Data Manager's Role in Data Quality
and
KPI for Data Management Process

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Agenda

- Why is the Data Manager So Important for Data Quality?
- Roles of Data Manager
- Core Elements for Quality Data Management
- Key Performance Indicators (KPI) for Data Management Process

Why is Data Quality So Important for Society?

ICH GCP

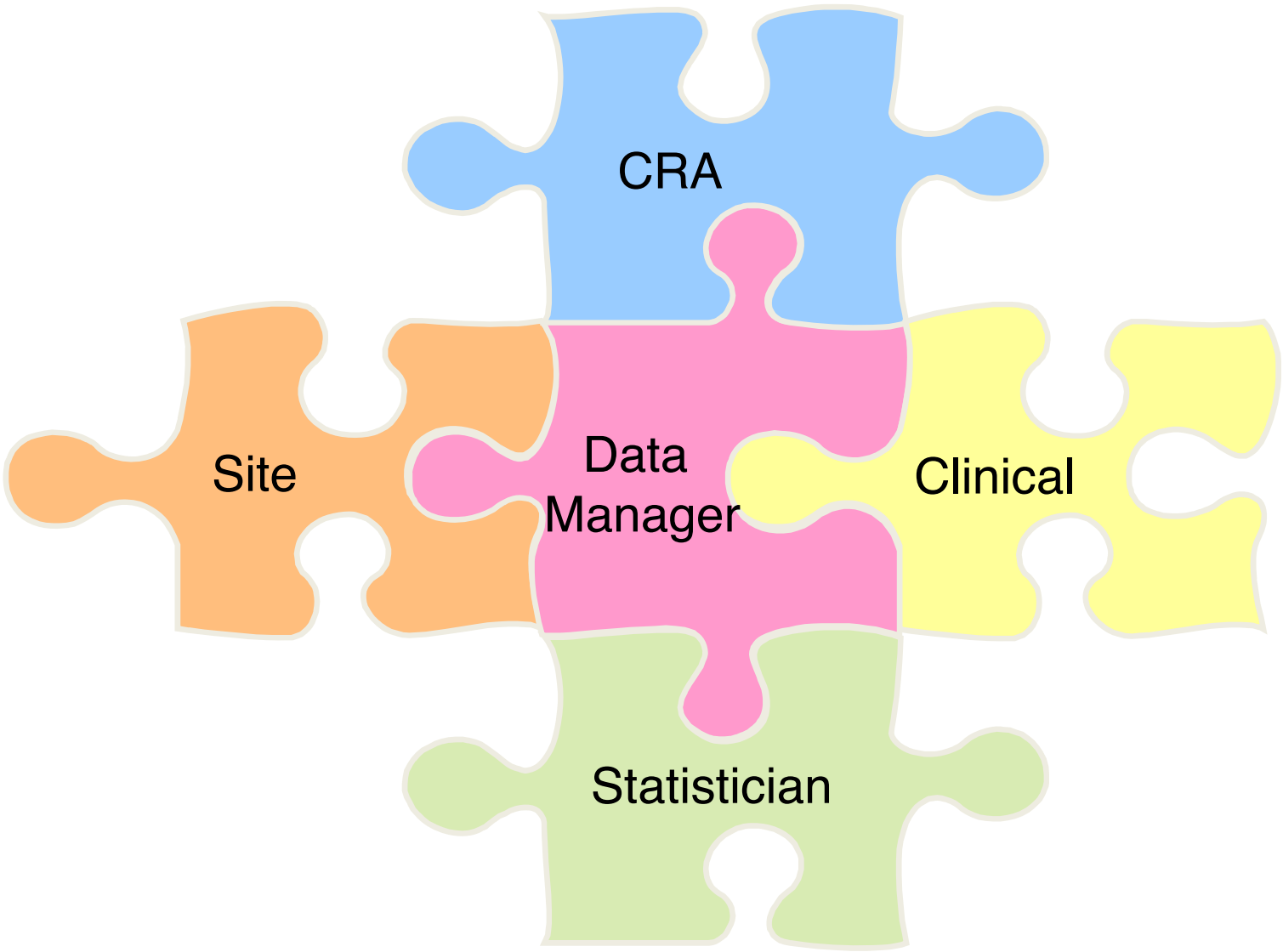
Section 2 – Principles of GCP:

- **2.10** All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
- **2.13** Systems with procedures that assure the quality of every aspect of the trial should be implemented.

Section 5 – Sponsor:

- **5.1.3** Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.

Data Manager is the Key Person to Unlock the Value of Clinical Data in Clinical Research



Reaching the Goal of Quality Data is a Shared Process !

Why is the Data Manager So Important for Data Quality?

- Provides accurate, complete and “fit for use” data for medical review and statistical analysis, which is critical for final report and clinical data submission to FDA or other agencies
- Reduces or eliminates critical changes after Database Lock (DBL)
- Enables analyses to be conducted during the study that may drive key program decisions (e.g. Interim Analysis drives Go/ No Go decisions)
- Provides accurate data for updates to Data Safety Monitoring Boards
- Allows for timely drug/vaccine approval
- Provides accurate data for publications

Roles of Data Manager

Study Setup

Data Management Plan Preparation
Design and Data Review Specifications
- CRF/Collector/DHG/DEG/Time&Event Schedule/Coding
- Edit Check/Data Validation Plan

External Data Specification & UAT
Mapping Specification
Collector UAT & Deployment
Data Review Tool UAT & Deployment
Data Repository Dataflow UAT

Study Conduct

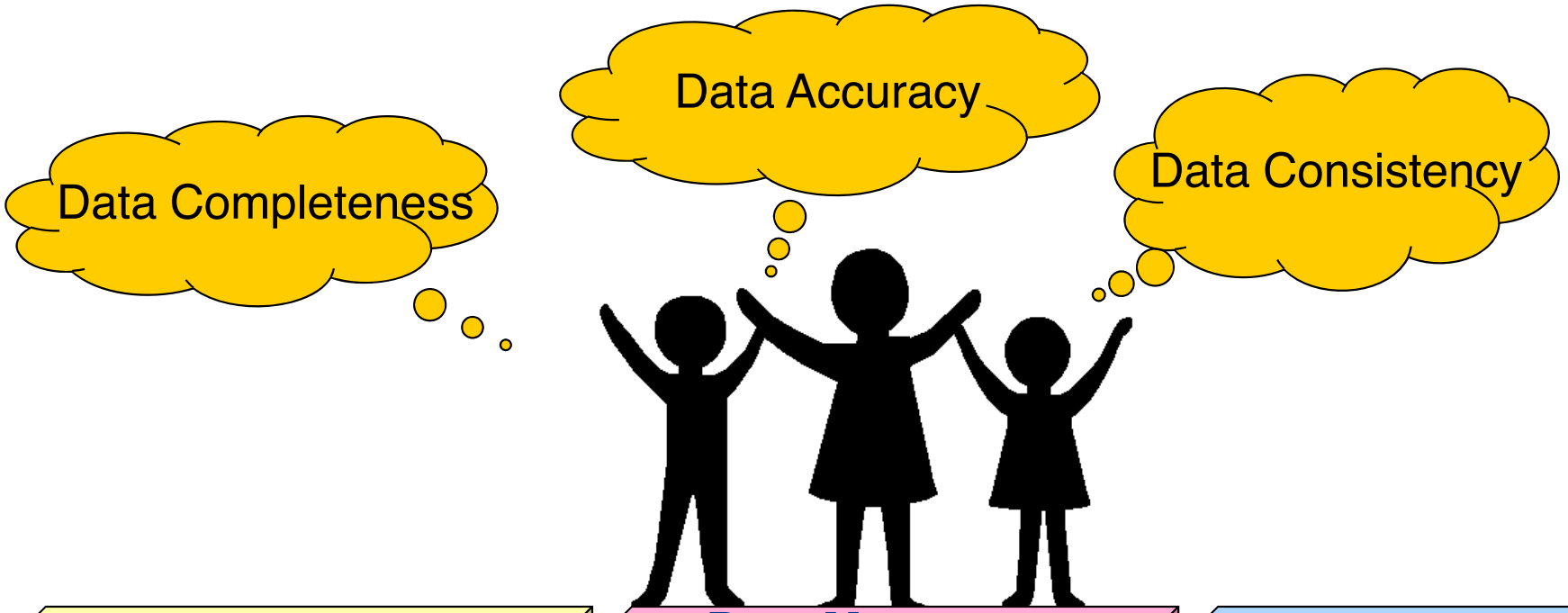
Data Integrity Review
Missing Visit Management
Query Management
Coding
Site DM Performance Management
External Data Processing & Loading
Post Production Change Management
- CRF/Collector/DHG/DEG/Time&Event Schedule/Coding
- Edit Check/Data Validation Plan

Study Closeout

Achieving Complete & Clean Data
Completion of Coding Quality Check
Resolution of Statistical Findings
External Data Verification
PI Signature
Database Lock
Data Repository Dataflow

Acronyms: CRF=Case Report Form; DHG=Data Handling Guideline; DEG=Data Entry Guideline; UAT=User Acceptance Test

Core Elements for Quality Data Management



Data Manager

Technology & Resources
Standard Template / Library
Check List / Job Aid
Training & Mentoring
Effective Tool Development

Operational Excellence
DMP, DHG, DEG, DVP
Cycle Time & Quality Metrics
Good Project Management
Communication & Collaboration

Control System
Access Control/Audit Trail
System UAT
QA / QC
Audit / Inspection

Industry & Company Standards
ICH E6 (GCP) / 21 CRF Part 11 / MedDRA
Company SOP, Procedure & Guidance Documents

Key Performance Indicators for Data Management

Operational Quality and Data Quality

CRF Design Cycle Time
Collector Development Cycle Time
Data Review Tool Development Cycle Time
Rounds of Changes in Specifications
Rounds of UAT for Collector, Data Review tool
No. of Post Production Changes
- CRF/ Collector/ DHG/ DEG
- Edit Check/ Data Validation Plan

LPLV – Database Lock Cycle Time
No. of Critical Deviation from DMP*
No. of Critical Changes post DBL
Mapping and Dataflow Error

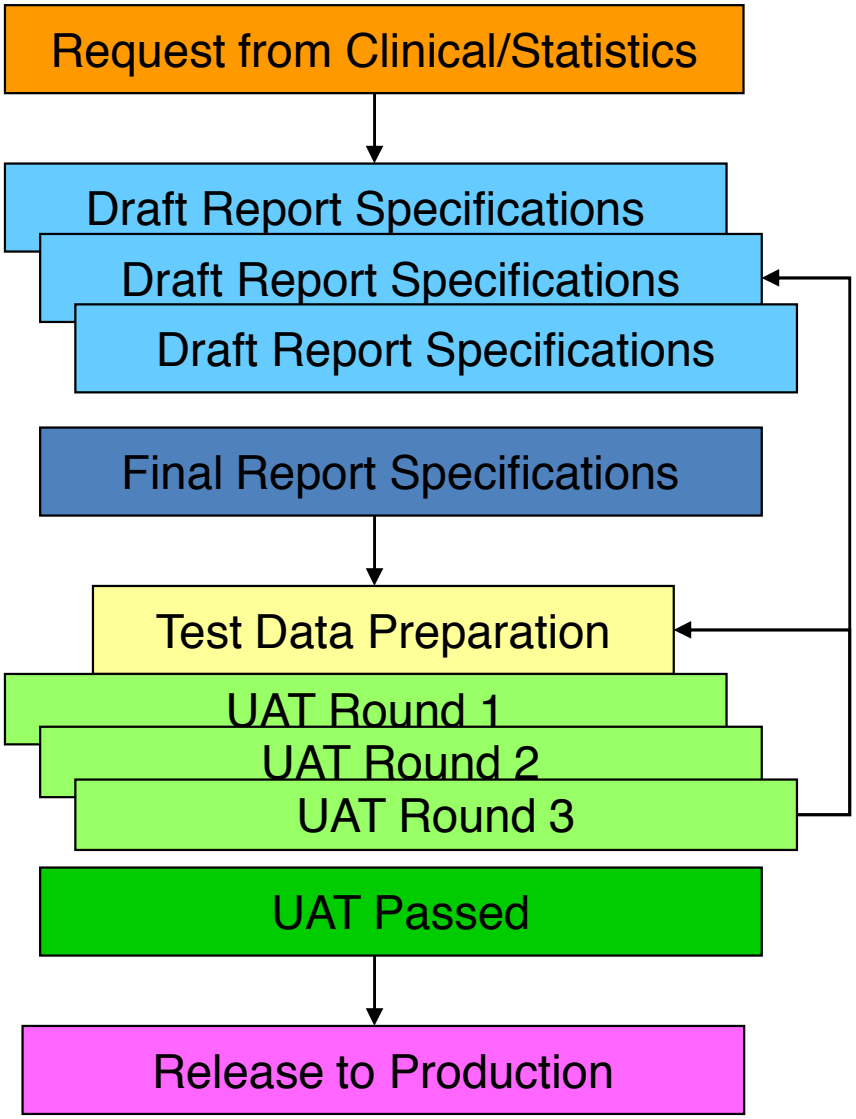
Study Setup	Study Conduct	Study Closeout

Data Entry and Review Cycle Time
Query Resolution Cycle Time
% Re-issue Queries (Poorly Written Queries)
% Queries without Data Changes (Non-value added Queries)
Coding Cycle Time
Data Entry Error
No. of Queries per Visit
Coding Accuracy
Data Review Quality Assurance*
External Data Loading Error

Critical Findings from Inspection, Internal Audit

*Also a KPI in Process Compliance

KPI Example: "Study Setup"
Report Specification/User Acceptance Test (UAT) Quality



Report ID	Tester Name	Protocol Number	UAT Round No.	UAT Result	No. of Findings result in Test Data Changes	No. of Findings result in Specification Changes
Report 01	Amy	123	1	Pass	0	0
Report 02	Amy	123	1	Pass	0	0
Report 03	Amy	123	1	Fail	2	1
Report 03	Amy	123	2	Pass	0	0
Report 04	Amy	123	1	Pass	0	0
Report 05	Amy	123	1	Fail	5	2
Report 05	Amy	123	2	Fail	1	0
Report 05	Amy	123	3	Pass	0	0
Report 06	Peter	123	1	Fail	4	2
Report 06	Peter	123	2	Fail	2	1
Report 06	Peter	123	3	Pass	0	0
Report 07	Peter	123	1	Fail	3	1
Report 07	Peter	123	2	Pass	0	0
Report 08	Peter	123	1	Pass	0	0
Report 09	Peter	123	1	Fail	6	3
Report 09	Peter	123	2	Fail	2	1
Report 09	Peter	123	3	Fail	1	0
Report 09	Peter	123	4	Pass	0	0
Report 10	Peter	123	1	Pass	0	0

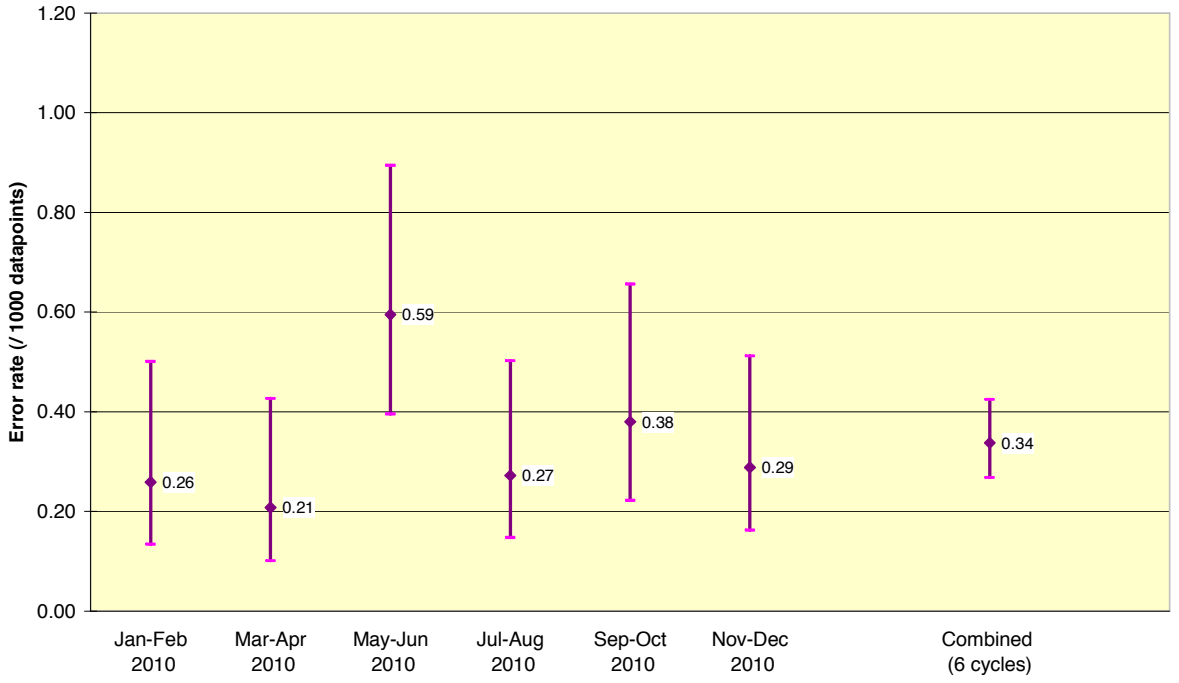
Behind Operational Quality, Poor Specifications/ Software Build Leads to Poor Data Quality!

KPI Example: "Study Conduct" Data Review Quality Assurance (DRQA)

- DRQA is an activity to understand the quality of data review according to Data Validation Plan (DVP)
  - Base on the objective, it can be conducted at portfolio or protocol level
- Qualified reviewer could select a sample of data to perform the followings:
  - Review if data review is executed according to DVP
  - Review all review report outputs
  - Review all queries issued and handled
  - Identify missing datapoints
  - Any findings result in critical data change

Data Review Quality Assessment Cycle: May-Jun 2010

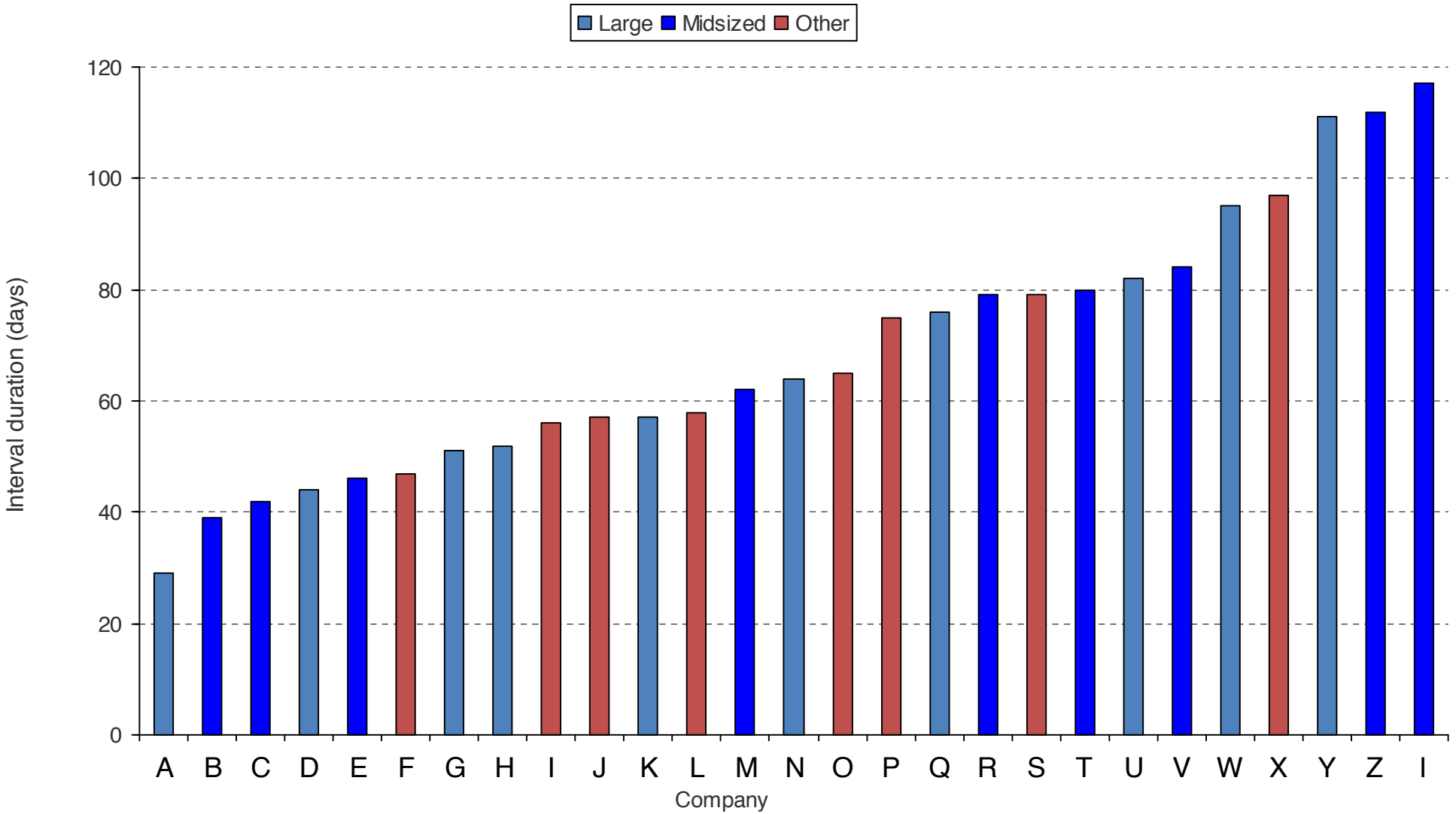
Protocol	Number of data points	Number of patients	Number of visits	Number of errors (Review reports)	Number of errors (Missing data)	Number of errors (Queries)	Total Errors	Overall error rate (per 1000)	Number of errors resulting in critical datapoint changes
A	3822	5	56	1	0	0	1	0.26	1
B	3255	4	14	0	0	3	3	0.92	0
C	4158	6	73	0	0	1	1	0.24	0
D	3675	9	50	0	0	1	1	0.27	0
E	9209	3	80	1	0	1	2	0.22	1
F	3618	18	132	0	0	0	0	0.00	0
Total	**6**		**27737**	**2**	**0**	**6**	**8**	**0.29**	**2**
Average			**4623**	**0.3**	**0.0**	**1.0**	**1.3**	**0.29**	



Not Only Data Entry Quality is Critical, Data Review Quality is Equally Important!

KPI Example: "Study Closeout" Database Lock Cycle Time (LPLV to DBL)

(Median Time for LPLV to DBL for Participating Pharmaceutical Companies)

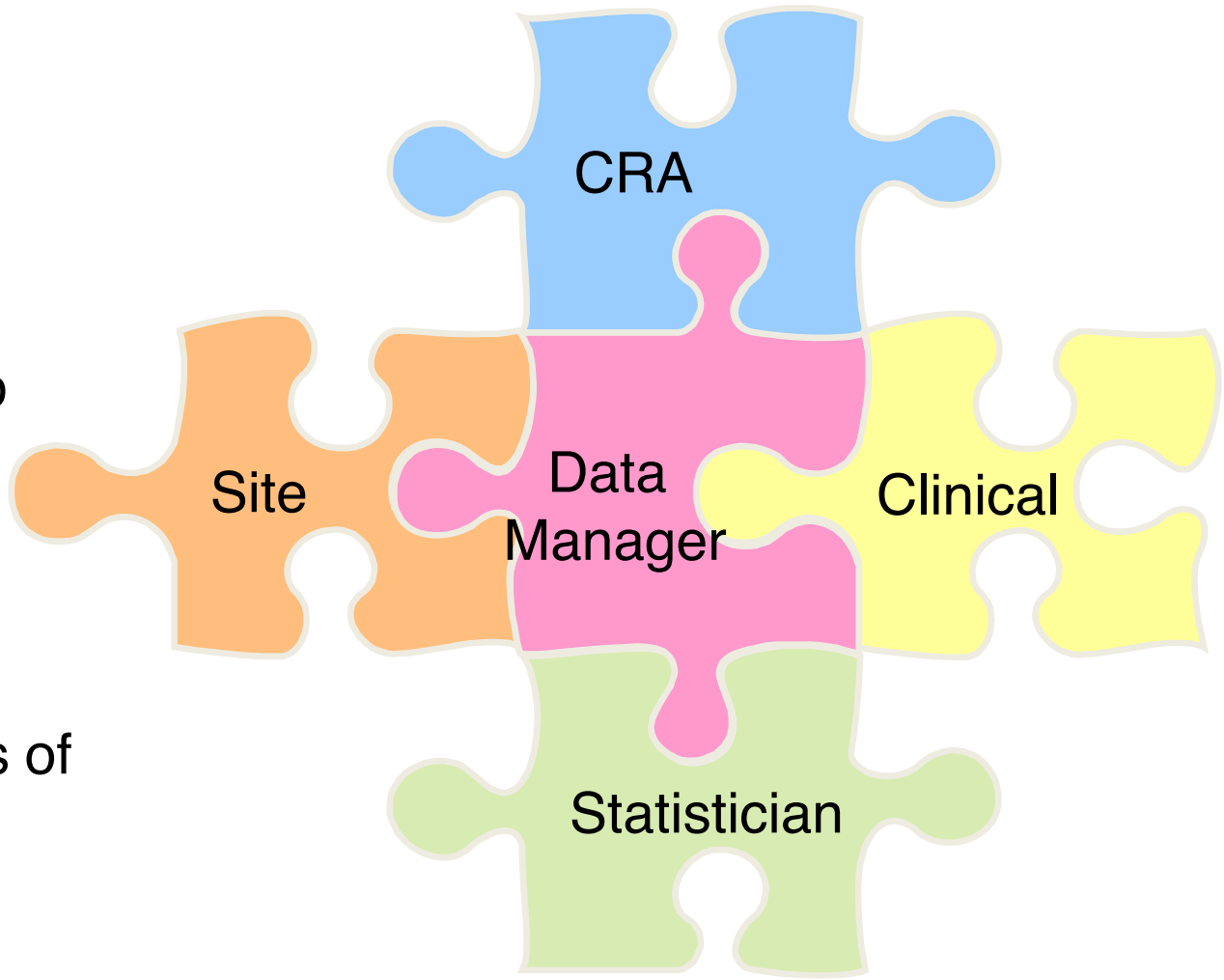


'Last patient last visit' to 'Database lock'. Source from CMR International. Data are shown for Phase Ib, Phase II and Phase III studies that were completed between 2007 and 2009. Extensions and terminated studies or studies associated with terminated projects have been excluded.

Benchmark Data Can Help You to Understand How Well You Perform in the Industry!

Summary

- Data Management is a critical step in Clinical Research
- Data Manager has important role in data quality from study setup until study closeout
- Key Performances Indicators (KPI) are effective measurements of timeliness, quality & compliance in Data Management Process



Thank You!

Study Setup

- Accountable for timely and quality delivery of Data Management deliverables that meet the requirements of the protocol and specifications set by Clinical/Statistics
  - Finalize Design & Data Review Specifications
    - Design: CRF/Collector/DHG/DEG/Time& Events Schedule/Coding
    - Data Review: Edit Check/Data Validation Plan
  - Finalize Data Management Plan
  - Collector UAT & Deployment
  - Data Review tool UAT & Deployment
  - External data specifications and UAT
  - Mapping programming and Data Repository dataflow UAT

Acronyms: CRF=Case Report Form; DHG=Data Handling Guideline; DEG=Data Entry Guideline; UAT=User Acceptance Test

Reference:
Roles of Data Manager

Study Conduct

- Accountable for timely and quality management of Clinical Data
  - Data Integrity Review & Query Management
  - Coding
  - Routine follow-up on outstanding issues with sites
  - External data processing & communication with vendors
- Liaise with Clinical/Statistics for Protocol Level Data Management Concerns *(Found during Medical Review, Interim Analysis and Database Lock)*
  - Assessment and follow up on needs for Post Production Changes

Study Closeout

- Accountable for timely, quality and complete delivery of Clinical Data
  - Close communication with CRA and Sites
  - Clearance of missing data and outstanding queries
  - Complete coding and finish coding quality check
  - Clean all critical data points and resolution of statistical findings
  - External data verification
  - Obtaining PI Signature
  - Lock database