
# Demystifying Data Management and TMF

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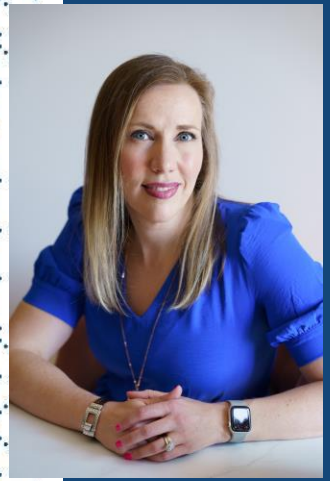
# Meet the Speakers

## Vishaal Patel

Title: Director, Data Management

Organization: Daiichi Sankyo, Inc.

Accomplished and quality-oriented professional with over 15+ years of diverse experience in Clinical Data Management, Operational Planning & Risk Assessments, Vendor Management, Technology Implementations, Business Process Improvements, Project Management as well as Clinical Outsourcing and Therapeutic Area Mgmt. Broad understanding of key drug development processes with professional focus centered on integrated innovation, corporate growth, and inspired leadership. Expertise in managing, analyzing, and skillfully employing functional and cross-functional area strategies for commercial valuation of R&D Portfolios, Project solutions and Drug Development challenges. In depth experiences in working with diverse EDC Technologies, Metadata Platforms, SAS Grids as well as CDISC / SDTM data standards. Vishaal holds his MBA in Finance and Masters in Pharmaceutical Management from Stevens Institute of Technology as well as BS in Biotechnology from Rutgers University, New Jersey.



## Laura Naranjo

Title: Director, TMF Operations and Records Management

Organization: Daiichi Sankyo, Inc.

After working for the federal government, Laura made the move to pharma and has been working in TMF since 2009. She has worked on both the sponsor and vendor sides throughout her career and joined Daiichi Sankyo TMF Operations in 2016. Laura holds a passion for inspection readiness and efficient CRO oversight. She holds her Masters of Science of Jurisprudence in Pharmaceutical and Medical Device Law and Compliance from Seton Hall Law School

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# Agenda

1) Data Management Processes vs TMF Reference Model Scope
2) Data Flow
3) Ensuring Inspection Readiness of DM documents
4) Breakdown of DM Documents
5) Building bridges together

# Data Management Processes vs TMF Reference Model Scope

# Slide Headline Maximum Two Lines Lorem Ipsum Dolor Sit Amet Sed Ut Labore Magnaer

**Here's a sample text slide with subhead in bold:**

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- Level one text autem vel eum iriure.
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  - Level two text autem vel eum iriure dolor in hendrerit.
  - Consequat vel illum dolore eu feugiat nulla facilisis.
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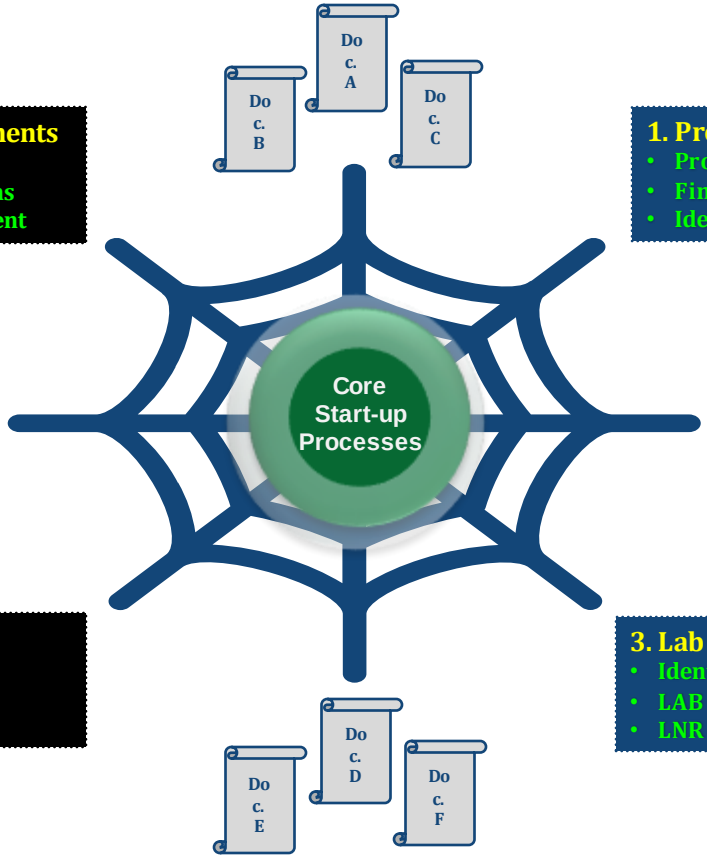
# Clinical Data Management – a *High Level* Overview "Start-up"




**1. Protocol Development**
- Protocol Profile Development
- Final Protocol Review
- Identification of Protocol Procedures

**2. EDC Design & Build**
- CRF Design & Review
- EDC Screens Development
- Edit Checks, UAT, Dynamics Encoding

**3. Lab Data Operations & Mgmt.**
- Identify Analytes & Units
- LAB Standards Review
- LNR Worksheet Review

**4. DM Document Development**
- CRF Completion Guidelines
- Data Management & UAT Plans
- eCRF & Edit Check Specifications

**5. Medical Data Coding**
- Medical Data Review Plan
- Dictionary Up Versioning
- Study Coding Conventions

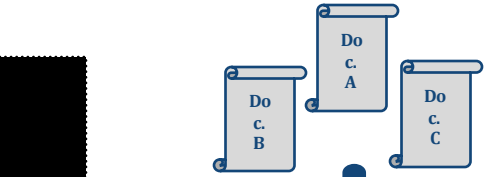
**6. DM Cross Functional Engagements**
- Cross Functional Plan Reviews
- Vendor Management & Integrations
- TLF Generations & CSR Development

# Clinical Data Management – a *High Level* Overview "Start-up"

## How Data Management Scope relates to the TMF Reference Model:

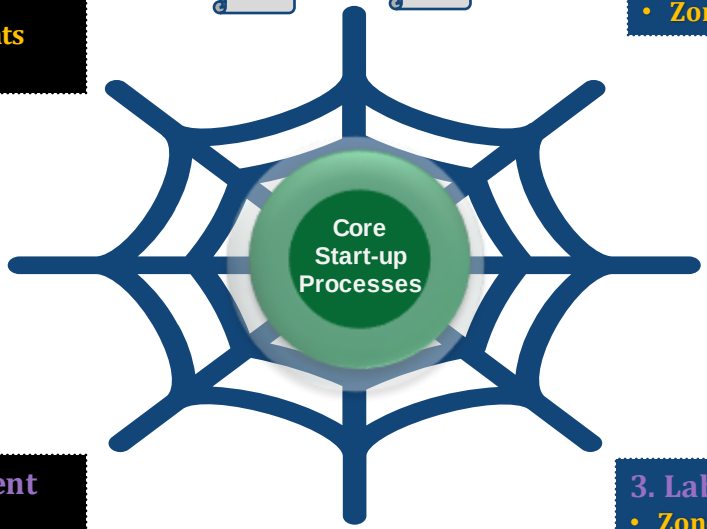
**6. DM Cross Functional Engagements**
- Zone 01: Trial Management
- Zone 02: Central Trial Documents
- Zone 09: Third Party Oversight

**1. Protocol Development**
- Zone 02: Central Trial Documents



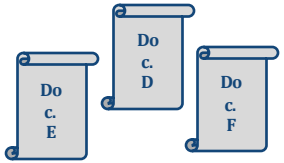

**5. Medical Data Coding**
- Zone 10: Data Management

**2. EDC Design & Build**
- Zone 10: Data Management

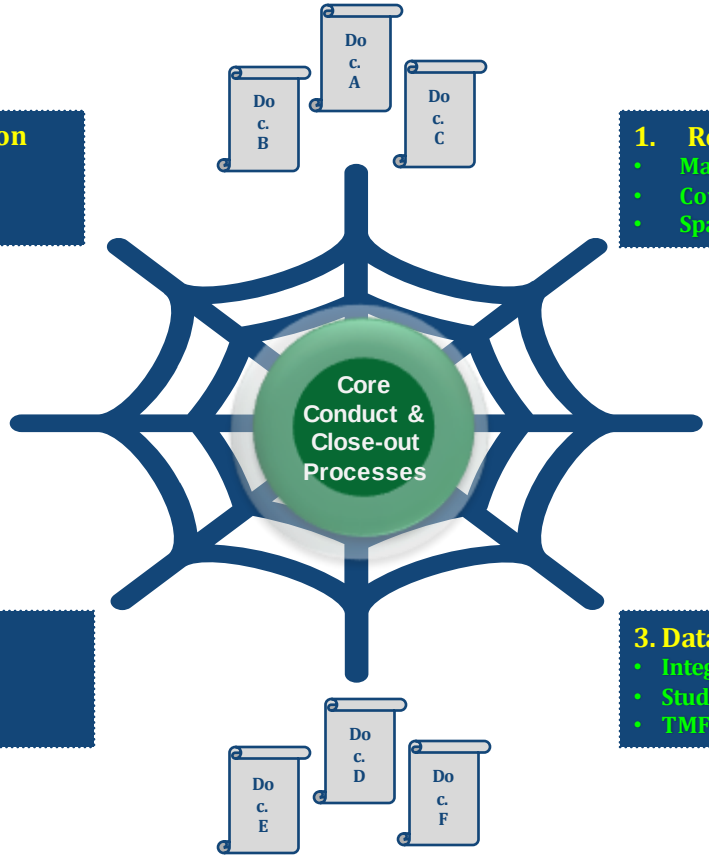



**4. DM Document Development**
- Zone 10: Data Management

**3. Lab Data Operations & Mgmt.**
- Zone 08: Central and Local Testing



# Clinical Data Management – a *High Level* Overview "Conduct & Close-out"




**6. Database Lock & Decommission**
- DBL Cleanup & Data Extractions
- Raw Data Extractions & Mapping
- ILD Patient Profiles

**1. Reports Development**
- Major Study Conduct Activity
- Covers variety of DM Reports
- Spans across diverse Stakeholders

**5. SAE Recons. + Milestones**
- Safety Data Review
- SAE Reconciliations
- Interim Analysis, DSURs, Data Cutoffs

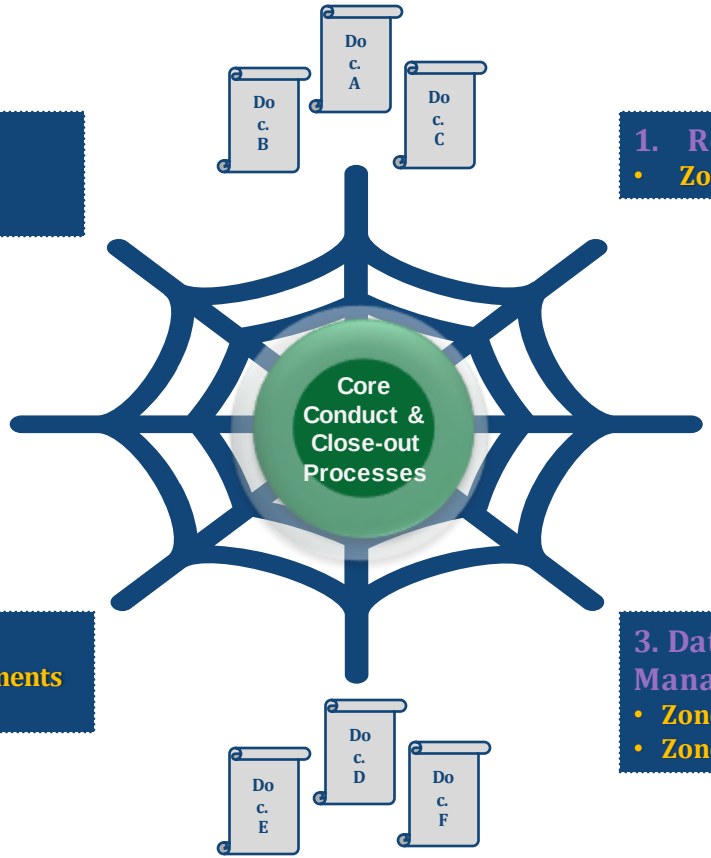
**2. External Data Mgmt.**
- Develop EFTs & eDTS
- Review Data Structures
- External Data Reconciliations

**4. Protocol Amendments**
- Protocol Review
- EDC Migration Impact Analysis
- EDC Database Design & Update

**3. Data Review & eTMF Management**
- Integrated & Medical Data Review
- Study Metrics & Data Health Summary
- TMF Planning, EDL & Next Gen Plan

# Clinical Data Management – a *High Level* Overview "Conduct & Close-out"

## How Data Management Scope relates to the TMF Reference Model:




**6. Database Lock & Decommission**
- Zone 10: Data Management

**1. Reports Development**
- Zone 10: Data Management

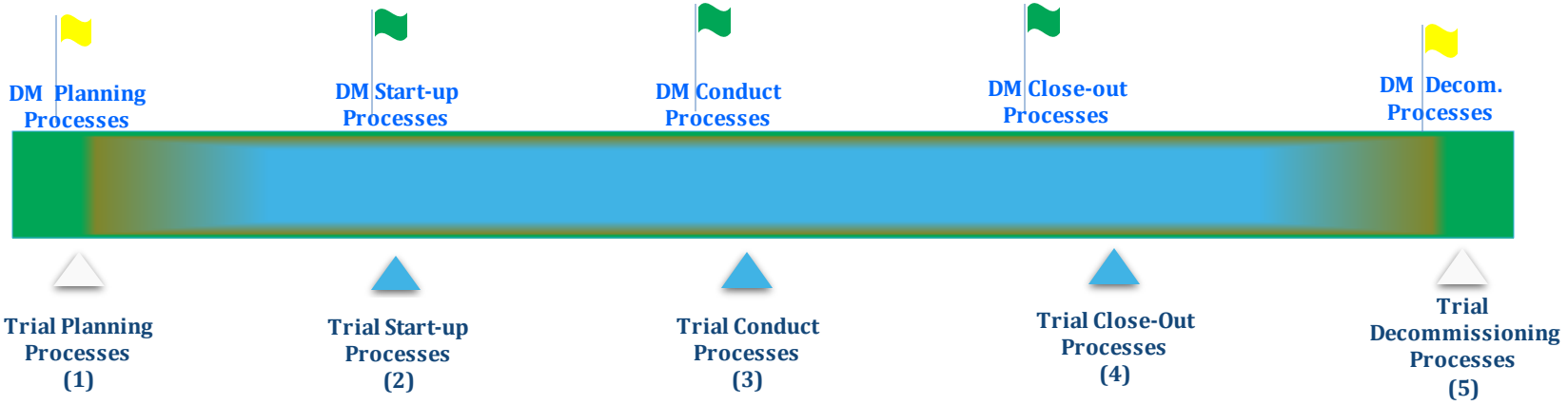
**5. SAE Recons. + Milestones**
- Zone 07: Safety Management
- Zone 11: Statistics

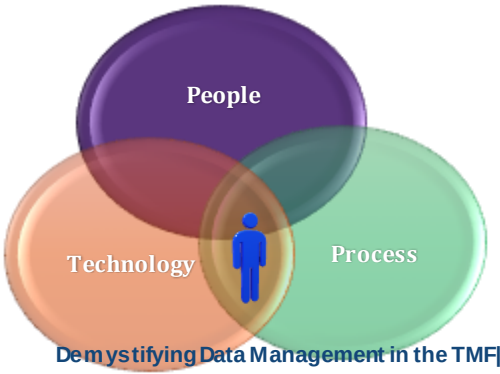
**2. External Data Mgmt.**
- Zone 01: Trial Management
- Zone 10: Data Management

**4. Protocol Amendments**
- Zone 02: Central Trial Documents
- Zone 10: Data Management

**3. Data Review & eTMF Management**
- Zone 01: Trial Management
- Zone 10: Data Management

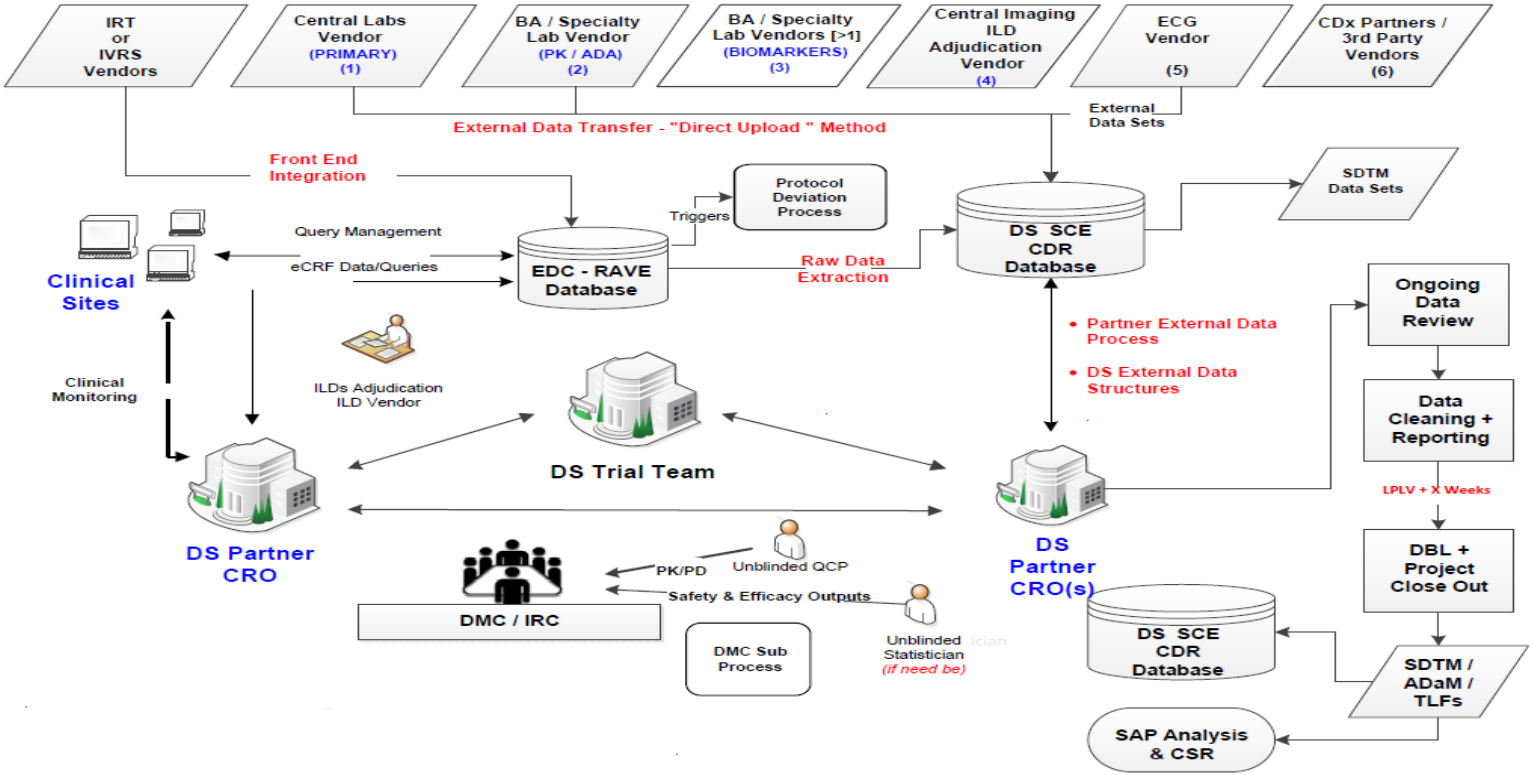
# Data Management Processes – *Heat Map*



# Data Flow

# Data Flow Diagram

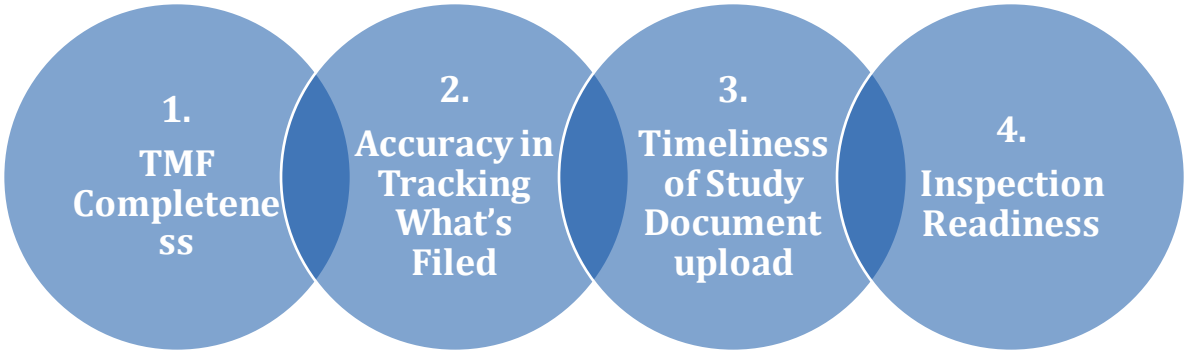


# Data Management Inspection Readiness

# Sponsor Functional QC & Inspection Readiness

**As Sponsor, we hold an obligation to demonstrate oversight of outsourced activities, including accuracy & timely upload of our documents!!**

- **Our Study Team members are familiar with the TMF expectations for their function(s) & role(s)**
- **Diverse Study Team members are responsible and accountable for ensuring study specific documents are filed in Veeva**
- **All Functions use our *TMF Management Plan and TMF Index* for ensuring their documents are being tracked and uploaded correctly**
- **Our Oversight of the TMF focuses on:**



# The Importance of Sponsor Functional QC

## Common 'Checks' we perform during a Sponsor Functional QC

- ✓ Should the document being viewed be linked to another document in the system to help an inspector or user logically navigate to that document during an inspection?
- ✓ Does this document only tell part of the story and am I missing the rest of the story?
- ✓ Does the content of the document present a risk which was previously unnoticed and may require generation of additional documentation or storyboarding?
- ✓ Does the document demonstrate study adherence

## Sponsor Functional QC is not focused on the following

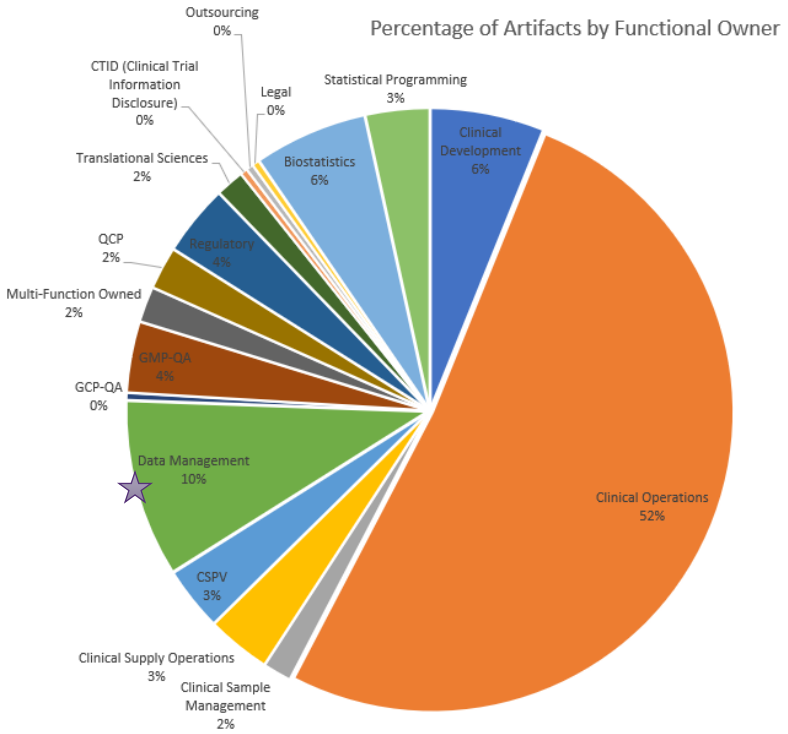
- ✗ Document metadata
- ✗ Filing Location
- ✗ Image Quality

**Over 75% of our eTMF Vault documents go through an independent QC for metadata, filing location, and image quality!!**

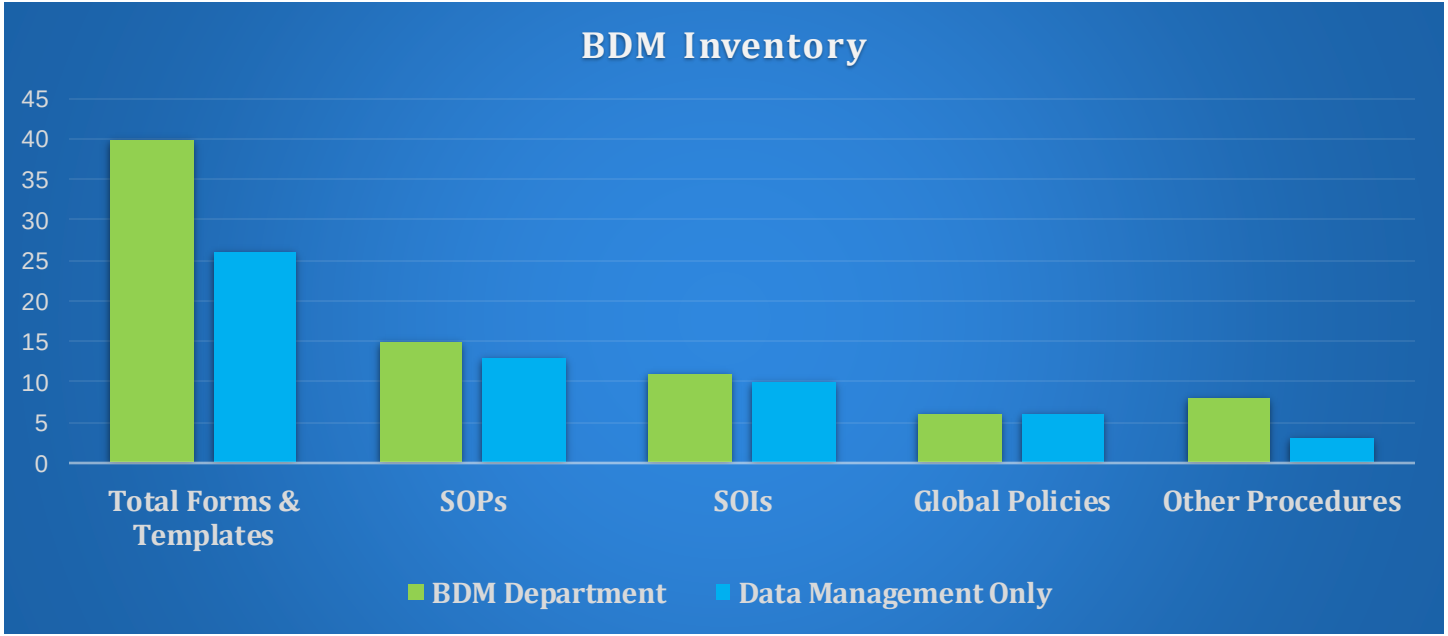
# Breakdown of DM Documents

# eTMF Documents Index – *Functional Breakdown*

| Functional Owner | Number of Artifacts |
|---|---|
| Clinical Development | 16 |
| Clinical Operations | 135 |
| Clinical Sample Management | 4 |
| Clinical Supply Operations | 9 |
| CSPV | 9 |
| Data Management | 25 |
| GCP-QA | 1 |
| GMP-QA | 10 |
| Multi-Function Owned | 5 |
| QCP | 6 |
| Regulatory | 10 |
| Translational Sciences | 4 |
| CTID (Clinical Trial Information Disclosure) | 1 |
| Outsourcing | 1 |
| Legal | 1 |
| Biostatistics | 16 |
| Statistical Programming | 9 |
| **Grand Total** | **262** |

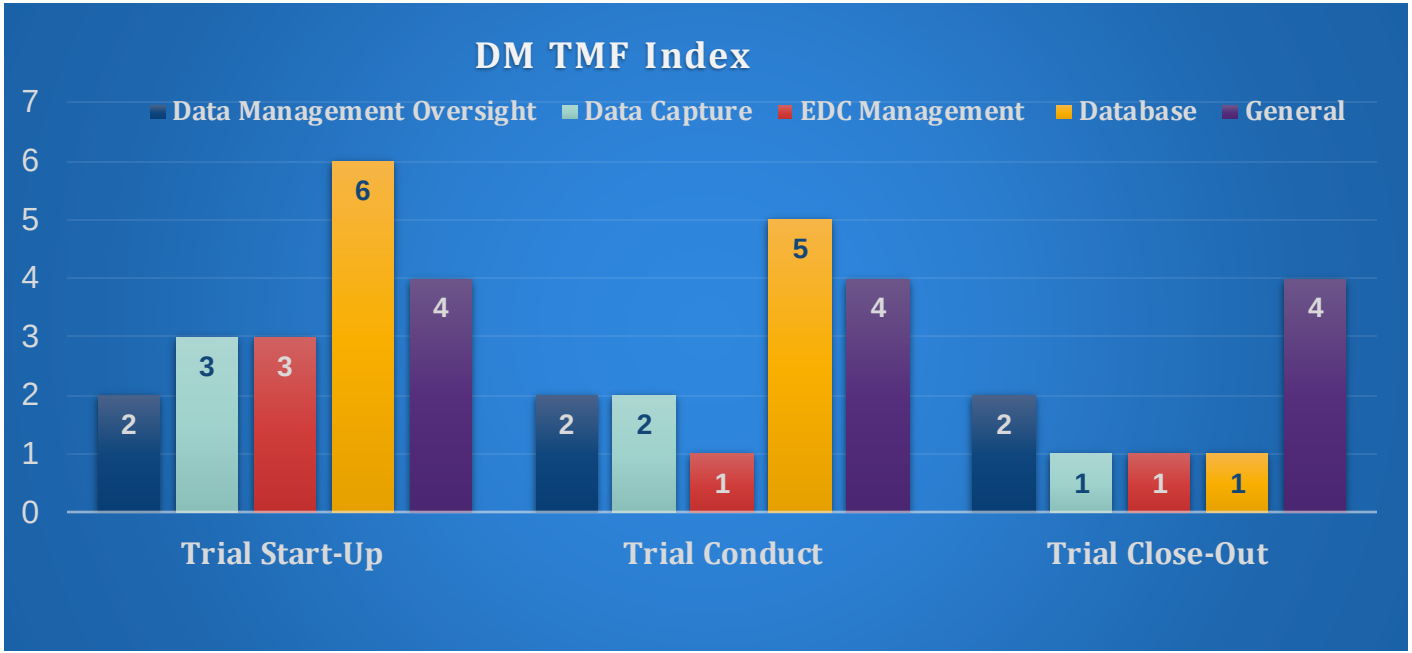


# eTMF Documents Overview – *DM* Documents Inventory




| BDM Function eTMF Documents Breakdown | | | | | |
|---|---|---|---|---|---|
| Function | Total Forms & Templates | SOPs | SOIs | Global Policies | Other Procedures |
| BDM Department | 40 | 15 | 11 | 6 | 8 |
| Data Management | 26 | 13 | 10 | 6 | 3 |

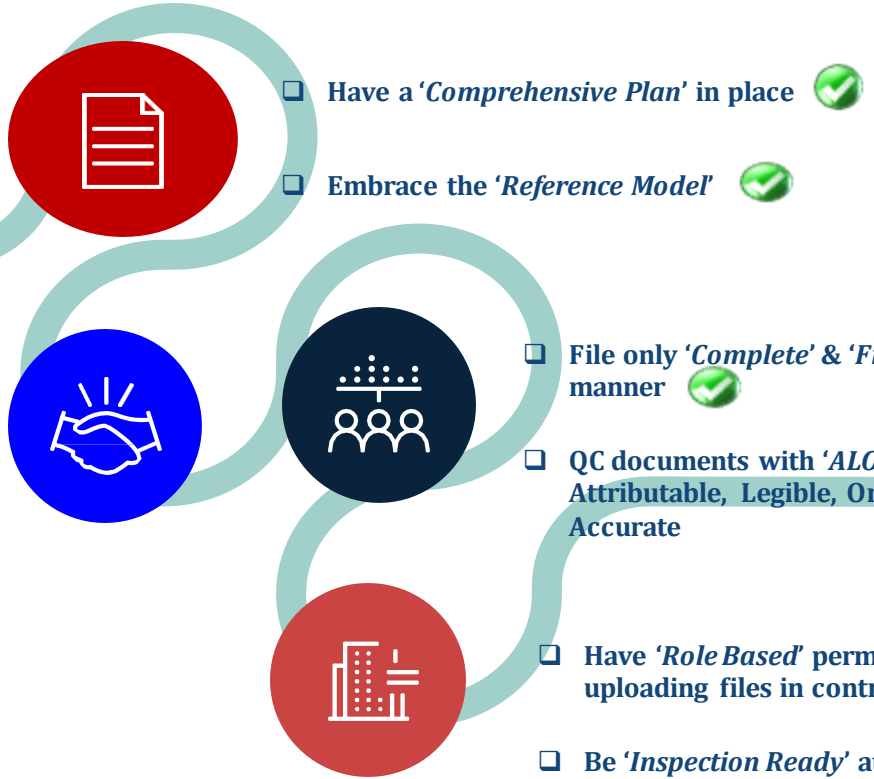
# TMF Index Overview – *DM* eTMF Index




| Daiichi Sankyo Data Management TMF Index | | | | | |
|---|---|---|---|---|---|
| Trial Phase | Data Management Oversight | Data Capture | EDC Management | Database | Other DM Documents |
| Project Start-Up | 2 | 3 | 3 | 6 | 4 |
| Project Conduct | 2 | 2 | 1 | 5 | 4 |
| Project Close-Out | 2 | 1 | 1 | 1 | 4 |

# Building Bridges Together

# eTMF Document Management - *Our* Approach



- Have a '*Comprehensive Plan*' in place
- Embrace the '*Reference Model*'
- File only '*Complete*' & '*Final*' docs in timely manner
- QC documents with '*ALOHA*' (i.e. ALCOA++)– Attributable, Legible, Original, Harmonio Accurate
- Have '*Role Based*' permissions for accessing & uploading files in controlled environment
- Be '*Inspection Ready*' at all times
- Follow all '*Regulatory*' requirements
- Comply w/h Investigator, Sponsor and ICH-GCP Standards
- Monitor to ensure milestone documents are being received on time
- Avoid Notes to File whenever possible

# Questions

Contact Lnaranjo@dsi.com or vispatel@dsi.com