INA RESPOND
INDONESIA RESEARCH PARTNERSHIP ON INFECTIOUS DISEASE

Clinical trial databases are a crucial investment in clinical research

Part 4 - The "Life" of a Data Manager - Project Manager for the Database

PIT PETRI 2018
B-IDeaS

1st Annual Scientific Meeting of the
Indonesian Society of Tropical and Infectious Disease
in conjunction with
The 7th Annual Bandung Infectious Disease Symposium
Harnessing innovative strategies tocontrol and manage infectious diseases
October 12th-14th 2018 | El Royale Hotel, Bandung

Speakers: M.Duvenhage
K. Laras
S. Erari
12 Oct 2018

Overview of Project Management

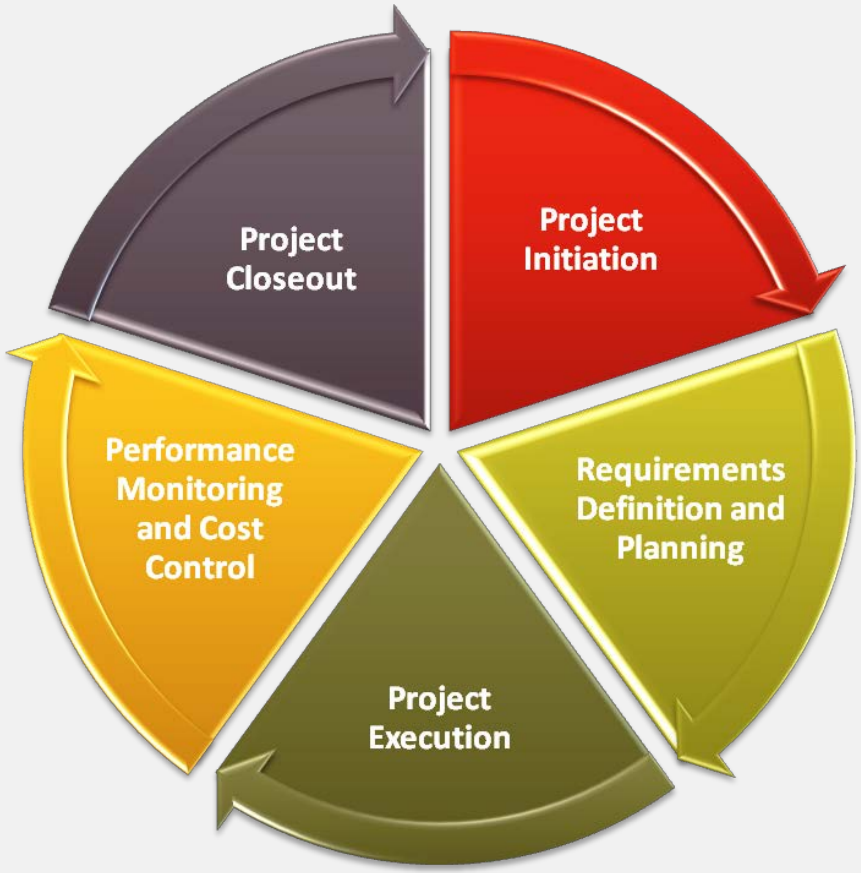
Project management is crucial for the success of any Clinical Data Management project

Minimum Requirements

- Identify all data management study team members, stakeholders (as well as backup team members)
- Identify, define, and document all study-specific processes
- Setup clear, comprehensive, and technically feasible timelines
- Monitor, track and document projected costs and timelines against actuals
- Identify potential risks and mitigation strategies
- Create a project team communication plan
- Assessment the CDM team members familiarity with clinical study processes, disciplines, or functional lines
- Provide project- and study-specific training
- Ensure compliant electronic, virtual, and physical resources will be available for CDM deliverables

Project Management Overview

- Data managers should know basic principles of the formal discipline of project management
- 5 stages of Project Management
- Data Managers should learn how to effectively employ these 5 stages of Project Management within their Data Management setting



Project Management Knowledge Areas

Integration management

- Processes needed to identify, define, combine, and coordinate the various processes and project management activities

Scope management

- Processes required to ensure that the project includes the work required, and only the work required, to complete the project successfully

Time management

- Processes required to manage timely completion of the project

Project Management Knowledge Areas

Cost management

- Processes involved in estimating, budgeting, and controlling costs of a project

Quality management

- Determine quality policies, objectives, and responsibilities so that the project will satisfy the needs for which it was undertaken

Human Resource management

- Processes that organize, manage, and lead the project team

Project Management Knowledge Areas

Communication management	• Ensure timely and appropriate generation, collection, distribution, storage, retrieval, and ultimate disposition of project information
Risk management	• Conducting risk management planning, identification, analysis, response planning, monitoring and control of a project
Procurement management	• Processes necessary to purchase/acquire products, services, or results needed from outside the project team

Meetings (a special mention)

- Integral part of successful project management
- Regular meetings are specified for all five stages of project management
- Predetermined Agenda, documented via Meeting Minutes
- Discuss progress and upcoming milestones, corrective actions, risk identification and mitigations and lessons learned

CDM Project Management in action

Initiation

- Compiling the forecasted task/resource/time requirements as assessed for the study
- Clarify study assumptions
- Identify the CDM contributions to the overall study team scope, and goals
- Identify data manager(s) and CDM support personnel
- May include IT support personnel, database programmers, data coordinators, entry team members and other team members who will contribute to CDM activities

CDM Project Management in action

Planning

- Review the finalized study protocol
- Assess resources and training needed for study execution
- Document roles and responsibilities within the study; consider using a RACI chart (Responsible, Accountable, Consulted, Informed).
- Confirm technical qualification of site(s) has been completed
- Identify stakeholders and confirm their roles and expectations.
- Identify vendors and service providers
- Develop high-level CDM project milestones
- Review protocol and communicate any inconsistencies
- Review preprogrammed metrics reports and any other standard reporting tools

CDM Project Management in action

Executing

- Establish date for internal kickoff meeting
- Technical and procedural training has been delivered and documented
- Ensure access (including passwords) to systems
- Develop detailed CDM timelines (for CRFs, DB development and production go-live, database lock)
- Develop the data management plan (DMP), CRFs, CRF completion guidelines, and other necessary documents and reports
- Identify medical coding practices and dictionaries
- Establish a detailed communication plan
- Participate in investigator meetings or other appropriate training
- Perform assessment to confirm the quality of the first data received

CDM Project Management in action

Monitoring and Control

- Verify with stakeholders that initiation plans continue to be aligned with the project plan
- Conduct mid-study vendor/CRO assessment(s) as necessary
- Conduct CDM team meetings according to a schedule; also attend the project team meetings
- Planned production reports continue to meet user expectations
- Monitor study reports and metrics (against projected targets
- Evaluate CDM team performance (standard metrics)
- Initiate corrective and preventative actions
- Identify, plan, and carry out training/retraining
- Staff who leave the project returned study materials, study access removed completed appropriate exit consultations / transition documents

CDM Project Management in action

Closing

- Confirm all final deliverables are received or transferred
- Ensure access (including passwords) to systems is restricted
- Achieve, deliver and communicate database release to stakeholders
- Close all relevant contracts/procurements
- Confirm all regulatory submission needs from CDM are met (e.g. annotated CRFs, blank CRFs, DMPs)
- Archive database(s), CRFs and data clarification forms (DCFs / Queries).
- Archive CDM components of study master files
- Convene closing and lessons learned meetings
- Confirm sites receive copies of electronic CRFs and DCFs

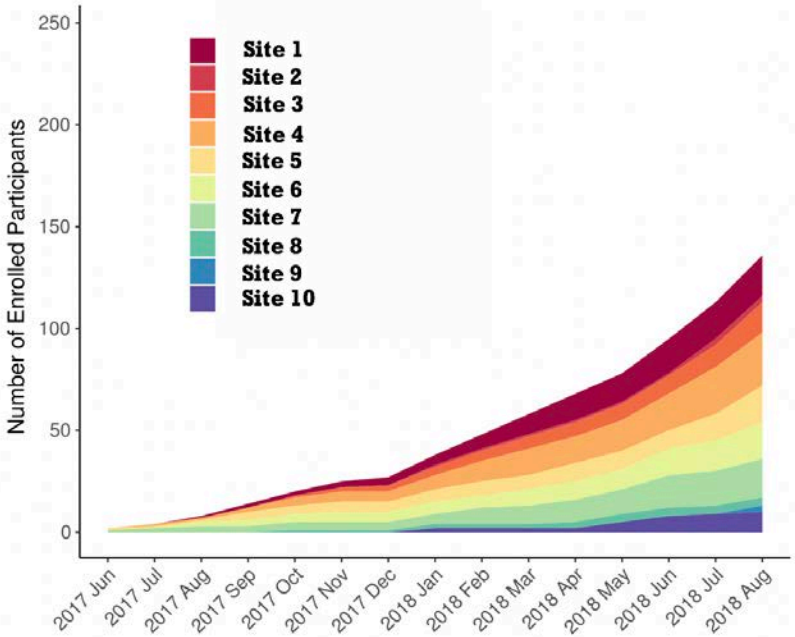
Competencies of Project Management (within the CDM context)

- **Technical knowledge** - To be a good CDM project manager, must first have the technical knowledge needed to be a successful data manager
- **Problem-solving Strategies -** Ability to accurately assess a potential problem and formulate a successful solution is imperative for an effective CDM project manager. Ensure ongoing management (via SOPs) of problems
- **Facilitation/Communication/Mediation/ Negotiation Skills** - required to have effective communication, facilitation, mediation and negotiation skills, and be able to summarize discussions and make appropriate decisions. Without good communication skills, a CDM project manager cannot successfully manage the most important component of any project, which is the personnel involved
- **Leadership** - even more important for those data managers assuming project management roles

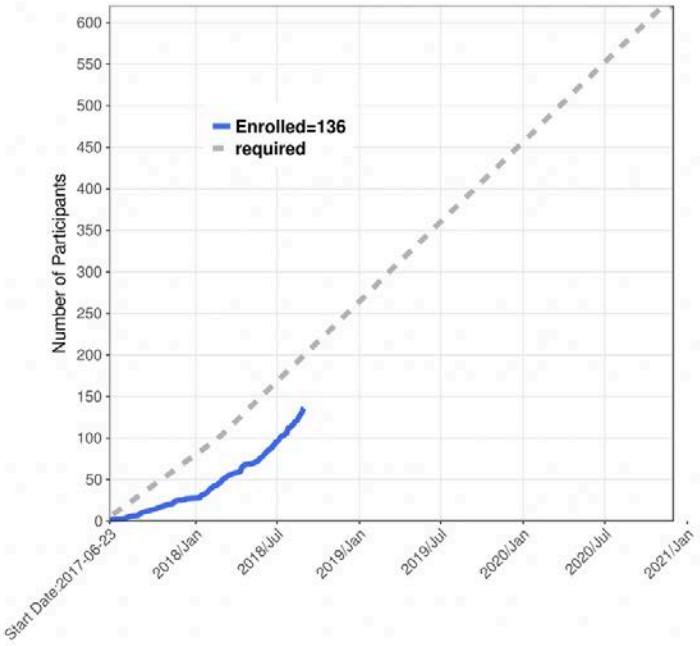
Identifying Metrics

Example of CDM Metrics

Site Enrollment Report



Enrollment Projection Report



Example of CDM Metrics

CRF and Query Tracking Report

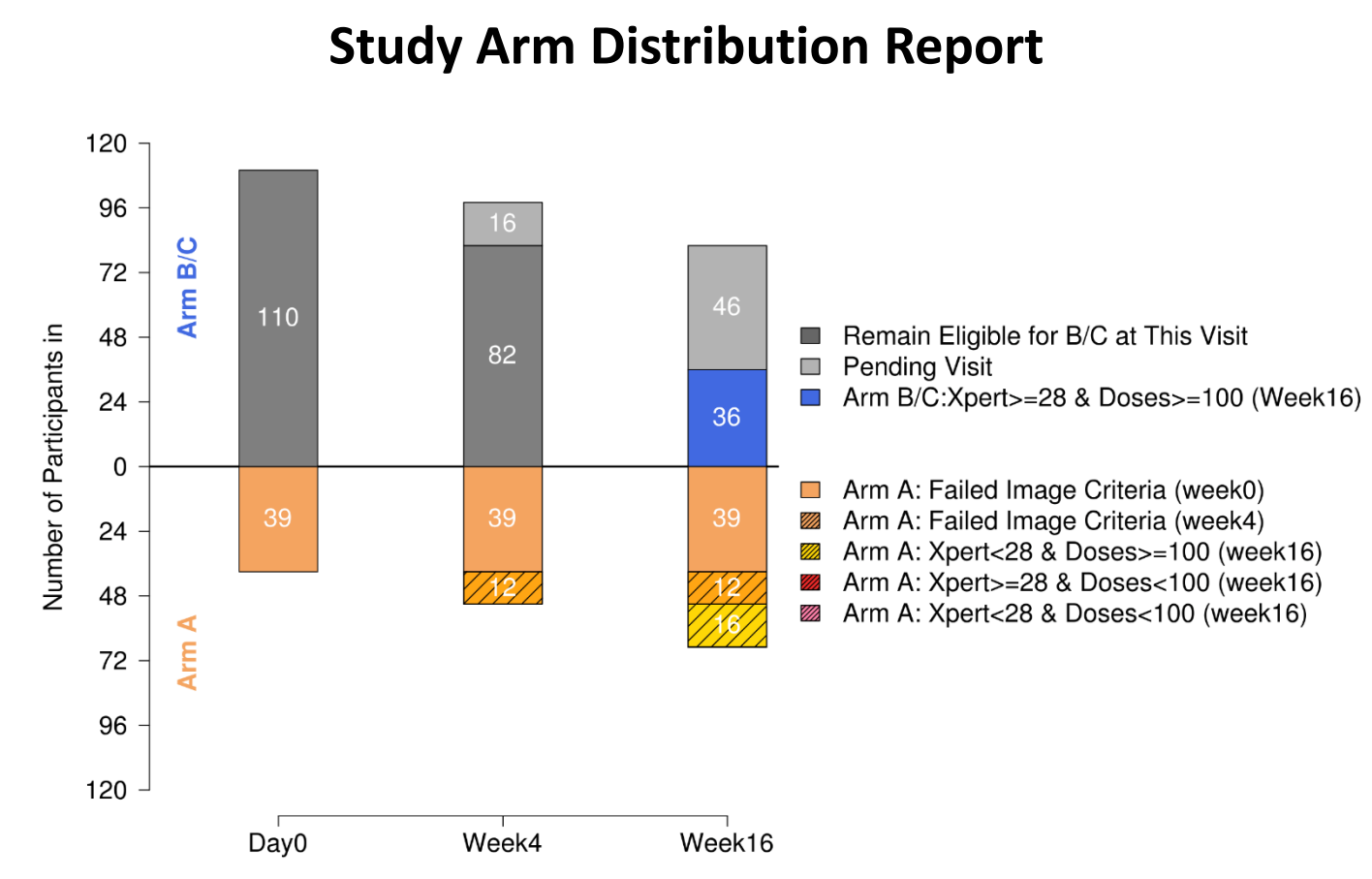
Site	Subject Number	CRF Pages received	CRF Pages expected (up to visit completed)	% Completed	Queries issues	Queries resolved	Outstanding
Site 1	1001	56	86	65.12%	19	10	9
Site 1	1002	12	30	40.00%	2	0	2
Site 1	1003	10	30	33.33%	1	0	1
Site 1	1004	9	30	30.00%	0	0	0
Site 1	1005	0	30	0.00%	0	0	0

Example of CDM Metrics

Missing CRF Page Report

Site.Name	Participant	Visit	Plate.Number	Plate.Name	Days.Overdue
Site 1	11029	Week2	24	BLOOD AND URINE BIOMARKER STORAGE	21
Site 1	11029	Week2	46	MRNA	18
Site 1	11030	Screening	7	TB SYMPTOMS	12
Site 1	11030	Screening	9	SPUTUM SAMPLE COLLECTION 3	14
Site 1	11030	Screening	9	SPUTUM SAMPLE COLLECTION 2	14
Site 1	11030	Day0	9	SPUTUM SAMPLE COLLECTION 2	14
Site 1	12029	Week8	13	XPERT	4
Site 1	12029	Week8	24	BLOOD AND URINE BIOMARKER STORAGE	4
Site 1	12034	Week1	24	BLOOD AND URINE BIOMARKER STORAGE	10
Site 1	12034	Week2	24	BLOOD AND URINE BIOMARKER STORAGE	3
Site 1	13010	Week24	22	PET/CT AND SALIVA	73
Site 1	13010	PK Substudy Visit 1	32	PK SUB-STUDY BLOOD COLLECTION	199
Site 1	13010	PK Substudy Visit 2	32	PK SUB-STUDY BLOOD COLLECTION	199
Site 1	13020	PK Substudy Visit 1	32	PK SUB-STUDY BLOOD COLLECTION	28

Example of CDM Metrics



Metrics driven - CDM Reports

Criterion	Study Startup	Study Conduct	Study Closeout
Quantity	Number of expected subjects	Amount of data entered	Final number of subjects
	Total number of data fields (may be quantified differently by different organizations)	Amount of data cleaned	Number of outstanding queries
		Expected amount of entered data compared to data in database	Missing pages report
Cost	Total estimated resources (such as people, licenses, infrastructure, printing, etc.) needed for a study	Number of monitoring visits	Total study costs
			Average cost per subject enrolled
Time	Projected overall study timeline	Time from subject visit to data available to CDM	Time from first subject enrolled to last subject visit
	Time needed for protocol/CRF review and finalization	Time from subject visit to data cleaned and locked	Time from last subject visit to final database lock
	Final approved protocol to database activation		Time from final database lock to clinical study report

Metrics driven - CDM Reports

Criterion	Study Startup	Study Conduct	Study Closeout
Quality	Systems validation results	Number of queries and re-queries	Number of data errors per number of total data fields (error rate) (used in paper studies)
		Number of data transfer errors	Number of protocol deviations
		Metrics generated from audit trail	
Performance	Number of programmed procedures that validate correctly	Comparison of data entry rates across sites	Number of database unlocks to correct data errors
		Time from subject visit to data entered	
		Average time for query resolution	Number of protocol amendments

Questions