HOW TECHNOLOGY CAN HELP MAKE DATA-DRIVEN DECISIONS

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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 an enormous amount 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

How can big data be managed and used?

Storage: Data repositories and data lakes

Analysis: Machine learning, predictive modeling, and other advanced analytics
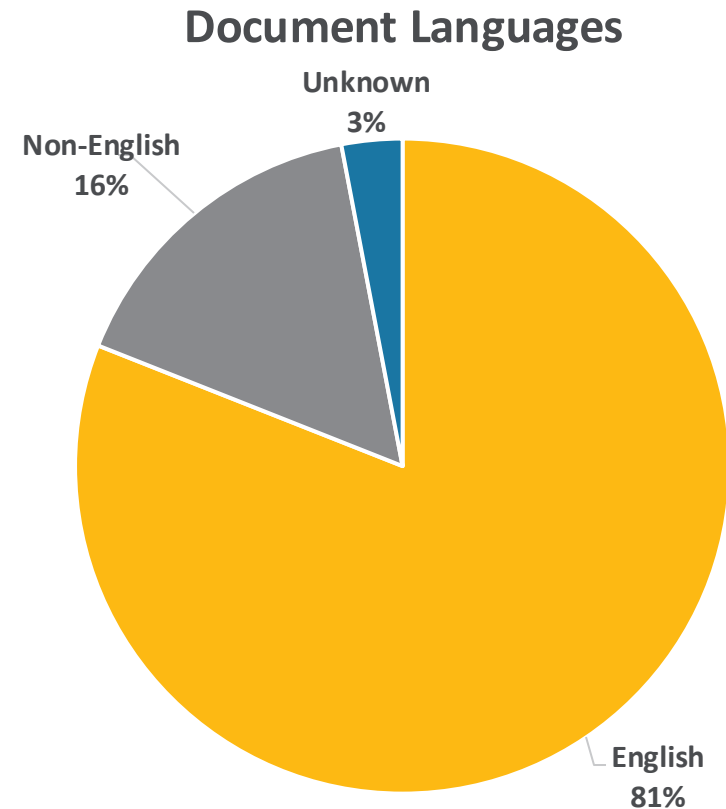
Example 1: Adding TMF Bot Multilingual Support

Prediction metrics help us understand how the TMF Bot is working, including:

- Documents processed
- Documents not processed

Observation: The TMF Bot cannot act on non-English language documents, but non-English documents make up a decent portion of all documents

Solution: Add multilingual support to increase the efficacy of the TMF Bot

Document Languages

Unknown
3%

Non-English
16%

English
81%

Data in the TMF

- **Documents**

- Metadata

- Related Objects
  - Quality Issues, Studies, Site Personnel

- **Audit Trail**

- **Process-Related Data**
  - TMF Bot
  - Workflows
  - Expected documents
  - Milestones

Unstructured, difficult to analyze, rapid growth

Technology Solutions for Utilizing Data

✓ In-system reporting

✓ Data extraction tools

✓ Data warehouses/business intelligence

✓ Cloud storage/data lakes

✓ AI and large language models

Example 2: Analyzing Changes to Final Documents

Using the audit trail

Observation:
The audit trail is structured but not easy to report on and grows rapidly

Solution:
Use the direct data API to extract the audit log to a data lake and leverage analysis tools to target specific audit updates (e.g., how often final documents are modified)

Technology-Enabled Data Can Lead To:

- More confident decision-making
- Up-to-date intelligence
- Smarter risk management
- More efficient operations
- Better position for innovation