

# Leveraging Data Enablement for Enhanced eTMF Interoperability and Collaboration Presented By: Meghan Valnoski, Advanced Clinical Consultant, NNIT,



# **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.



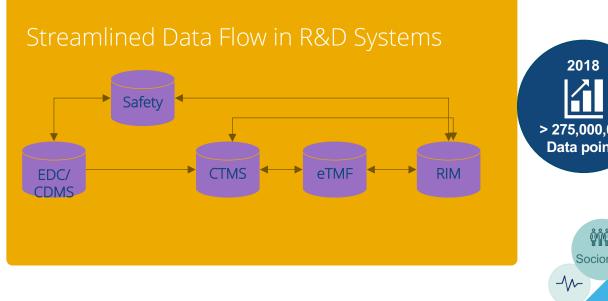
# Agenda

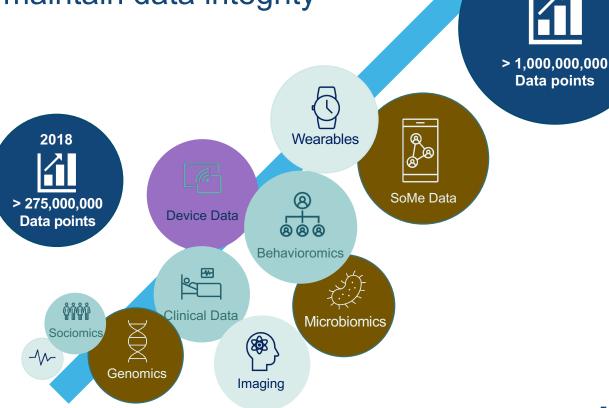
- 1. Explosion of data
- 2. The quality challenge
- 3. From chaos to order
- 4. Applying principles to TMF Management
- 5. Use-Cases

Key question: How can data enablement be a game-changer for eTMF?

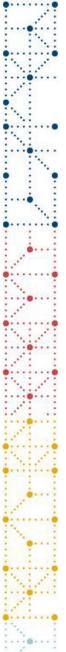
# We are witnessing an explosion in data

- 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





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# **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** 





# Increasing the Quality of Data

### <u>Data Enablement</u>

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

Look at it as a restaurant kitchen



# **CHAOS**

**Ingredients** (=Data)

**Chefs** (=Data Managers)

**Meals** (=Operational data)

Scattered around everywhere with no order

 $\langle \rangle$ 

Running around in different directions, trying to find the right tools and ingredients

Are inconsistent, wrongly prepared or is lacking quality



# ORDER

Everything is neatly labeled, stored, and easy to find

Strict procedures are in place, resulting in everyone knows exactly what to do and how to do it

Consistently delights end users with high consistency and quality



# **High-Quality Data is not an Accident**

Steps to ensure data quality



### Data Governance

Consistent informed decisions about data, and the data strategy



### Lifecycle Activities

Prioritize planning and design for data for usage

### **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

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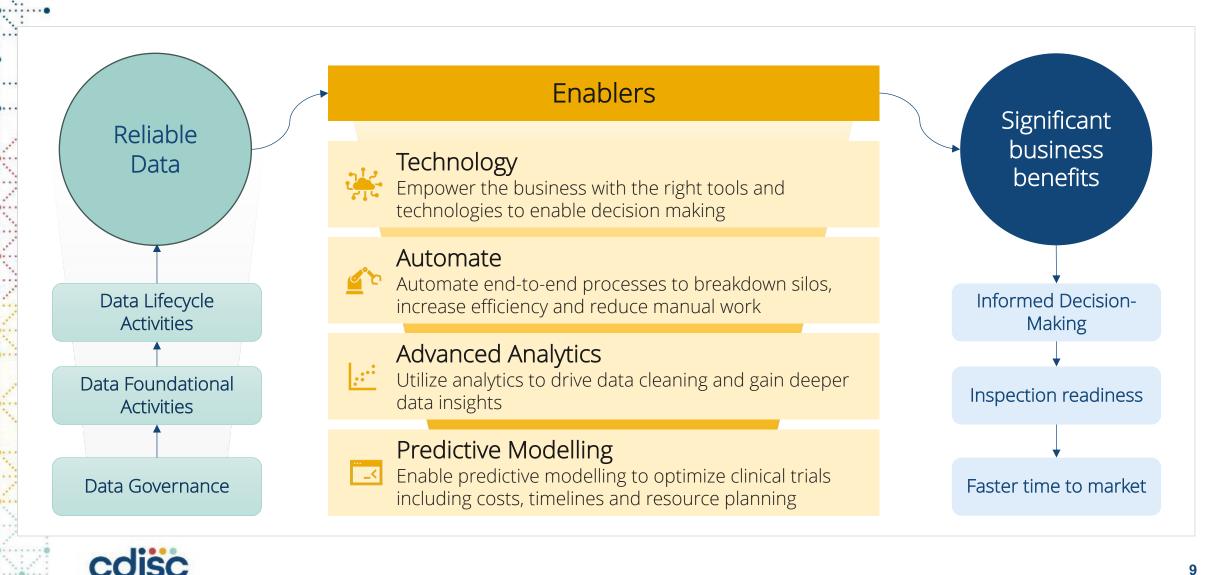
### **Checklist:**

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

### **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**





# **Benefits Data Enablement**



### Enhanced Data Quality

- Error Reduction
- Operational Efficiency
- Enhanced Collaboration



# **Operational Efficiency**

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



### **Regulatory Compliance**

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



# **Cost Savings**

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

### **Data Security**

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



# **Faster Decision-Making**

- Accelerates decisionmaking
- Promoting efficient collaboration and interoperability



# 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









Delayed regulatory submissions

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

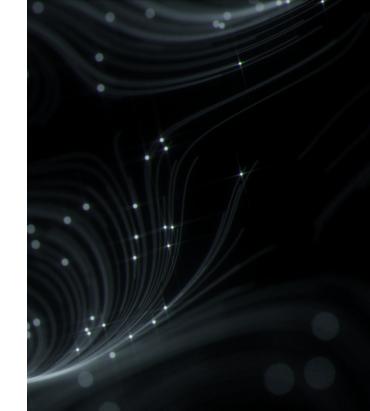
### Unlocking the potential

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



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 realtime insights
- Enables proactive decision-making and risk management
- Fosters collaboration for more efficient timelines

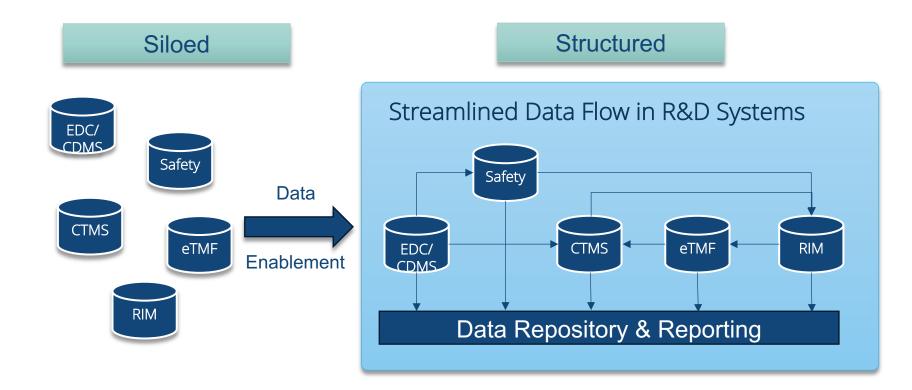


### Accelerating Regulatory Timelines

- 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**

# **Controlled Terms**

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# **Complexities eTMF Content Migration**

Standard

Lexicon

Common

vocabularies

### **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

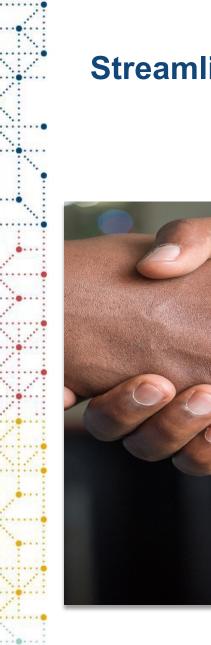
### **Standardization Efforts:**

• 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.

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- **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 wellmonitored and controlled data during integration.





# Meghan Valnoski <u>megh@nnit.com</u>



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.