Project Management for the Clinical Data Manager

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Abstract

Clinical data managers often assume some degree of project management responsibilities. This chapter discusses the discipline of project management and how to effectively apply project management principles to clinical data management. The chapter describes specific project management activities within a clinical data management department, and discusses the desired competencies of a data manager assuming project management responsibilities.

Introduction

Project management is crucial for the success of any project or endeavor. However, many people mistakenly believe that project management skills only equate with being organized and being able to communicate. Although project management does require organization and communication skills, it encompasses much more than these two skills. 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]

The degree of project management activities performed by data managers varies widely between organizations. Many organizations will have separate departments for project management; however, data managers should know basic principles of project management, regardless of the extent of project management activities that are assigned to clinical data management (CDM). Effective application of project management principles results in improved quality and timeliness of CDM deliverables, as well as increased efficiency of CDM functions.

Although a clinical study can be thought of as a single project, each clinical study is made up of many components. One component is CDM, the ultimate

goal of which is to complete a study with a quality dataset that is appropriate for analysis. As the individuals responsible for overseeing CDM, data managers need to have varying degrees of project management skills. In addition to managing the internal resources and timelines of a study, CDM project managers may also manage external vendor relationships, necessitating awareness of contractual resources and scope restraints. For detailed information about managing external relationships, see the GCDMP chapter entitled "Vendor Selection and Management."

Scope

This chapter discusses project management principles and activities as applied to CDM within the context of a single study. Although project management within clinical research has a scope that encompasses much more than CDM activities, this chapter will not address project management activities and responsibilities that are beyond the CDM activities of an individual study. The activities described in this chapter are not applicable for all data managers, but do usually apply to those who are project leads or who assume project management responsibilities within CDM.

Minimum Standards

- Identify all data management study team members, stakeholders, and respective alternates wherever possible and as early in study setup as possible. Ensure information is documented and updated regularly, with documentation centrally located or otherwise easily accessible to the study team regardless of their physical location. Clearly identify the individual(s) responsible for information updates. For an example of what should be included in a project plan, see Appendix A: Sample Project Plan Template.

- 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.

- Ensure clear, comprehensive, and technically feasible timelines with dependencies that are created and documented such that all personnel are

in agreement and can access timelines relative to their scheduled tasks. This may take the form of Gantt charts (derived from a project plan).

- 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).

- 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 study life cycle.

- 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.

- Assure a thorough assessment has been made of CDM team members' familiarity with clinical study processes, disciplines, or functional lines.

- Ensure appropriate project- or study-specific training is delivered, maintained and documented for all study personnel performing CDM tasks.

- 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.

Best Practices

- Create a responsibility matrix that describes activities to be conducted during the course of the study.
- 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.
- 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.

Overview of Project Management

A project can be defined as "A temporary endeavor undertaken to create a unique product, service, or result."[1] Data managers should know basic principles of the formal discipline of project management to achieve the results desired from CDM. As with any other scientific or business-related discipline, project management employs basic theoretical constructs that underpin effective implementation. As a formal discipline, project management seeks to successfully complete specific projects in an effective and efficient manner by applying standard principles to project planning, organization and management.

Five Stages of Project Management

Every project can be divided into the following five primary stages, although each of these stages can be subdivided into numerous smaller stages and steps.

- *Initiating* defines the scope and nature of a project, identifying the project's primary goals and stakeholders.
- *Planning* lays the groundwork for a project by developing project timelines, establishing project milestones, identifying needed resources and personnel, and establishing processes to be followed and tasks to be completed during the project.

- *Executing* follows up on the planning phase by implementing the processes and tasks that were previously defined.

- *Monitoring and controlling* refers to processes and tasks that are intended to ensure project execution is progressing as intended. This phase encompasses assessing project metrics and implementing corrective actions, if needed.

- *Closing* encompasses activities undertaken as a project comes to an end, including file archival and documentation of lessons learned, which can subsequently be applied to future projects.

Nine Knowledge Areas of Project Management

In addition to the five stages of project management, the discipline is divided into nine key knowledge areas. Effective project management should examine each of these areas to ensure all aspects of project needs are adequately addressed.

- Integration management "…includes the processes and activities needed to identify, define, combine, unify, and coordinate the various processes and project management activities."[1]

- Scope management "…includes the processes required to ensure that the project includes all the work required, and only the work required, to complete the project successfully."[1]

- Time management "…includes the processes required to manage timely completion of the project."[1]

- Cost management "…includes the processes involved in estimating, budgeting, and controlling costs so that the project can be completed within the approved budget."[1]

- Quality management "…includes the processes and activities of the performing organization that determine quality policies, objectives, and responsibilities so that the project will satisfy the needs for which it was undertaken."[1]

- Human resource management "…includes the processes that organize, manage, and lead the project team. The project team is comprised of the people with assigned roles and responsibilities for completing the project."[1]

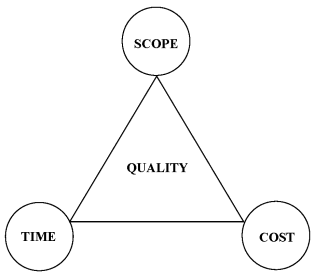
- Communication management "…includes the processes required to ensure timely and appropriate generation, collection, distribution, storage, retrieval, and ultimate disposition of project information."[1]

- Risk management "…includes the processes of conducting risk management planning, identification, analysis, response planning, and monitoring and control of a project. The objectives of project risk management are to increase the probability and impact of positive events, and decrease the probability and impact of negative events in the project."[1]

- Procurement management "…includes the processes necessary to purchase or acquire products, services, or results needed from outside the project team. The organization can be either the buyer or seller of the products, services, or results of a project."[1]

Although all nine of these knowledge areas are important components of project management, a special relationship exists between scope, time, and cost management. Sometimes known as the triple constraint, these three areas are often presented as a triangle, as depicted in Figure 1. If any one of these three components changes, the other two are also impacted. If the scope of a project increases, time and costs will typically increase as well. If the allotted time of a project is reduced, the scope must also be reduced in most cases. Although quality is an area in which most project managers do not want to compromise, changes to any of the three components of the triple constraint can negatively impact quality if changes are not properly balanced.

Figure 1. The Triple Constraint



Meetings

Because meetings are an integral part of successful project management, regular meetings are specified for all five stages of project management. Each meeting should have a predetermined agenda and be documented via meeting minutes recorded by someone other than the individual leading the meeting. Ideally, meeting agendas and minutes should be formatted according to a standard predetermined template. Meeting attendance should be documented, and all meeting documentation should be appropriately archived.

Progress and upcoming milestones should be discussed during meetings, as well as corrective actions, if needed. As milestones are achieved, collect and compile lessons learned up to that milestone. This can be accomplished by adding the lesson learned as a note attached to the milestone in the project timeline. Collecting and processing lessons learned on an interim basis will facilitate earlier process improvements toward achievement of the next milestone, and make the final lessons learned meeting at the end of the study more robust.

Project Management Activities Within CDM

To effectively apply principles of the project management discipline to CDM, data managers should determine which tasks belong in each of the five stages of project management. Although this chapter classifies CDM activities according to each of the five stages, stage assignment of various tasks may vary between organizations and studies. Some activities may also relate to more than one stage and some of these activities may not be the direct responsibility of CDM personnel in all organizations.

Initiating

During the initiation stage of a study, CDM tasks include, but are not limited to, the following activities.

- Share and discuss with individual(s) responsible for compiling requests for proposal the forecasted task/resource/time requirements as assessed for the study. This is the data manager's opportunity to clarify assumptions to be included in the contract. The result of this discussion will lead to an

accurate proposal and ultimately reduce out-of-scope hours or activities during the study life cycle.

- Define CDM contributions to the overall study team mission statement, scope, and goals in accordance with a funded portfolio or contract.

- Form or confirm core CDM team for the study: identify data manager(s) and CDM support personnel. Depending on the company's structure, the core CDM team may include IT support personnel, database programmers, and other team members who will contribute to CDM activities throughout the life cycle of the study. This core CDM team should meet regularly throughout the course of the study.

Planning

The planning stage is crucial to the ultimate success of any project. During the planning stage, data managers assess study needs and determine how to best meet those needs. Planning includes, but is not limited to, the following CDM activities.

- If applicable, review the finalized study protocol or clinical development plan (CDP), which would typically include definitions of research questions, hypotheses, estimated study duration, and estimated number of subjects required to achieve statistical power. Note, data managers working for CROs may not have access to finalized CDPs.

- Assess resources and training needed for study execution (including personnel, hardware, software, and budget, as applicable).

- Document roles and responsibilities within the study. Responsibilities are often documented with a RACI chart (Responsible, Accountable, Consulted, Informed), which is a matrix specifying which individual(s) or group(s) will be responsible for each activity or group of activities. For an example of what should be included in a RACI Chart, see Appendix C: Sample RACI Chart Template where the RACI activities and designations can be changed according to your organization's needs. In some companies, the roles and responsibilities are described in SOPs and Work Instructions, and they should not be duplicated for the specific project.

- Confirm technical qualification of sites has occurred. Although IT personnel will handle many of the details of technical qualification, data managers should be involved with making certain specific functions (e.g., data uploads) operate as intended. This confirmation includes ensuring necessary hardware and software provisioning are in place at all sites, including validation documentation.

- Identify relevant stakeholders and confirm their individual roles and expectations. Facilitate introductions to stakeholders outside CDM who may impact or be impacted by CDM, and schedule regular meetings with these stakeholders.

- Identify vendors and service providers to be involved with the study, including confirmation of vendor qualification and contracts (e.g., requests for proposal development).

- Confirm identification to or from vendors regarding version of licensed tools used in the study, such as medical coding dictionaries. For example, if MedDRA is used, both the sponsor and the company coding data must have a current MedDRA license, although sites, monitors, biostatisticians, and CROs handling raw data do not need to be licensed. For any licensed tool, make certain the conventions of the license-issuing entity are closely followed.

- Develop high-level CDM project milestones and disseminate these milestones to the lead project manager for incorporation into the overall operations project timelines. More detailed CDM project milestones are addressed during the execution stage.

- Review the study protocol for consistency throughout and document and communicate inconsistencies to the trial manager or study team. Note that some organizations may not involve CDM until the protocol is approved.

- Review preprogrammed metrics reports and any other standard reporting tools for content, usability, and format. Share these templates with the team to solicit feedback and ensure end user reporting requirements are met. Identify and document report customizations or new metrics and reports requirements so necessary programming can be completed and outputs are ready immediately during study execution.

Executing

As project management activities transition from the planning stage to the executing stage, many high-level planning tasks are defined in more detail. Executing includes, but is not limited to, the following CDM activities.

- Establish date for internal kickoff or initiation meeting (terminology may vary between organizations), and ensure all core CDM team members and support staff attend.
- Ensure technical and procedural training has been delivered to all internal or external staff, and that training is documented and archived. Provide similar training and documentation as staffing changes dictate.
- Ensure access (including passwords) to systems is enabled as appropriate, and confirm installation of any hardware or equipment, if applicable.
- Develop detailed CDM timelines that include, but are not limited to, a list of core deliverables such as CRFs, database build, edit check specifications, production database deployment, medical coding reviews, database lock, and interim or final quality reviews. After development, accepted timelines should be stored in a central location accessible to the study team. Within the description of each deliverable, identify the detailed CDM subtasks required. These detailed subtasks that drive intradepartmental staff activities may not need to be shared with the entire study team.
- Develop the data management plan (DMP), CRFs, CRF completion guidelines, database structure building plans, and other necessary documents and reports. For more information about DMPs and CRF completion guidelines, see the GCDMP chapters entitled “Data Management Plan” and “CRF Completion Guidelines.”
- Identify medical coding practices, dictionaries to be used, frequency of listing reviews (e.g., ambiguous term reports and unique term reports), and the frequency of dictionary upgrades or updates both during study conduct and at the point of final study reporting.
- Establish a detailed communication plan to ensure methods of communications between vendors, sponsor, and sites are clear, and storage locations are documented.

- Participate in investigator meetings or other appropriate training venues. It is critical to ensure site personnel and investigators receive adequate training and understand CDM expectations for the study, including proper completion of study-related documents. For more information about CDM's participation in investigator meetings see the GCDMP chapter entitled "CDM Presentation at Investigator Meetings."

- Perform an internal assessment to confirm the quality of the first group of data received.

Monitoring and Controlling

Once the study is underway, CDM project managers should begin performing monitoring and controlling procedures, which include, but are not limited to, the following activities.

- Verify with major stakeholders that initiation plans continue to be aligned with the project plan.

- Conduct midstudy vendor/CRO assessment(s) as necessary, including confirmation that all vendor contracts are being adhered to in a satisfactory manner. Assessments are typically made using internal study timelines, predefined metrics reports, and the vendor contract as the basis for comparison.

- Conduct core CDM team meetings according to a predetermined schedule, although additional meetings may be held as needed. In addition to these meetings of the core CDM team, data managers should attend the project team meetings with other functional groups.

- Verify all planned production reports continue to meet user expectations. There should be minimal changes to these previously validated outputs in terms of content and format. At this point, the study team may need to provide justification because any further modifications or customizations could be considered out of scope. The first set of finalized outputs has probably been distributed based on previously agreed frequency and recipient lists.

- Carefully monitor study reports and metrics.

- Evaluate CDM team performance.
- Initiate corrective actions when deemed necessary using the risk management plan as a guide.
- Identify, plan, and carry out training/retraining as necessary, and provide additional training sessions for new staff that may come on board during study conduct. Ensure that staff who leave the project have returned all study materials, have study access removed and have completed appropriate exit consultations.

Closing

Proper execution of the closing stage of CDM project management is crucial to ensuring the study's final deliverables meet expectations set at the initiation and planning phases of the study. Closing activities also help facilitate process improvements for future projects. Some of the CDM project management activities executed during closing include, but are not limited to, the following activities.

- Confirm all final deliverables are received or transferred and meet acceptable quality standards as defined by the organization's quality system. For information about quantification of quality standards, see the GCDMP chapter entitled "Measuring Data Quality," and for more information about quality systems, see the GCDMP chapter entitled "Assuring Data Quality."
- Ensure access (including passwords) to systems is restricted as appropriate, and confirm retrieval of any hardware or equipment, if applicable.
- Achieve, deliver and communicate database release to all relevant internal or external stakeholders. For more information about database release, see the GCDMP chapter entitled "Database Closure."
- Close all relevant contracts/procurements.
- Confirm all regulatory submission needs from CDM are met, such as annotated CRFs, sample blank CRFs, etc.

- Archive database(s), CRFs and data clarification forms (DCFs). For more information about data archiving, see the GCDMP chapter entitled "Clinical Data Archiving."
- Archive CDM components of study master files.
- Convene closing meetings, which should encompass lessons learned.
  - ☐ An internal closing meeting should encompass corrective actions to improve processes in the future.
  - ☐ An external closing meeting should be held with sponsors and vendors to improve the working relationships for future collaborations.
- Confirm sites receive copies of electronic CRFs and DCFs.

Competencies of Project Management

A successful project manager should possess the skills needed to facilitate the success of each contributor to the project. Within the context of CDM, project management competencies should facilitate efficient production within CDM and departments affecting and affected by CDM. Although some of the competencies of a project manager are similar to those of a data manager, the interrelatedness of project management may require a higher level of proficiency.

Technical Knowledge

Although project management is a unique discipline unto itself, a project manager should also be knowledgeable in the discipline(s) encompassed by the project. To be a good CDM project manager, one must first have the technical knowledge needed to be a successful data manager. In addition, a CDM project manager should have a good understanding of the operations of departments and stakeholders that impact or are impacted by CDM. A CDM project manager should also be well versed in the principles and practices of the discipline of project management.

Problem-solving Strategies

Problem-solving abilities are crucial to the success of a data manager, but become even more crucial for a CDM project manager. Many of the problems that arise in CDM are similar to problems that may have been faced in the past, meaning SOPs and past experiences can often address these problems adequately. However, project management often faces unique challenges that require sound problem-solving strategies to devise unique solutions. The ability to accurately assess a potential problem and formulate a successful solution is imperative for an effective CDM project manager.

Facilitation/Communication/Mediation/Negotiation Skills

Because project managers must coordinate with a wide range of roles and departments, CDM project managers need to have effective communication, facilitation, mediation and negotiation skills, and be able to summarize discussions and make appropriate decisions. The key to all of these skills is effective communication. A CDM project manager must be able to listen to study team members, understand their needs, and effectively communicate proposed solutions for meeting those needs. Without good communication skills, a CDM project manager cannot successfully manage the most important component of any project, which is the personnel involved with achieving the project's goals.

A CDM project manager typically interacts with personnel from multiple departments and stakeholders, necessitating the ability to facilitate and mediate communications and deliverables between those departments and stakeholders. When CDM project managers assume responsibility for managing external vendors, they may also be involved with negotiating contracts that fit the needs of the project while staying within time, scope and budgetary constraints.

Leadership

Leadership is a quality that is needed in any individual managing and leading others. While this is a needed quality for data managers, leadership is even more important for those data managers assuming project management roles and responsibilities. Although data managers must provide leadership and direction for personnel in the CDM department, a CDM project manager must also provide leadership to individuals from other functional areas of the

project. Some of the specific leadership functions that a CDM project manager should perform include the following:

- A CDM project manager should establish standards of collaborative conduct that facilitate effective communication and teamwork between various personnel and departments. A CDM project manager should not only possess effective communication skills, but they should also be able to use their communication skills to facilitate effective collaboration, negotiation, mediation and teamwork between other members of the CDM and study teams.

- Standards of professional conduct are typically established by an organization's upper management. A CDM project manager should clearly adhere to these standards and lead others to do so by example.

- Team and individual coaching/mentoring are crucial to improving the skills of each individual and the team as a whole. A CDM project manager may mentor other data managers on the team, who will in turn coach or mentor other CDM personnel.

- A CDM project manager should establish what is expected of the team's performance, and continually assess team performance to gauge whether or not those expectations are being met. Performance assessments can identify areas where elements of the team are not meeting expectations, after which the CDM project manager can propose corrective actions to improve those areas. Any team is only as strong as its weakest link.

Recommended Standard Operating Procedures

- Vendor Management

- Contract Management

- Document Management and Version Control

References

3. Project Management Institute. *A Guide to the Project Management Body of Knowledge (PMBOK® Guide)—Fourth Edition*. Newtown Square, PA: Project Management Institute, Inc.; 2008.

Further Reading

Terms used in this chapter may be found in the *Good Clinical Data Management Practices* Glossary.

International Conference on Harmonisation. *ICH Expert Working Group: Guideline for Good Clinical Practice, E6.* Geneva, Switzerland: 1996.

Verzuh, E. *The Fast Forward MBA in Project Management*. New York, NY: John Wiley & Sons, Inc.; 1999.

Chapter Revision History

Publication Date	Comments
June 2010	Initial publication.

Appendix A: Sample Project Plan Template

Project Title

Project Plan Approval

Name	Role	Signature	Date
	Project Manager		
	Project Sponsor		
	Other Stakeholders		

Project Plan Table of Contents

1. Introduction

    1.1. Project plan—Overview and the schedule and processes that will be involved in updating the project plan

    1.2. Summary of the project

2. Business Requirements

    2.1 Project history, business needs, and business drivers descriptions

    2.2. Expected project benefits

    2.3. Identification of responsibilities for any business-related changes

3. Project Definition

    3.1. Project description, including project scope, costs, and schedule

    3.2. Prioritized project objectives

4. Project Organization

    4.1. Roles and responsibilities

    4.2. Interfaces between different functional groups

    4.3. Project authority hierarchy

5. Project Delivery Strategy

5.1. Lessons learned from previous projects

5.2. Project roadmap

5.3. Risk management strategy

5.4. Critical issues for project success

5.5. Project funding strategy

5.6. Contracting and procurement strategy

5.7. Monitoring and controls strategy

5.8. Project communication strategy

5.9. Project management tools to be used

6. Project Plan Details

6.1. Revision history

6.2. Revision strategy

6.3. Review and approval

6.4. Project plan distribution and archival

7. References

8. Appendices

8.1. Project roles and responsibilities

8.2. List of referenced documents

8.3. Other appendices as needed for the specific project

Appendix B: Sample Communication Plan Template

Communication Plan Approval

Name	Role	Signature	Date
	Project Manager		
	Project Sponsor		
	Other Stakeholders		

Communication Plan Table of Contents

1. Purpose (of the communication plan)

2. Scope (of the communication plan)

3. Overview (of communications planning methodology)

4. Roles and responsibilities

5. Project communications

    5.1 Communication goals

    5.2 Communication documentation

        5.2.1. Communications log

        5.2.2. Managing communication materials

6. Stakeholder management

    6.1. Stakeholder directory

    6.2. Stakeholder classification

7. Training

    7.1 Therapeutic area and protocol review

    7.2 Tools and systems

    7.3 SOPs and working processes

8. References

9. Communication plan revision history

10. Appendices

    10.1. Role definitions

    10.2 Stakeholder classification

Appendix C: Sample RACI Chart Template (3 pages)

R	**Responsible**: The individual(s) who performs a task. The doer, responsible for recommendation, action and implementation.
A	**Accountable**: The individual (s) who is accountable for ensuring alignment with the overall plans and ensures the quality/performance/outcome of the activity.
C	**Consulted:** The individual(s) or team(s) who are asked to provide input and/or insight prior to an action being taken or a recommendation being made.
I	**Informed:** The individual(s) or team(s) who need to be informed when an action is taken or a decision is made either verbally or through documentation.

	Activity	Lead CDM	CDM staff	Mgmt contact	Quality contact	Clinical contact	S&P contact
Study set-up	Protocol review for CDM	A/R					
	CRF review for CDM	A/R					
	Randomization review	A/R					
	Site Clarification Agreement Document	A/R	I				
	Create study specification	C	A/R			C	C
	Complete test transfer for electronic data	I	A/R			I	I
	Set up Study File	A	R				
	Develop Data Validation Specifications (DVS)	I	A/R				
	Data Capture Testing	I	A/R				
	Creation of Data Entry Guidelines	I	A/R				
	Run checks to test set-up	I	A/R			I	I
	Liasing with Central and/or Local Labs	I	A/R				
	Develop and maintain Data Handling agreement	I	A/R	C			C
Tracking	Track receipt of CRF paper data from Site(s)	I	A/R				
	Track receipt of CRF paper data from Data Entry Group	I	A/R				
	Track and monitor miscellaneous data not captured in CRF i.e. electronic data	I	A/R				
	Track outstanding data queries (DQ)	I	A/R				
	Run missing page report	I	A/R				
	Check received data against expected data (end of study/interim activity)	I	A/R				
Data Processing	Resolution of flags, automated and manual discrepancies including DCF creation and resolution		A/R				
	Liaise with dictionary group for coding and query management of AEs and Con meds		A/R				
	Action required as the result of Unique Terms report (UTR) and/or Ambiguous Terms report (ATR)	I	A/R				
	Loading of electronic data	I	A/R				
	Post-entry review of CRFs (ie: missing data/pages and reconcile DE flags)		A/R				
	Cleaning of Lab data and liaison with lab personnel	I	A/R				
	Complete SAE reconciliation activities (run reports, liaise with Pharmacovigilance Group (PVG) and dictionaries)	I	A/R				
	Perform QC activities defined in the quality audit framework document	I	A/R		I		

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	Activity	Lead CDM	CDM staff	Mgmt contact	Quality contact	Clinical contact	S&P contact
Data Processing	Run edit Checks	I	A/R			I	I
	Complete Database Release (DBR) and Database Freeze (DBF) authorization checklist	I	A/R				
	Complete data transfer to DM area	I	A/R			I	I
	Declare/send DBR and DBF communications	A/R	I			I	I
Study Conduct	Arrange study team kickoff meeting	A/R	C				
	Generate and communicate minutes	I	A/R	-			
	Protocol Amendments	A/R	I	-			
	Maintain DVS	I	A/R				C
	Develop Data Quality Assurance document for Clinical Study report	A/R	I		C		
	Maintain and complete Data Quality Assurance document for Clinical Study report	A/R	I		C		
	Maintain Study File	A	R				
	Data Management review of Reporting and Analysis Plan (RAP)	A/R	I				
	Generate and communicate status/metric reports	I	A/R				
	Review status/metric reports and action where needed to resolution	C	A/R				
	Provide outstanding DQ reports to Clinical if applicable	I	A/R			I	
	Provide missing page reports to Clinical if applicable	I	A/R			I	
	Problem solving and escalation of issues (to CDM)	C	A/R	I			
	Problem solving and escalation of issues (to Clinical and Statistics & Programming (S&P))	A/R /C	I			I	
	Negotiate timelines with Clinical	A/R	C	I		I	I
	Schedule validation batch jobs		A/R				
	Timely feedback on validation checks	I	A/R				
	Timely feedback on CRF completion (data quality and monitor performance)	C	A/R				
	Attend matrix team meetings (attendance from Clinical, S&P, CDM, Safety etc. at study level)	A/R	I			I	
	Attend DM update meetings	A/R	R				
	Monitor requirements for data looks and interim analyses	A/R	I			I	C
	Communicate to study team DBR achieved	A/R	I	I		I	I
	Communicate post DBR queries	A/R	I				
	Resolve post DBR queries	A	R			C	C
	Adhoc Submission requests	A	R	I			
	Action post DBR data edits	A	R			I	I

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	Activity	Lead CDM	CDM staff	Mgmt contact	Quality contact	Clinical contact	S&P contact
Study Conduct	Post DBF edits approval request (after consultation with Manager)	A/R	I	I		I	I
	Request database lock	A	R			I	
	Unlock database and action edits if approval given	A	R			I	
	Reconciliation of Study File before archiving	A	R				
	Send documents to CDM in archive-ready state	A	R				
Study Oversight	Resource planning of processing activities (i.e. recruitment, staff changes on a study)	I	A/R	I		I	I
	Oversight of tracking tool	A/R	I			I	I
	Maintenance of RACI	A/R	C				
	Quality Review if planned	C	I	I	A/R		

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