TMF Technology Trends: Insights from TMF Data

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14-May-2025

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2025 CDISC + TMF EUROPE INTERCHANGE

GENEVA

CONFERENCE & EXPO: 14-15 MAY | TRAININGS: 12, 13, 16 MAY

TMF Technology Trends: Insights from TMF Data

Jim Horstmann, Senior Product Manager Veeva eTMF
Veeva Systems

Meet the Speaker

Jim Horstmann

Title: Senior Product Manager, Veeva eTMF

Organization: Veeva Systems

Jim has spent his career working on document management solutions for the Life Sciences industry with the last 13 years focused on eTMF applications. Jim is driven by finding ways to make processes more efficient and to improve user experiences to ultimately make managing TMF documentation easier and to increase the quality of the TMF. Additionally, Jim is interested in how new technologies and insights into data can be leveraged to innovate and drive the industry forward.
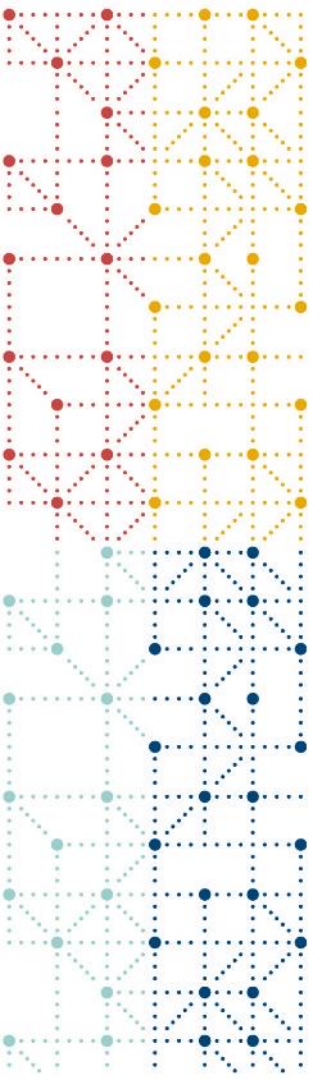
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Agenda

1. TMF and Big Data
2. Technology and Big Data
3. Considerations for Leveraging Big Data
4. What Does the Data Tell Us?

TMF and Big Data

The next phase of TMF Innovation

Intersection of TMF Innovation and Big Data

- The TMF contains a vast amount of clinical trial data and process data (big data)
- Large-scale clinical trials generate enormous amounts of structured and unstructured data
- TMFs will become even more automated, intelligent, and data-driven

Takeaway

The intersection of TMF and big data creates innovative opportunities in TMF management

Big Data Overview

What is it?

Large and diverse collections of structured, unstructured, and semi-structured data that grow rapidly

What is the impact on an organization?

Traditional data management systems cannot store, process, and analyze big data. Requires specialized skillset to manage.

How can big data be managed and used?

Storage: Data repositories and data lakes

Analysis: Machine learning, predictive modeling, and other advanced analytics

Big Data in the TMF

- **Documents** ······················

- Metadata

- Related Objects
  - Quality Issues, Studies, Site Personnel

- **Audit Trail** ······················

- **Process-Related Data** ·················
  - AI data
  - Workflows
  - Expected documents
  - Milestones / Events

Unstructured, difficult to analyze, rapid growth
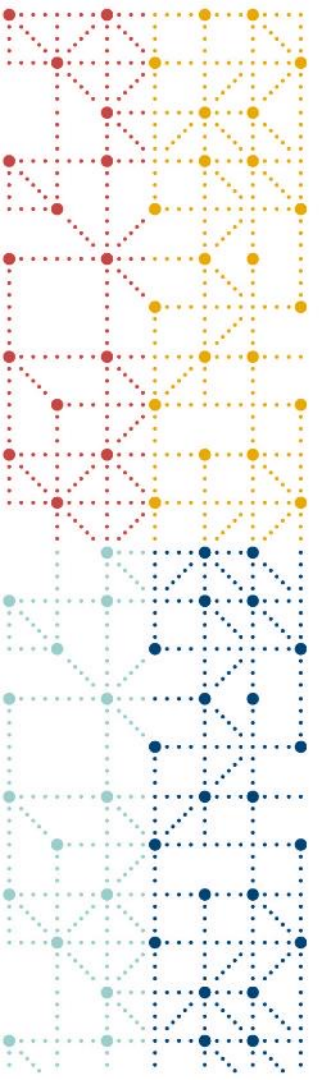
Technology and Big Data

The future within reach

Process for Utilizing Big Data

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Data Governance

1. **Collection**
   - Raw data from multiple sources
2. **Storage**
   - Data Lakes, Warehouses, Hybrid solutions
3. **Processing / Preparation**
   - ETL / ELT (Extract, Transform, Load)
   - Removing bad data, data transformation, joining datasets
4. **Analysis and Modeling**
   - Descriptive, Diagnostic, Predictive
5. **Visualization / Interpretation**
   - Dashboards, Reports
6. **Insights and Action Items**
   - Decisions are made!

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How to bridge the gap?

Process for Utilizing Big Data

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• Cloud offerings
• More "off the shelf" tools
• Resource and skillset demands reducing

Considerations for Leveraging Big Data

What is valuable and what is a distraction?

Considerations for Leveraging Big Data

- Take ownership for your data

- Start with clear business questions

- Build a data-driven culture
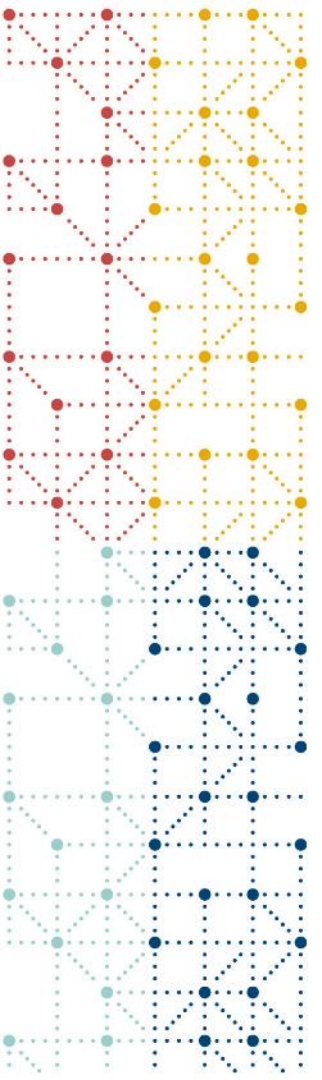
- Collaborate with leaders of other departments

- Focus more on outcomes, less on the reports / dashboards
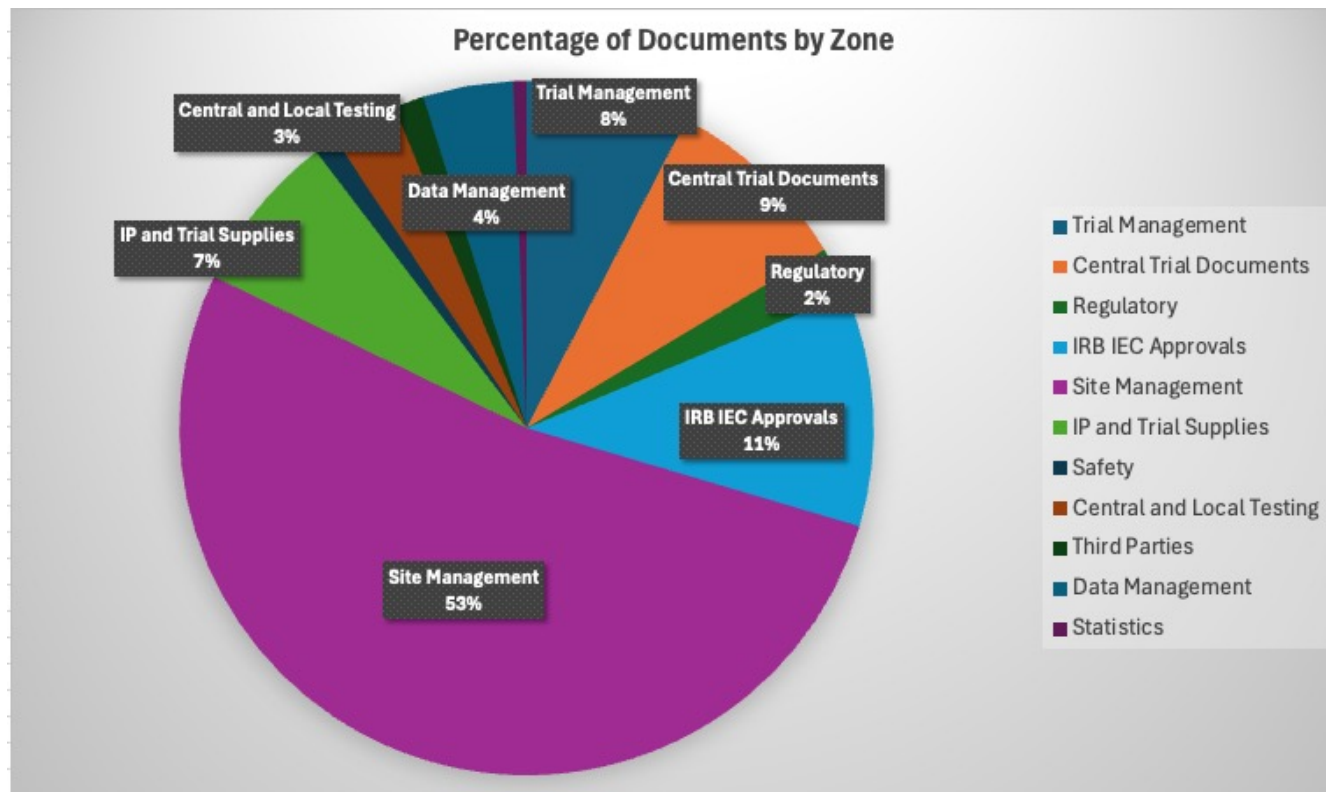
- Let requirements for data insights evolve over time

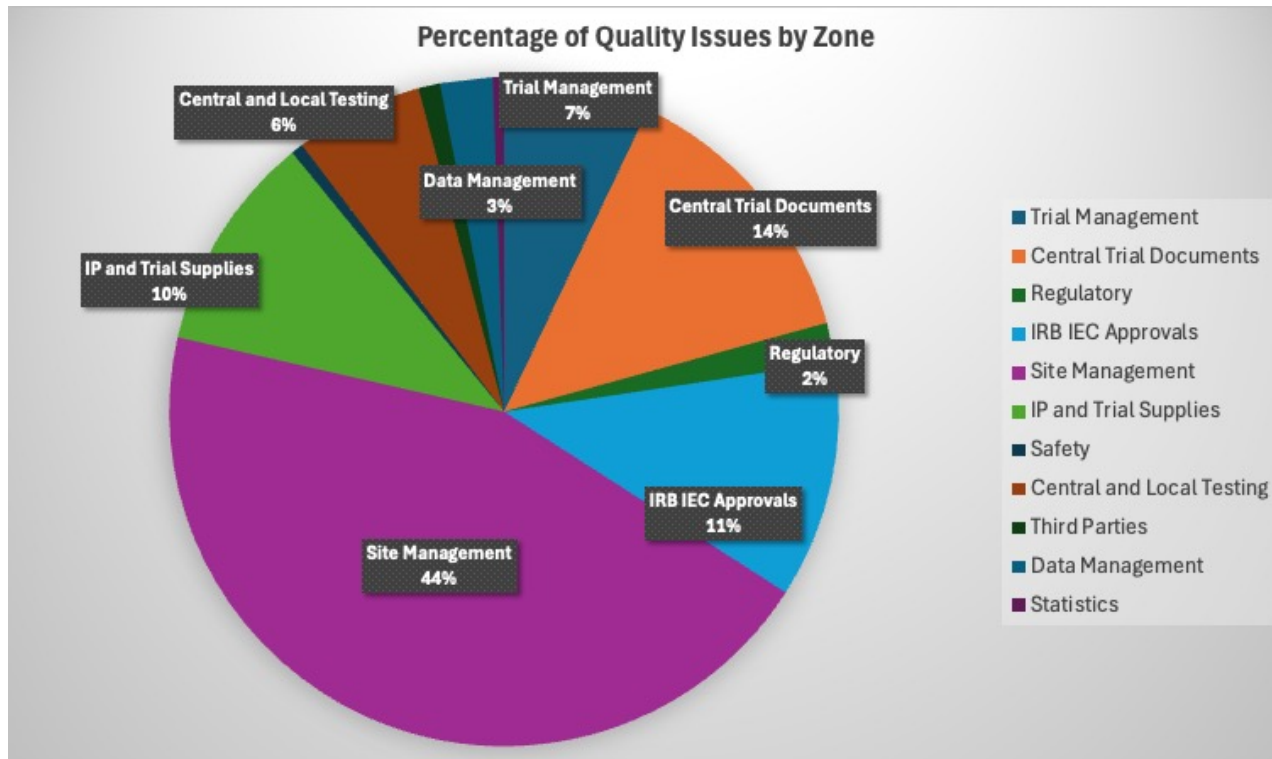- Invest in data solutions (don't wait for others to solve the problem for you!)

What Does the Data Tell Us?

Trends in TMF Data

Data Trend #1: Document Creation by Zone

Percentage of Documents by Zone

- Trial Management
- Central Trial Documents
- Regulatory
- IRB IEC Approvals
- Site Management
- IP and Trial Supplies
- Safety
- Central and Local Testing
- Third Parties
- Data Management
- Statistics

Trial Management 8%
Central Trial Documents 9%
Central and Local Testing 3%
Data Management 4%
Regulatory 2%
IP and Trial Supplies 7%
IRB IEC Approvals 11%
Site Management 53%

Data Trend #2: Percent of Quality Issues

Percentage of Quality Issues by Zone

- Trial Management 7%
- Central Trial Documents 14%
- Regulatory 2%
- IRB IEC Approvals 11%
- Site Management 44%
- IP and Trial Supplies 10%
- Central and Local Testing 6%
- Data Management 3%

Legend:
- Trial Management
- Central Trial Documents
- Regulatory
- IRB IEC Approvals
- Site Management
- IP and Trial Supplies
- Safety
- Central and Local Testing
- Third Parties
- Data Management
- Statistics

Data Trend #2: Percent of Quality Issues Relative to Total Docs

Percentage of Quality Issues per Document by Zone
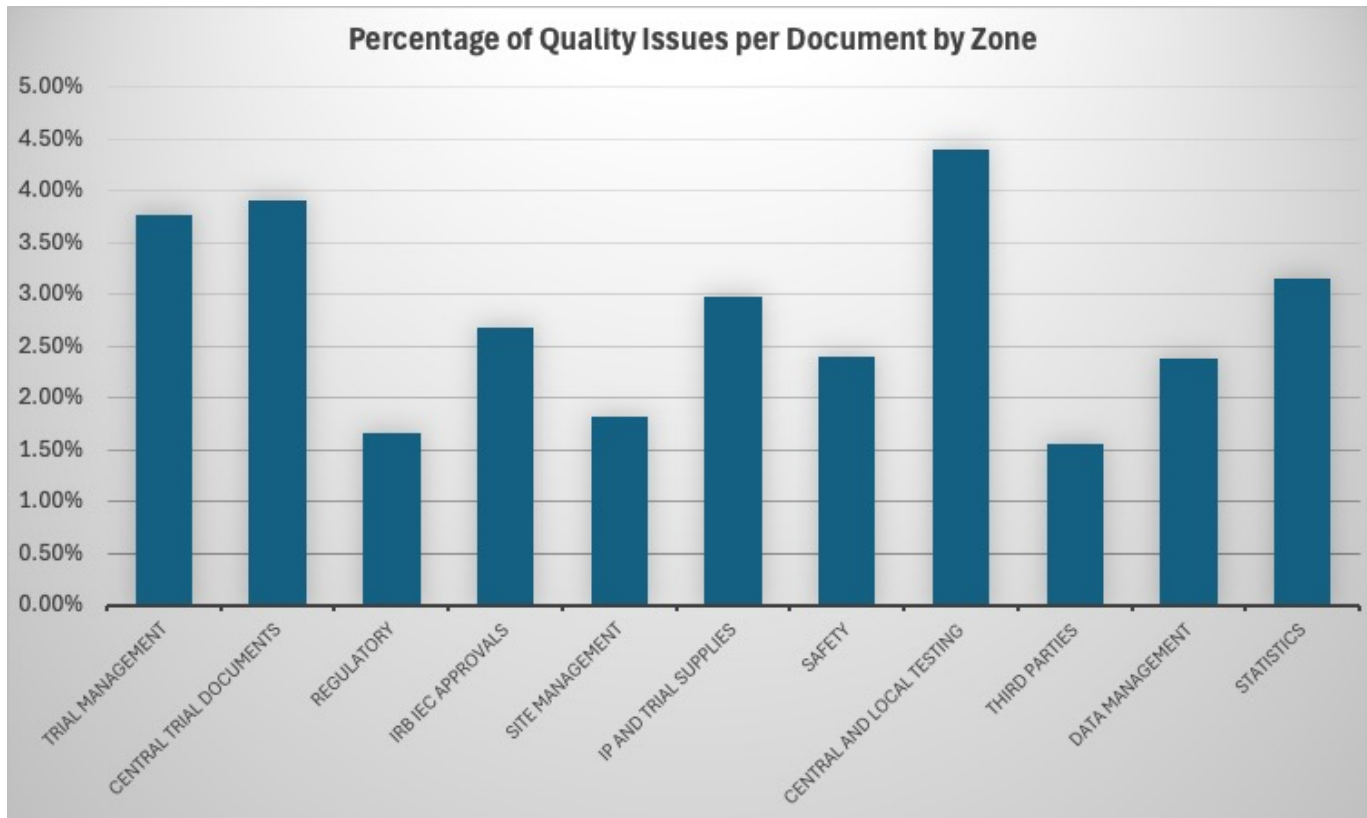
Data Trend #3: In-House vs. Outsourced – TMF Quality

TMF Quality Issues by Operating Model

- IN-HOUSE: 3.60%
- HYBRID: 11.60%
- OUTSOURCED: 14.42%
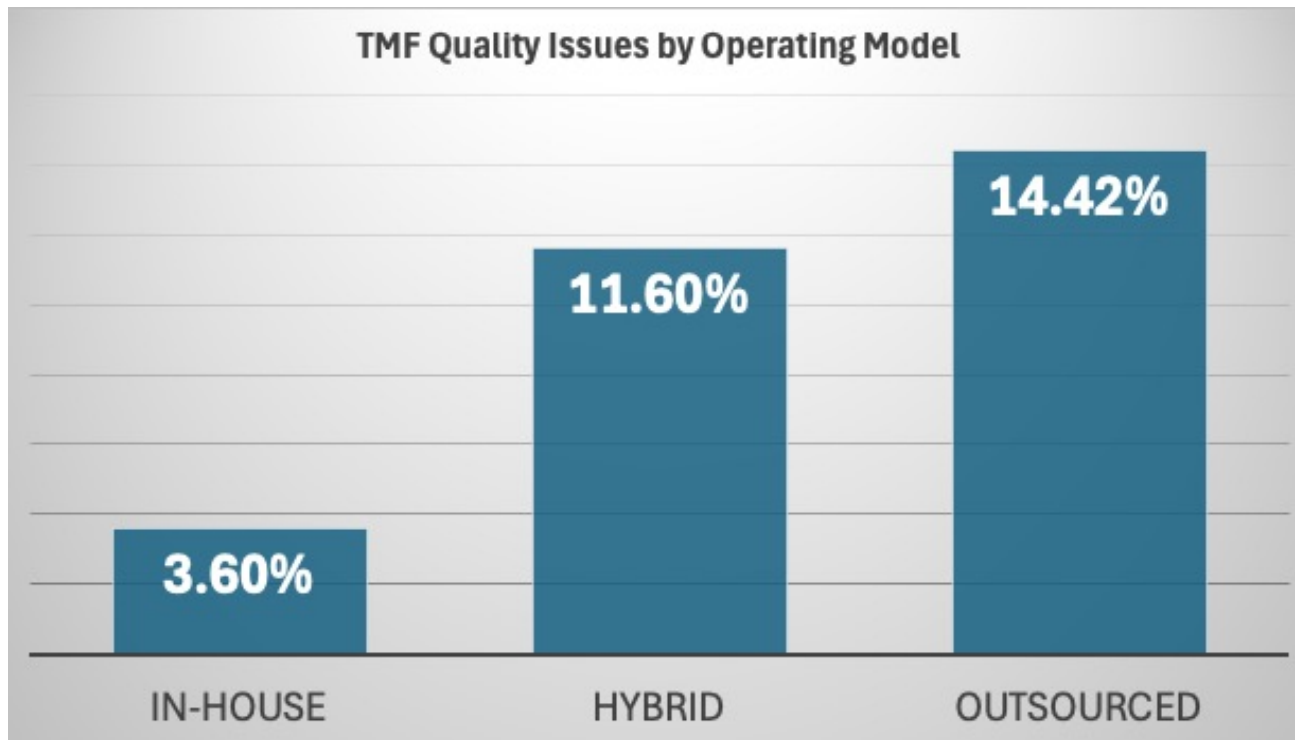
Data Trend #4: AI and Misclassifications

Percent of Misfiled Documents

- AI ASSISTED FILING: 0.80%
- NO AI FILING: 3.23%

Thank You!