2024)[12]. 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

- Risk management in clinical trials involves identifying potential risks early and proactively mitigating them through strategic planning.
- Tools like the Risk Assessment and Categorization Tool (RACT) from Transcelerate Biopharma help assess the impact, probability, and detectability of identified risks, ensuring that critical processes like informed consent and adverse event reporting are handled appropriately (Alsumidaie, M. 2015.)[13] (Harvard University Information Technology, 2024)[12].
- 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 (Amatya and Edgerton, 2021)[5].
- Maintain frequent communication with vendors, ensuring that all procurement activities are executed on schedule and within budget. 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 (Paandi-Perumal Sr et al, 2015)[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 that they are kept informed of progress, risks, and mitigation strategies. This fosters a collaborative environment that supports the trial's objectives.

Monitoring and controlling are fundamental to the successful management of clinical trials. By applying structured project management practices across key areas such as scope, cost, schedule, and risk management, data managers can ensure that the clinical trial progresses smoothly, with high data integrity and compliance. Proactive identification and mitigation of risks, combined with effective communication and resource management, are essential for keeping trials on track and delivering timely, accurate results (Fleming et al. 2017)[9] (Lu & Su, 2010)[10]. Each of these actions contributes to the overarching goal of clinical trials: to provide reliable, actionable data while ensuring patient safety and regulatory compliance.

12) Closing

The end of a study is not just the locking of the database but requires skills in other areas such as budget reconciliation, DM Trial Master File (TMF) QC to ensure all DM documents during the project life cycle, final data delivery confirmation, etc.

Project Data Management - Integrations

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

Project Scope Management

- Action invoices and change orders as applicable.
- Revoke access to database, SharePoint, SFTP as applicable.
- 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.

Project Schedule / Timeline Management

- Review and adjust timeline for database lock and study closure with cross-functional input. Activities to be considered include but are not limited to final data entry, data review and reconciliation, medical coding, query resolution, SDV, 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.

Project Cost Management

- Reconcile or participate in budget reconciliation for data management related deliverables and activities for each vendor.

Project Quality Management

- Ensure all the data management study plans are fully executed and represented by actual activity performed.
- Ensure all the CAPAs are closed out.
- Ensure all DM 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 subject data is provided to respective sites and sponsors depending on the regulatory requirement about media and IT capability.

Project 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 closeouts, final budget/change order reconciliations, etc. and plan resourcing accordingly to ensure these tasks are supported.

Project Communication Management

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

Risk Management

- Review final Risk Management Plan and update as applicable.

Project Procurement Management

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

Project 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.

13) Recommended SOPs

Vendor Management
Contract Management
Vendor Oversight
Document Management Control
Data Management Start-up
Data Review/Maintenance
Database Lock/post-Lock

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16) Paper Version History

Version No.	Finalized Date	Authors
V1	June 2010	SCDM (JSCMD published 2023)
V2	TBD 2025	Amatya, S., Edgerton, D., Fasshauer, H., King, S., Sage, E.

17) Keywords

Project Management
Clinical Data Management/Data Management
Clinical Data Manager/Data Manager
Clinical Trial
Database/EDC
eCOA /ePRO/eDiaries
IRT
Decentralize
eClinical
Portfolio, Project, Program
PMBOK
Strategy/Strategies
Clinical data
Integration
Scope
Timeline
Cost / Budget
Resource
Communication
Risk
Procurement
Stakeholder
Initiating
Planning
Executing
Monitoring
Closing

18) Abbreviations

AE - Adverse Event
CAPA - Corrective and Preventive Action
CCG - CRF completion Guidelines
CDM - Clinical Data Manager
CDS - Clinical Data Scientist
CPM - Critical Path Method
CRA - Clinical Research Associate
CRF - Case Report Form
CRO - Clinical Research Organization

DM - Data Manager/Management
DMC - Data Monitoring Committee
DTA - Data Transfer Agreement
eCOA - Electronic Clinical Outcome Assessment
eConsent - Electronic Consent
EDC - Electronic Data Capture
EHR - Electronic Health Record
ePRO - Electronic Patient Reported Outcome
FPFV - First Patient First Visit
FPI- First Patient In
IM - Investigator Meeting
IP - Investigational Product
IRT - Interactive Response Technology
JSCDM - Journal of the Society for Clinical Data Management
LPLV - Last Patient Last Visit
PI- Principal Investigator
PMP - Project Management Professional
QC - Quality Control
RACT - Risk Assessment Categorization Tool
SAE - Serious Adverse Event
SDV - Source Data Verification
SFTP - Secure File Transfer Protocol
SIV - Site Initiation Visit
SOP - Standard Operating Procedure
SOW - Scope of Work
TMF - Trial Master File
UAT - User Acceptance Testing

Appendix A: Clinical Data Management Project Management Plan Template (eClinical Focus)

Project Title:
Sponsor/Protocol ID: Date: Version:

1. Introduction

- Purpose:
  Define the objectives and structure for managing clinical data effectively using eClinical tools, ensuring compliance with ICH GCP, FDA 21 CFR Part 11, and ALCOA+ principles.
- Scope:
  Covers all data management processes and tools, including EDC, IRT, eCOA, eTMF, and associated integrations.

2. Objectives

- To ensure seamless integration of eClinical systems (e.g., EDC, IRT, eCOA) for data collection and management.
- Maintain data integrity, security, and regulatory compliance.
- Facilitate timely database locks and regulatory submissions.

3. Key Stakeholders

Stakeholder	Role	Responsibilities
Clinical Data Manager	Data oversight and query management.	Ensures data quality and compliance.
IRT Specialist	IRT setup and maintenance.	Manages subject randomization and drug inventory tracking.
eCOA Vendor Representative	System configuration and data flow.	Ensures eCOA data integration with EDC.
Biostatistician	Statistical oversight.	Ensures datasets meet analysis requirements.
Site Investigators	Data collection.	Inputs accurate and timely data into systems.
IT Support/EDC Administrator	System uptime and issue resolution.	Maintains system performance and access control.

4. Tools and Systems

System	Purpose	Vendor
EDC (e.g., Medidata Rave)	Electronic data capture.	[Insert Vendor Name]
IRT (e.g., IWRS)	Randomization and drug tracking.	[Insert Vendor Name]
eCOA	Patient-reported outcomes.	[Insert Vendor Name]
CTMS	Clinical trial management.	[Insert Vendor Name]
eTMF	Trial master file repository.	[Insert Vendor Name]

5. Roles and Responsibilities

Role	Key Responsibilities
Clinical Data Manager	- Oversee data collection and validation. - Ensure eCOA/IRT data integration. - Manage query resolution processes
IRT Specialist	| - Configure randomization and drug supply settings. - Resolve IRT-related issues
eCOA Vendor Representative	- Ensure system validation and compliance. - Troubleshoot eCOA system issues.
Biostatistician	| - Approve database specifications. - Ensure data readiness for analysis.

6. Communication Plan

Communication Type	Frequency	Participants
Kick-off Meeting	At project start	Full project team

Communication Type	Frequency	Participants
eClinical Systems Sync	Weekly	EDC, IRT, and eCOA leads
Data Quality Review	Bi-weekly	CDM, biostatistics, and clinical leads
Database Lock Meeting	As scheduled	CDM, regulatory, and clinical leads
Query Resolution Updates	Daily (if needed)	Site staff, CDM, and clinical ops

7. eClinical Systems Integration Plan

7.1. IRT Integration

- Setup and Configuration:
  - Define randomization schema and drug supply parameters.
  - Schedule User Acceptance Testing (UAT) with key stakeholders.
- Data Flow:
  - Real-time integration of IRT randomization data into the EDC system.
  - Track inventory and shipment data for compliance.

7.2. eCOA Integration

- Setup and Validation:
  - Ensure eCOA questionnaires are aligned with protocol requirements.
  - Perform UAT and ensure compatibility with the EDC system.
- Data Flow:
  - Map eCOA data fields to EDC datasets for consistency.
  - Define frequency of data transfers (real-time or batch).

8. Data Handling and Validation

- Data Cleaning:
  - Implement edit checks in EDC to reduce errors at the point of entry.
  - Regularly monitor query resolution rates.
- Reconciliation:
  - Compare IRT and EDC datasets to ensure consistency.
  - Reconcile eCOA data with clinical datasets for completeness.

9. Risk Management

Risk	Mitigation Plan
System Downtime	Maintain 24/7 IT support and disaster recovery plans.
Data Integration Issues	Schedule frequent system checks and vendor reviews.
Delayed Query Resolution	Allocate dedicated staff for query follow-ups.

10. Milestones

Milestone	Target Date	Owner
EDC System Go-Live	[Insert Date]	EDC Administrator
IRT System UAT Completion	[Insert Date]	IRT Specialist
eCOA Deployment	[Insert Date]	eCOA Vendor Representative
Database Lock	[Insert Date]	CDM

11. Metrics for Success

- Query Resolution Time: <48 hours.
- System Downtime: <1%.
- Data Completeness: >95% prior to database lock.
- Integration Success: No critical mismatches between EDC, IRT, and eCOA data.

12. Approval and Signatures

Name	Role	Date
[Clinical Data Manager]	CDM	[Insert Date]
[Sponsor Representative]	Project Lead	[Insert Date]
[eCOA Vendor Representative]	Vendor	[Insert Date]

Appendix B: Sample Clinical Data Management Project Communication Plan Template

Project Title:
Project Sponsor:
Date:
Version:

1. Introduction
   - Purpose:
     To outline communication strategies specific to data management activities, ensuring smooth coordination between internal teams, external stakeholders, and eClinical systems.
   - Scope:
     Focuses on clinical data management across all phases of the clinical trial lifecycle, including eClinical components (e.g., EDC, CTMS, ePRO).

2. Objectives of Communication
   - Ensure real-time and accurate data flow using eClinical systems.
   - Maintain compliance with GCP, regulatory guidance, and data integrity principles (e.g., ALCOA+).
   - Facilitate timely issue resolution and cross-functional collaboration.

3. Key Stakeholders
   - Internal Stakeholders:
     Data management team, biostatistics team, clinical operations, **medical, safety,** regulatory affairs, quality assurance, and IT support.
   - External Stakeholders:
     CROs, site staff, EDC vendor(s), **IRT vendor,** ePRO vendor(s), database programmers, and regulatory health authorities.

4. Roles and Responsibilities

Role	Responsibilities	Contact Information
Clinical Data Manager	Oversee data collection, cleaning, and validation.	[Insert]
EDC Lead	Manage system setup, UAT, and user access.	[Insert]
eCOA Lead	Manage system setup, UAT, and user access.	[Insert]
Biostatistics Lead	Coordinate data transfer and statistical requirements.	[Insert]
Clinical Operations Lead	Oversee site performance and query resolution.	[Insert]
IT Support	Ensure uptime and issue resolution for eClinical tools.	[Insert]

5. Communication Methods and Tools
   - Meetings and Frequencies:
     - Weekly Core Team meetings, Weekly Data Management meetings, Monthly Data Review Meetings, Databases (e.g. IRT, EDC, eCOA) build/modifications kick-off meeting, UAT kick-off meeting, Interim Analysis DBL kick-off meeting; Final DBL kick-off meeting, issue management and escalation calls.
     - Meeting agenda and minutes expectations
   - Tools:
     - EDC System (e.g., Medidata Rave), eCOA system, IRT system, CTMS, eTMF, collaboration platforms (e.g., MS Teams, SharePoint), SFTP
   - Documentation:
     - Data Management Plan (DMP), Query Management Log, System Validation Records, Data Transfer Agreement (DTA).

7. eClinical System Communication

- Data System(s) Setup and UAT:
  - Schedule kick-off, system design review, UAT and finalization call
  - Share user access setup timelines and roles.
- System(s) Issue Management:
  - Ticketing systems to log and track technical issues (e.g., system downtimes, query errors).
  - Escalation path if issue is unresolved
- Data Transfers:
  - Schedule regular data exports and SAS datasets reviews with biostatistics.
- Integration Coordination:
  - Coordinate data exchange between EDC, ePRO, and CTMS platforms.

8. Escalation Process

Define specific escalation pathways for data-related issues, such as:

- Define specific escalation pathways for data collection and review related issues, such as missing or incomplete data from sites; System outages or eClinical tool malfunctions; Unresolved queries affecting critical timelines.
- Escalation path for critical data and non-critical data, if any. Example:
  - Site issue → Clinical Data Manager → Clinical Operations Lead → Sponsor IT/EDC Vendor.

9. Metrics for Communication Effectiveness

- Query resolution time (e.g., <48 hours).
- eClinical system uptime percentage (e.g., >99.9%).
- Timely completion of database builds, locks and milestones.
- Adherence to data transfer timelines.

10. Approval and Signatures

Name	Title	Date
[Clinical Data Manager]	[Title]	[Insert Date]
[Project Manager]	[Title]	[Insert Date]

Appendix C: Sample RACI Chart Template for CDM with eClinical Systems

- **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 provide input or advice.
- **I (Informed):** The person(s) who need to be kept updated on progress or decisions.

Task/Activity	CDM	Project Manager	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)	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

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1. **Add Tasks as Needed:** Tailor tasks to your project.
2. **Customize Roles:** Modify stakeholder roles based on your organizational structure.
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.