Leveraging Data Enablement for Enhanced eTMF Interoperability and Collaboration

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Meet the Speaker

Meghan Valnoski

**Title:** Advanced Clinical Consultant

Organization: NNIT

Meghan Valnoski is a member of NNIT's Clinical Business Consultant team. She specializes in streamlining complex clinical trial processes, particularly with Veeva Vault Clinical Suite, to elevate efficiency and quality. With a decade of industry experience, Meghan excels in fostering effective communication and seamless process integration within clinical trial teams. She played a lead role in the transition from paper TMF to a fully functional eTMF system. As she progressed into Project Management, she continued to oversee the eTMF system, providing her extensive background in navigating the intricacies of the TMF and understanding the challenges faced by various departments.

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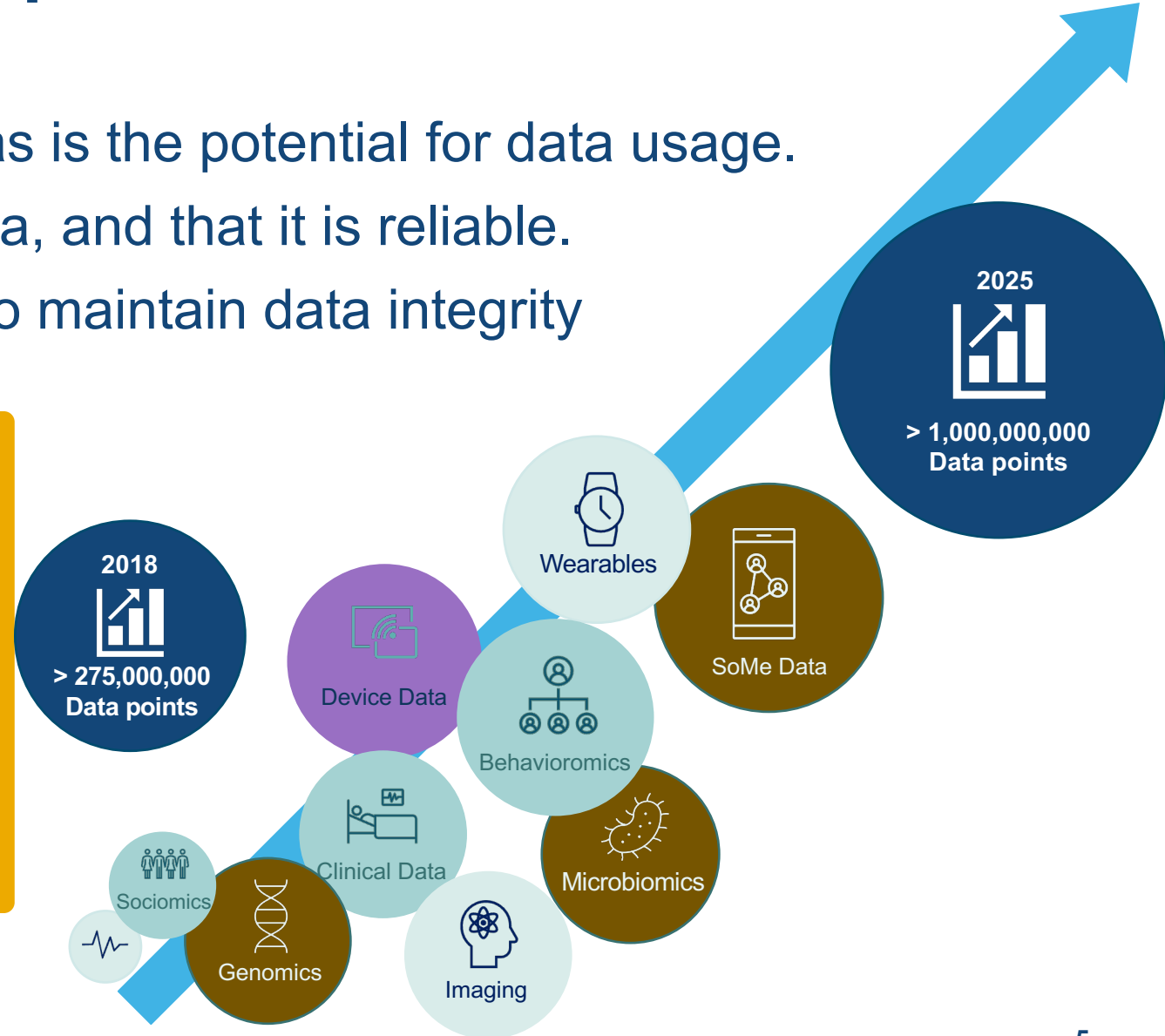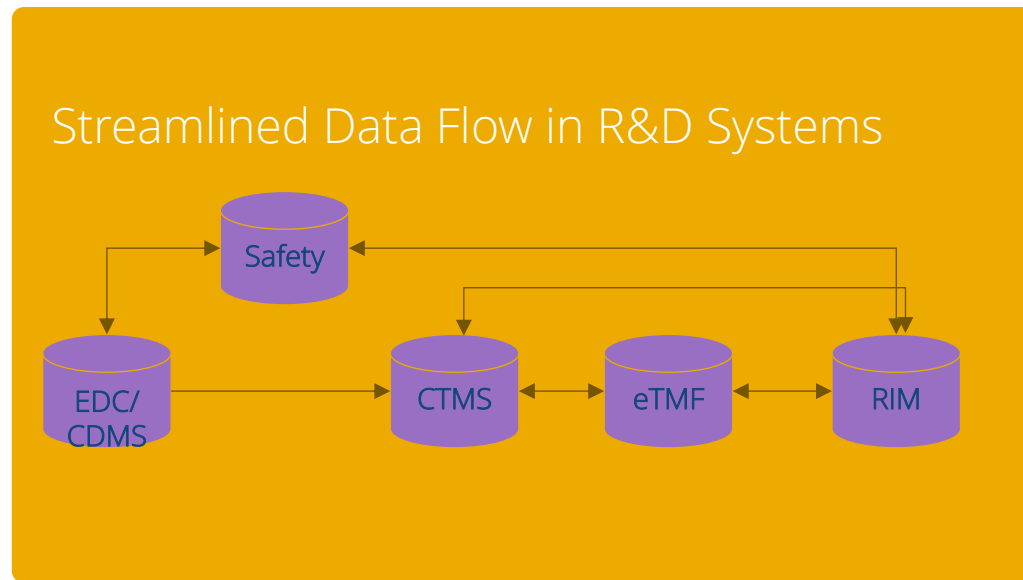*The author has no real or apparent conflicts of interest to report.*
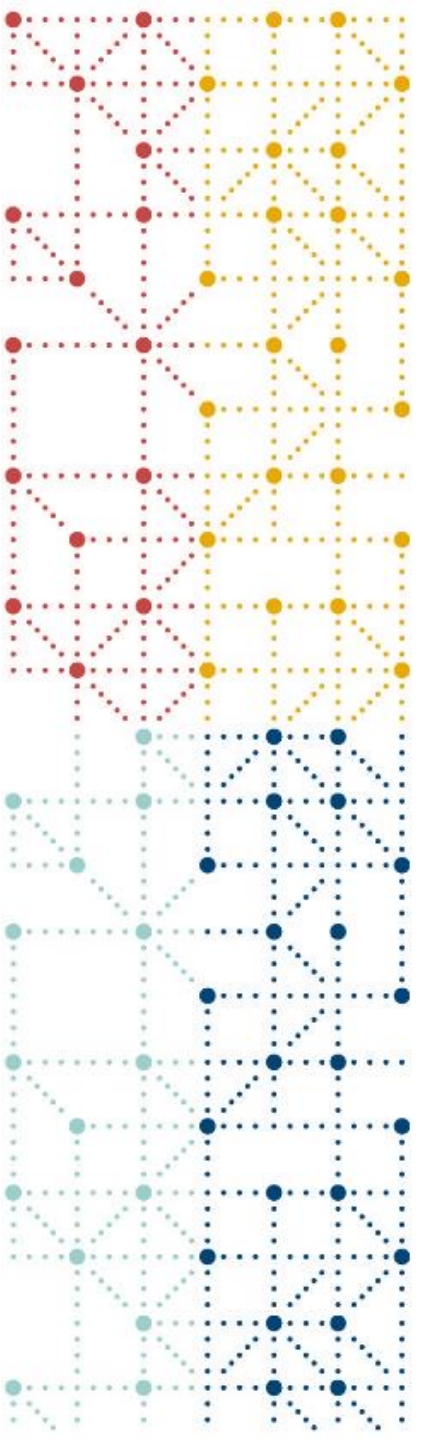
Agenda

1. Explosion of data
2. The quality challenge
3. From chaos to order
4. Applying principles to TMF Management
5. Use-Cases

We are witnessing an explosion in data

- The amount of data is surging, as is the potential for data usage.
- We must be able to trust our data, and that it is reliable.
- We must implement measures to maintain data integrity

Streamlined Data Flow in R&D Systems

Safety

EDC/CDMS — CTMS — eTMF — RIM

2018
> 275,000,000
Data points

2025
> 1,000,000,000
Data points

Wearables

SoMe Data

Device Data

Behavioromics

Clinical Data

Microbiomics

Sociomics

Genomics

Imaging

The Quality Challenge

- Clinical data must be accurate, reliable, and relevant. Without quality data, our efforts to leverage this information become futile.

- High quality data ensures that it meets the business needs.

- If the data is not 'fit for purpose', our efforts to collect, store, secure, and enable access to it is wasted.

$3.1 Trillion is the yearly cost of bad data quality in US
IBM

High-quality data is the **cornerstone** of data enablement

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Increasing the Quality of Data

Data Enablement

- Increases data reliability
- Establishes structure
- Enhances data accessibility
- Drives growth and expansion

Look at it as a restaurant kitchen

Ingredients *(=Data)*

Chefs *(=Data Managers)*

Meals *(=Operational data)*

CHAOS		ORDER
Scattered around everywhere with no order	◄►	Everything is neatly labeled, stored, and easy to find
Running around in different directions, trying to find the right tools and ingredients	◄►	Strict procedures are in place, resulting in everyone knows exactly what to do and how to do it
Are inconsistent, wrongly prepared or is lacking quality	◄►	Consistently delights end users with high consistency and quality

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High-Quality Data is not an Accident

Steps to ensure data quality

Data Governance

Consistent informed decisions about data, and the data strategy

Checklist:
- Define Data Strategy
- Set policy
- Stewarding data
- Defining the value of data to the organization
- Eveolving the organizations mindset around data through culture change

Foundational Activities

Management, upkeep, and utilization of data over time

Checklist:
- Ensuring data is protected
- Managing metadata, the knowledge required to understand and use data
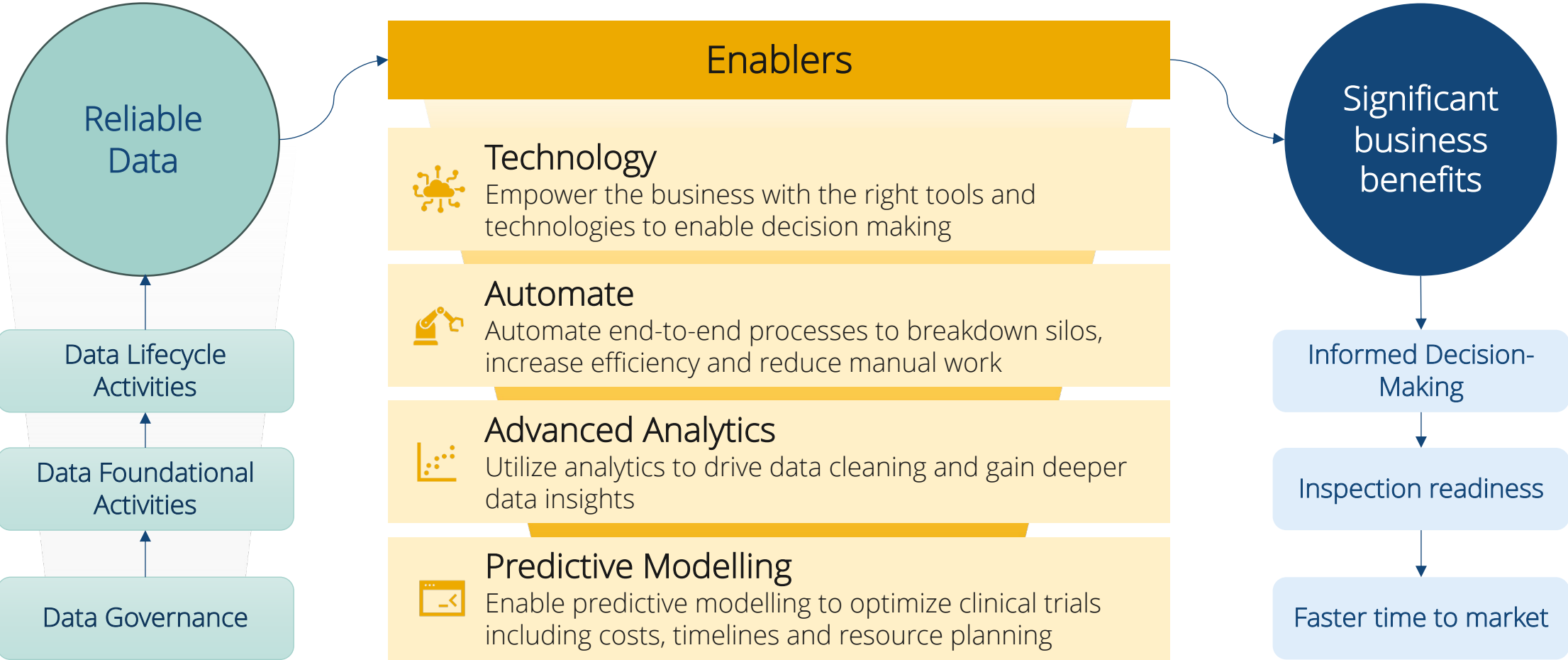- Managing the quality of data

Lifecycle Activities

Prioritize planning and design for data for usage

Checklist:
- Data Architecture
- Data Modeling
- Building and managing data warehouses
- Integrating data for use by Analysts
- Managing the lifecyckle of highly critical shared data, like
- Reference data and master data

Unlocking Business Benefits

Reliable Data

- Data Lifecycle Activities
- Data Foundational Activities
- Data Governance

Enablers

Technology
Empower the business with the right tools and technologies to enable decision making

Automate
Automate end-to-end processes to breakdown silos, increase efficiency and reduce manual work

Advanced Analytics
Utilize analytics to drive data cleaning and gain deeper data insights

Predictive Modelling
Enable predictive modelling to optimize clinical trials including costs, timelines and resource planning

Significant business benefits

- Informed Decision-Making
- Inspection readiness
- Faster time to market

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Benefits Data Enablement

Enhanced Data Quality

- Error Reduction
- Operational Efficiency
- Enhanced Collaboration

Regulatory Compliance

- Reduces the risk of penalties and legal issues
- Enhances RIM data & document exchange

Data Security

- Ensures data privacy and prevents data breaches
- Instills confidence in collaborative efforts

Operational Efficiency

- Improves data accessibility
- Standardizes processes
- Increases overall efficiency
- Interoperability between systems

Cost Savings

- Reduced errors result in significant cost savings
- Enabling investment in collaborative technologies

Faster Decision-Making

- Accelerates decision-making
- Promoting efficient collaboration and interoperability

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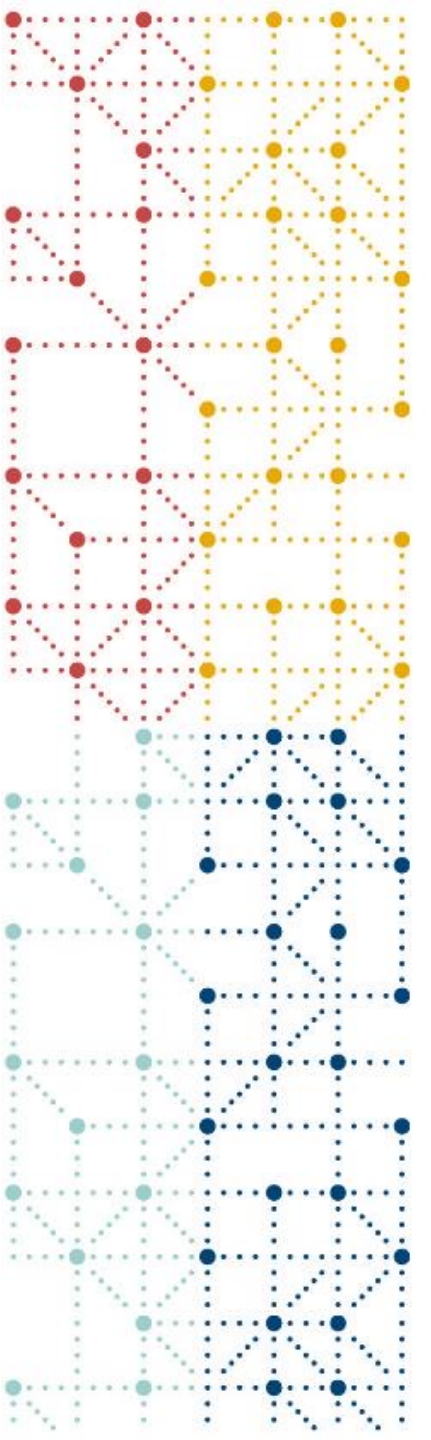
Data Enablement

In the Trial Master File

Navigating in a complex TMF landscape
TMF is a key component in the conduct of a Clinical Trial

In-efficient TMF operations

High timeline risks

Two confused study managers through the eyes of Vincent Van Gogh.
Generated by Bing Image Creator.

Lack of Compliance

Delayed regulatory submissions

Unlocking the potential

Using Data Enablement as a game-changer for TMF management

From Repository to Strategic Tool

- Transform the TMF from a document repository into a strategic tool

- Applying Data Enablement

- Transition from grey, outdated processes

- Building Blocks for Data Enablement

- Enhances operational efficiency, ensures compliance, reduces risks, and accelerates regulatory timelines

- Unlock the potiental for Interoperability

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Navigating the complex TMF landscape is about more than just managing documents - **it's about leveraging data as a strategic asset to drive innovation and success in clinical trials**

Achieving the Benefits of Data Enablement

Streamlined TMF Operations

- Enables automating tasks
- Reduces errors and boosts overall efficiency
- Provides real-time updates and efficient document tracking

Achieving Compliance

- Simplifies the process of achieving compliance
- Ensures data accuracy, completeness, and consistency
- Provides audit trails and version control.

Reducing Timelines

- Provides predictive analytics and real-time insights
- Enables proactive decision-making and risk management
- Fosters collaboration for more efficient timelines

Accelerating Regulatory Timelines

- Expedites regulatory timelines through efficient document management
- Allows for quick document retrieval
- Ensures timely fulfillment of regulatory requirements

Moving towards Interoperability

- Structured and streamline data flow due to data enablement
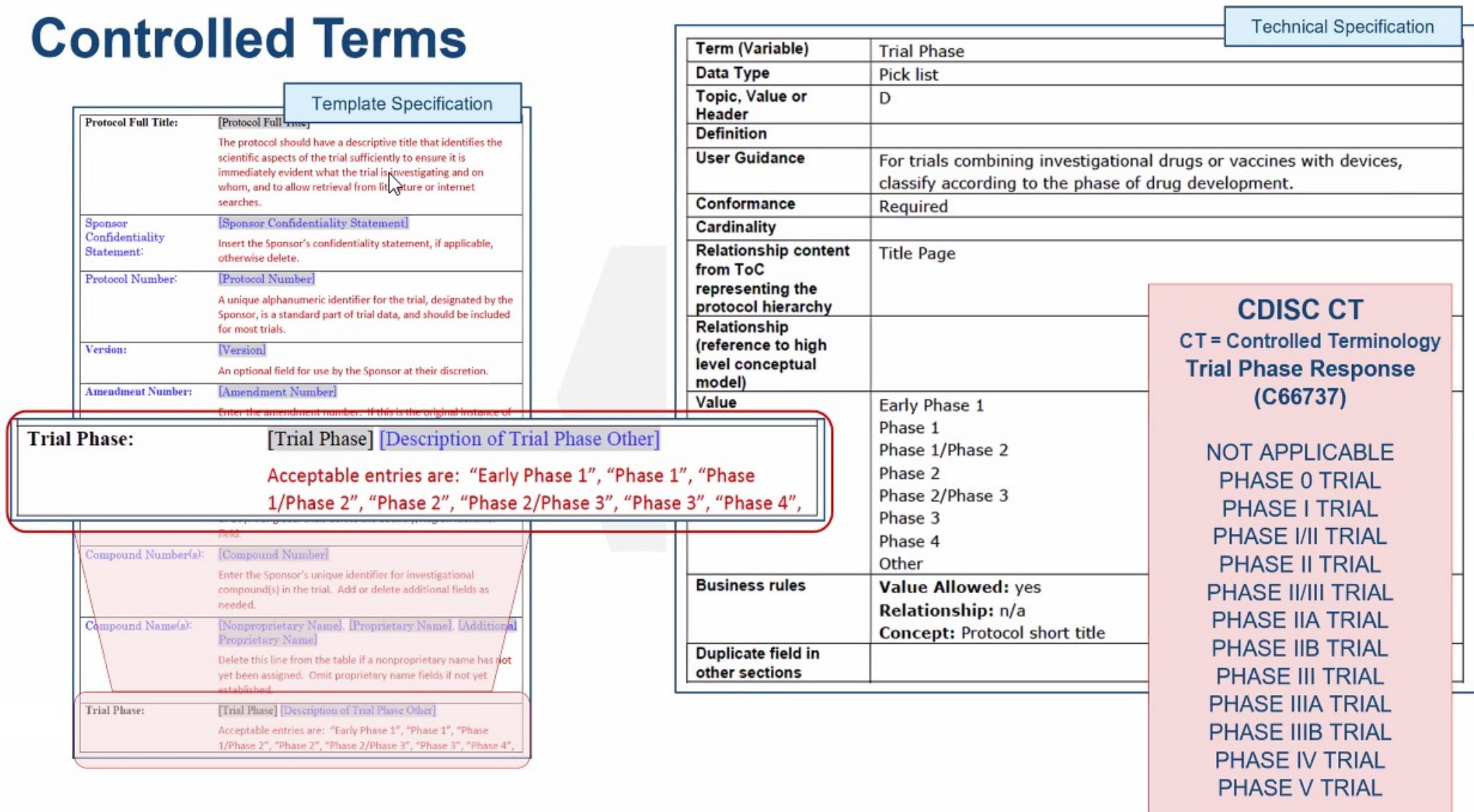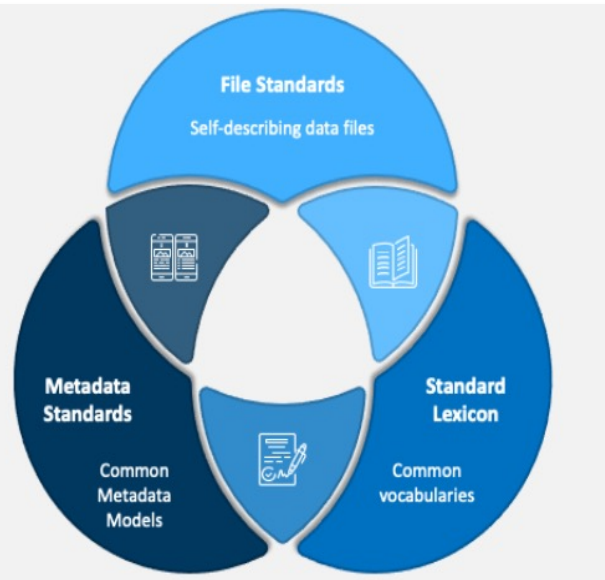- From siloed to holistic system management
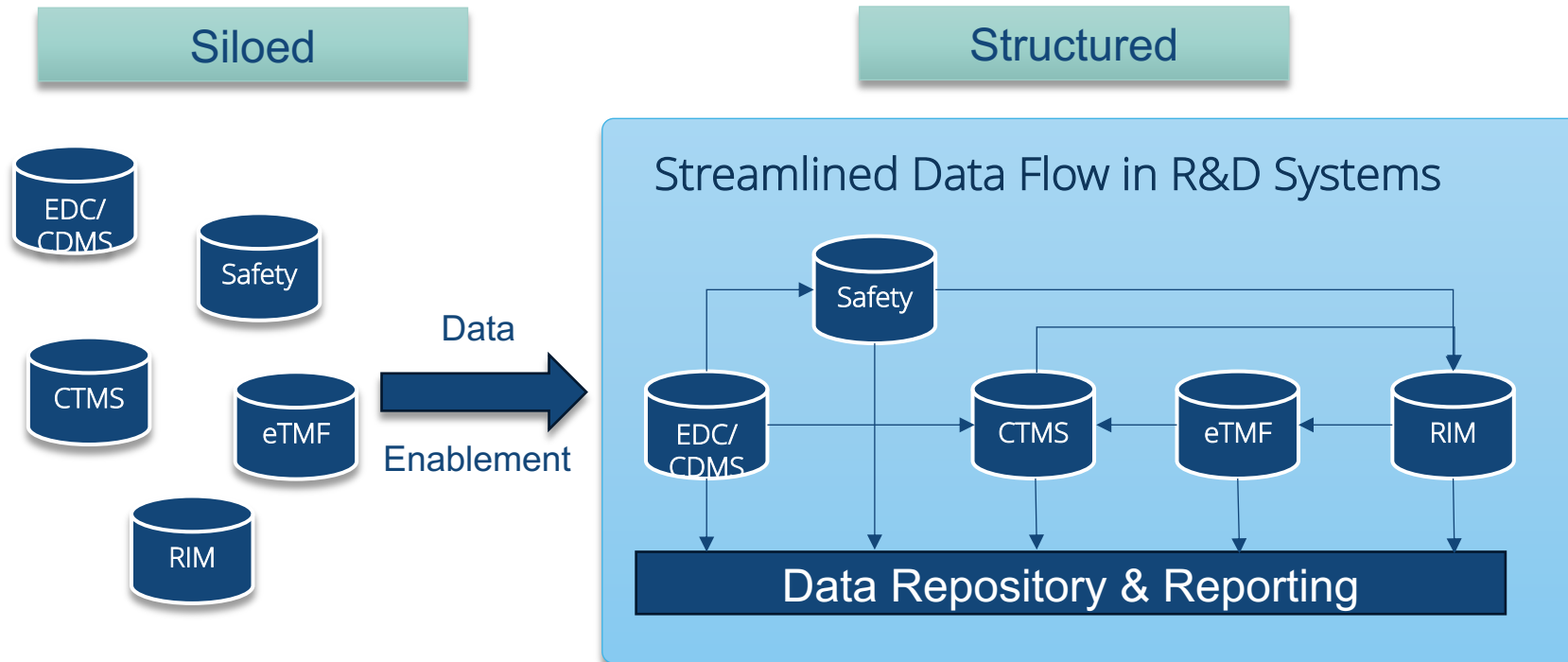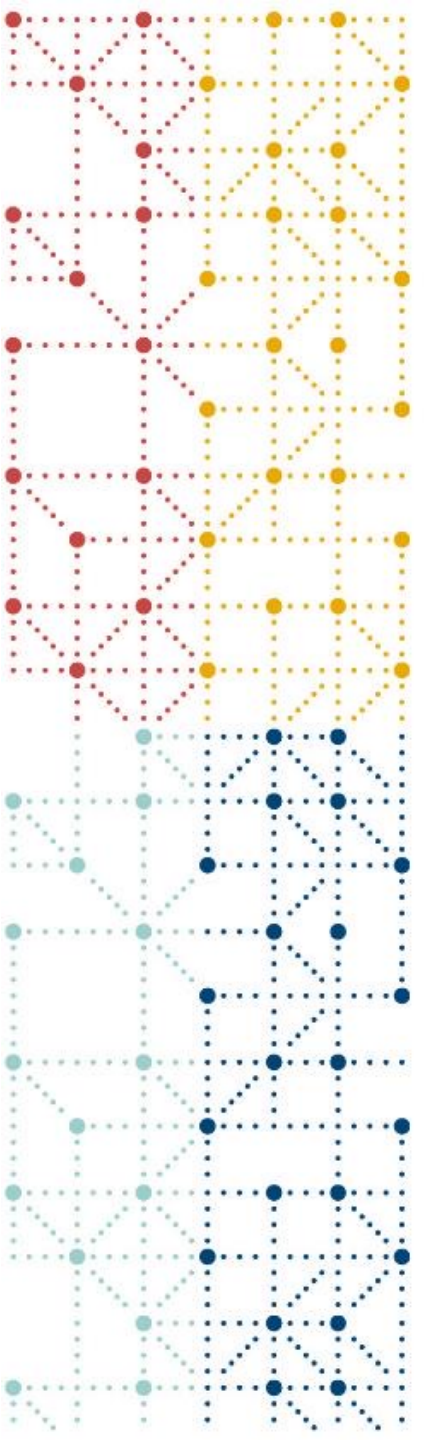
Applying principles to cases

- Migrations
- Content Transfers
- Mergers and Acquisitions

Impact of Different Terminology

Complexities eTMF Content Migration

Data Heterogeneity: **!**

- Different data structures, formats, and naming conventions

Data Volume and Variety:

- The vast data generated in clinical trials requires efficient management and seamless transfer

Standardization Efforts: ✓

- Establish data formats, naming conventions, and exchange protocols

Interoperability Solutions:

- integration tools facilitate seamless data transfers across disparate systems

Streamlining eTMF Transfers between Partners

Data Privacy and Security:

- Clinical trial data often contains sensitive patient information, necessitating privacy protection and compliance with data regulations.

- **Data Consistency:** Maintaining data consistency across partner systems is difficult due to varying data entry practices and protocol interpretations.

Data Governance:

- Robust data governance frameworks oversee data handling, including ownership, access controls, and compliance oversight.

eTMF Data Management in M&A Activities

Data governance fuels a company's attractiveness for acquisition, fortifying accuracy, compliance, and transparency.

Impeccable data management stands as a formidable asset.

Data Fragmentation: !

- Varying data structures lead to data fragmentation, complicating a unified eTMF maintenance

Data Quality & Inconsistency:

- Result in errors, compliance issues, and inefficiencies.

**Data Migration Complexity**:

- Time-consuming process required data accuracy and completeness.

Mapping and Transforming Data: ✓

- Convert data from various sources into a common format, ensuring compatibility in the integrated eTMF system.

Robust Data Governance:

- Strong data governance, including metadata management, ensures well-monitored and controlled data during integration.
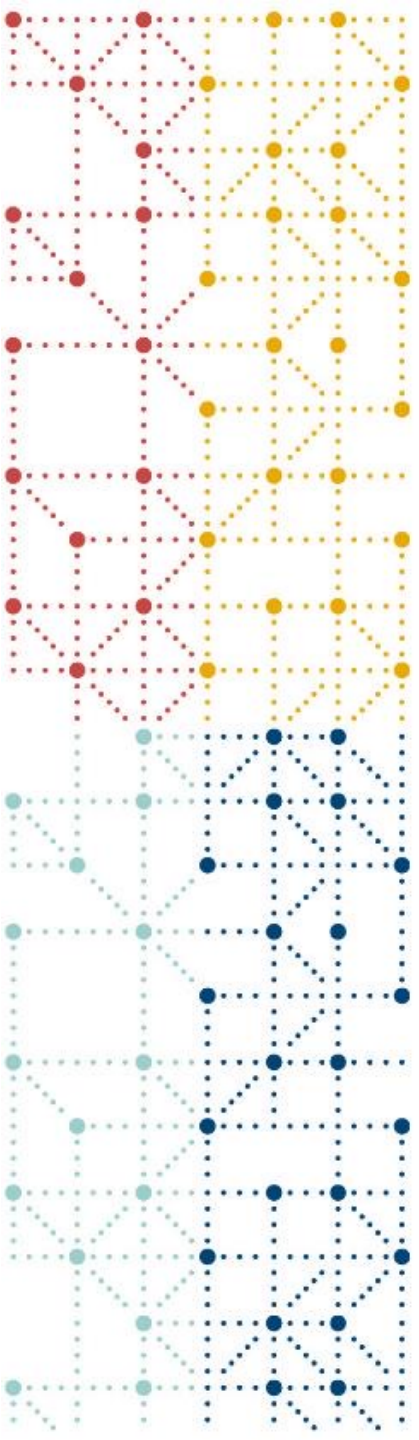
Thank You

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Data Enablement covers principles of making data **accessible, usable, and valuable** for various business or organizational purposes.

It **involves collecting, storing, organizing, and providing access** to data in a way that allows for effective analysis, decision-making, and automation.