



# 2023 CDISC TMF INTERCHANGE

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## How Merck and Veeva Drive Efficiencies and Quality with AI

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Christopher McSpirtt (Veeva Systems)

# Meet the Speakers

Bryan Souder

**Title:** Senior Director, TMF Head

**Organization:** Merck & Co., Inc.

Bryan leads TMF process at Merck & Co., Inc. He has spent more than a decade evolving trial master file processes and technologies.



Chris McSpiritt

**Title:** Senior Director, Clinical Operations Strategy

**Organization:** Veeva Systems

Chris leads clinical operations strategy at Veeva. He's worked for almost 20 years in the life sciences arena, both at software companies and consulting firms.



# Where Can AI Play a Role in Clinical Trials?



# Where Can AI Play a Role in Clinical Trials?



**Clinical Operations**  
*(e.g., study design)*

**Clinical Data**  
*(e.g., simulated cohorts)*

**Safety**  
*(e.g., safety case intake)*

# Automation and AI for TMF



TMF  
structure  
generated  
automatically



Documents  
classified



Documents  
migrated  
from other  
internal  
systems



Select  
documents  
quality  
checked



Users  
prompted to  
collect  
documents  
based on  
study roster

**Automation and AI Enable More Efficient and Strategic TMF Management**



# AI in TMF at Merck

# In-Sourced TMF Operating Model

130

Record management specialists (indexers)

9

Essential document specialists (TMF monitors)

8

Essential document leads (leadership team)

5

Technical document operations specialists (special projects)

85,000

Documents per month

In-Sourced with Centralized Indexing

# Decision-Making Process to Implement AI

## What We Automate

- **Eliminate touch-time** related to TMF activities
- **Ensure timeliness and “presentness”** of essential documents that originate in other internal systems

## How We Prioritize

- **Well-structured document filing** in systems that easily enable connectivity
- **Time reduction benefits** relative to the cost of PRA construction



# Example: Bot Creation Sprint

1A

## INSPECTION READINESS

1. Review if expected documents are present in approved status
2. Bot reviews TMF metadata and marks correct docs as inspection-ready



1B

## MISSING DOCUMENTS

1. Bot cross-checks source system versus TMF and migrates missing copies
2. Bot cross-checks supporting docs versus TMF



2

## COGNITIVE COMPONENTS

1. Include cognitive components where we'll use natural language processing (NLP)

# Why AI in Document Processing?

**1****Document contributors submit records**

- Speeds up document classification
- Mitigates risk of misfiling or misclassification

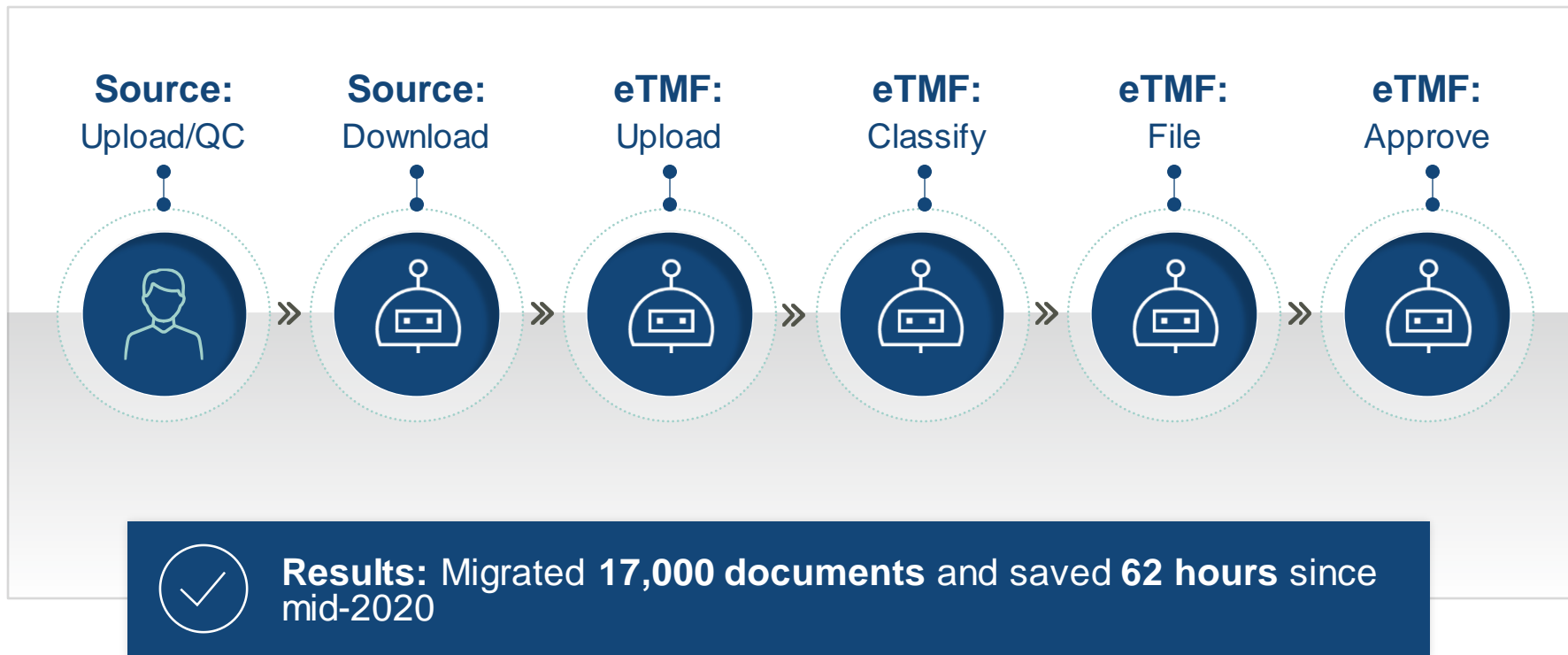
**2****Centralized indexing & QC**

- Ensures faster document finalization with greater reliability
- Leverages expertise of document experts

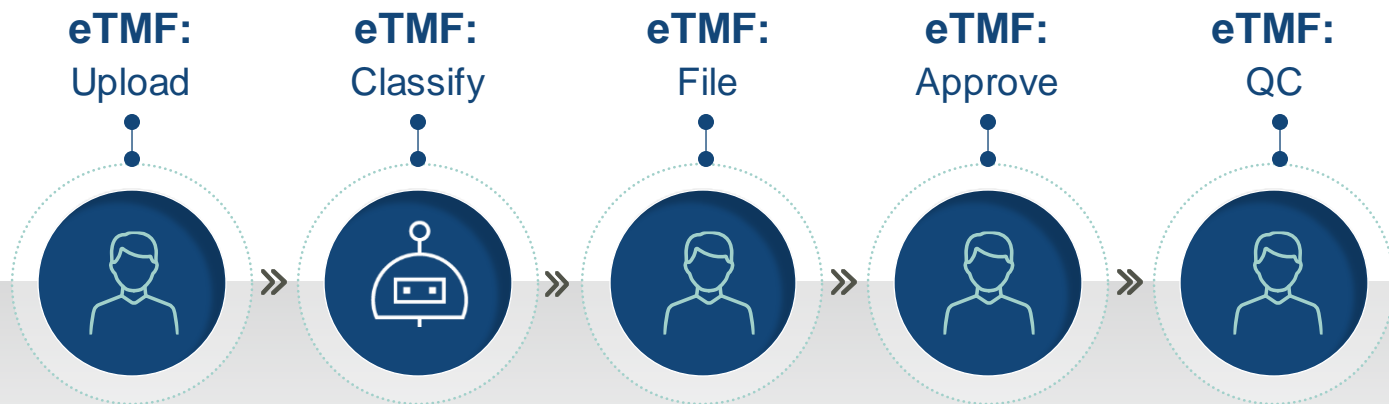
**3****Centralized secondary QC**

- Ensures that a core team focuses on high-value activities to drive quality

# Example: Bot for System-to-System Migration



# Example: Veeva TMF Bot for Auto-Classification



**Results:** Auto-classify 1.02 million documents and save 18,000 hours per year

# Monitoring Bots: Oversight, Controls, and Issues



## OVERSIGHT

- Hypercare surveillance
- Periodic surveillance
- User reported notifications of issues



## CONTROLS

- System reporting
- Random sampling
- User reported notifications of issues



## ISSUES

- Echoes/duplicates
- Blank pages
- Illogical dates
- Insufficient meta data

# Merck's Key Learnings to Leverage AI

## Technical Process

Be strategic when identifying documents for training, train multiple times, and tweak trainings based on analysis

## Business Process

Utilize conservative estimates, allow time to retrain if needed, and don't take immediate action regarding process or contractual changes

## Business Improvements

Most benefit in expediting contemporaneous management of records



# Future of AI in Clinical Trials

# Future of AI in Clinical Trials: Discussion







Questions?