



## **How Pfizer is Modernizing Its TMF Strategy for Efficiency and Collaboration**

VonDiza Flix, TMF Operations, Sr Manager, Pfizer  
Neha Ramani, Manager, Customer Success, Veeva Systems

# Meet the Speakers

Von'Diza Flix

**Title:** TMF Operations Lead, Sr. Manager

**Organization:** Pfizer



Neha Ramani

**Title:** Manager, Customer Success, Clinical Operations

**Organization:** Veeva Systems

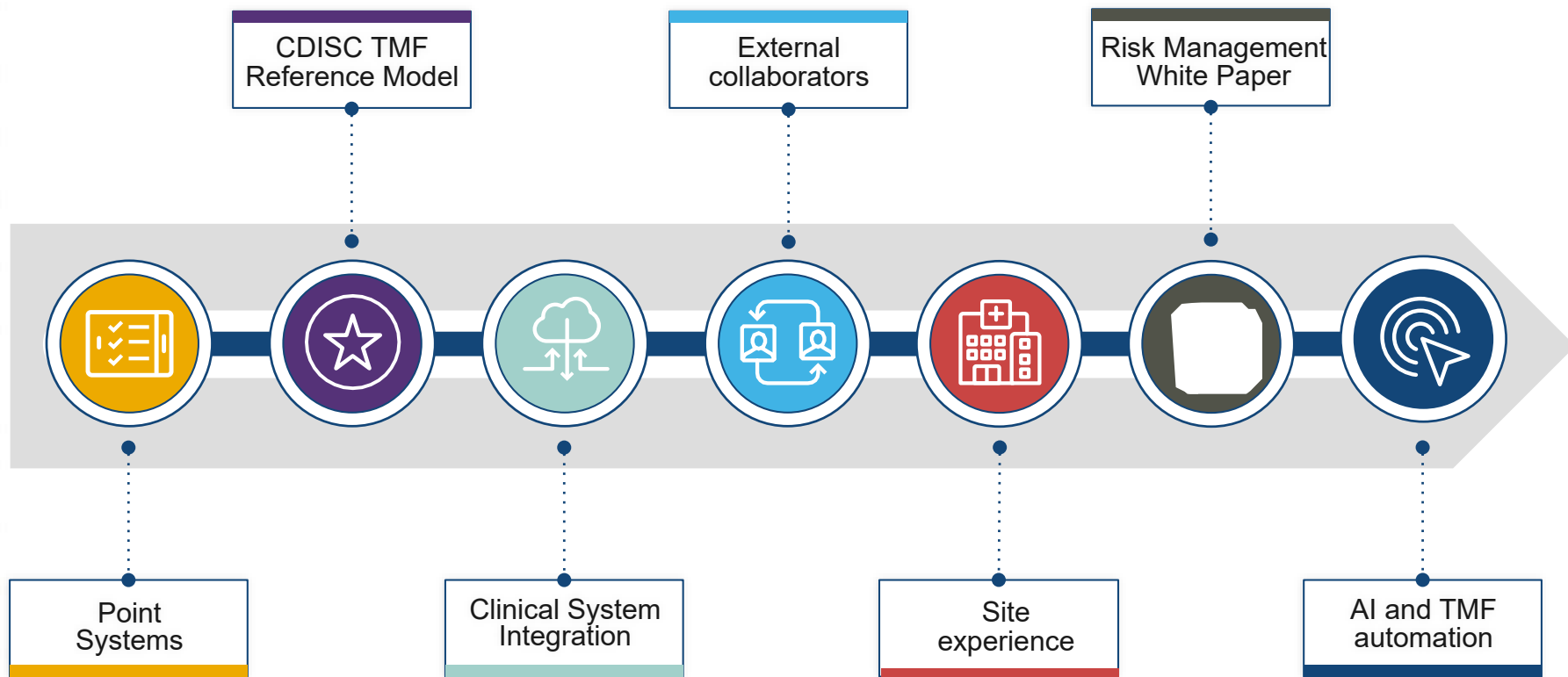




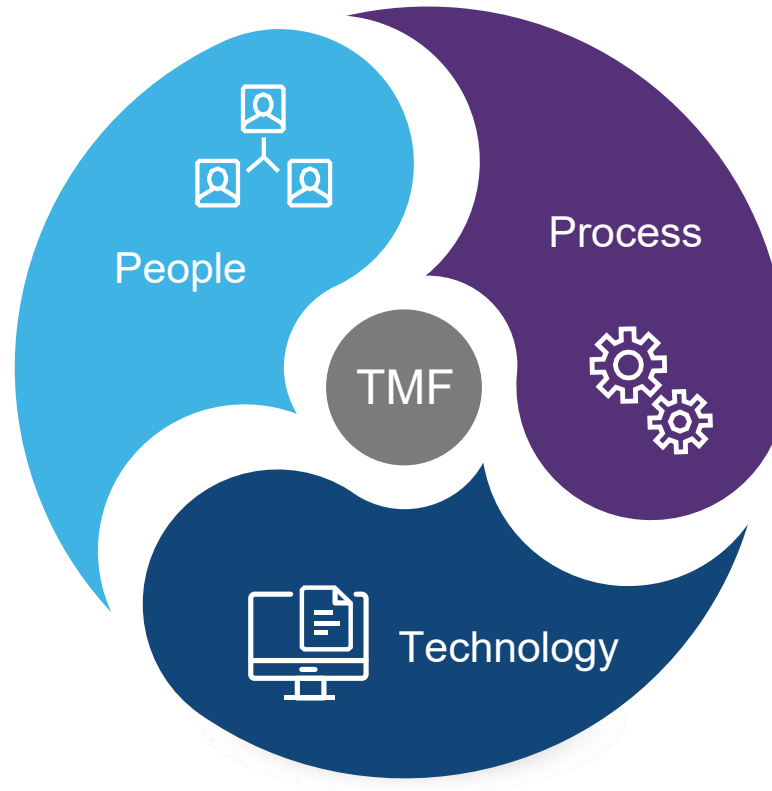
# Disclaimer and Disclosures

The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC or Pfizer.

# Evolution of the TMF Industry and Technology



# Everyone Plays a Role in Improving TMF



# An Integrated Approach to TMF Transformation

## > **People**

Create ideas and drive innovation

## > **Process**

Improve efficiency through collaboration

## > **Technology**

Enable new ways to solve problems and connect people and process



## **Takeaway:**

TMF transformation requires a collaborative effort. Technology helps to improve compliance, and real-time accessibility, and the people and processes drive its success.



# Pfizer's Clinical Transformation Initiative

# Pfizer's TMF Team Manages 400+ Studies



## Unified

TMF operating  
model  
*with CROs working  
in Pfizer system*



## 130+

TMF staff



## 400+

ongoing studies,  
including 50+ from  
acquisition



# Building the Clinical Data and Information Sciences Team



# Goals for Bringing Veeva eTMF into the Landscape

1

## Compliance

Drive better inspection readiness with a centralized system

2

## Approach

Adopt a proactive approach to TMF management

3

## Workflow

Map out document and data flows between people and departments

4

## Unification

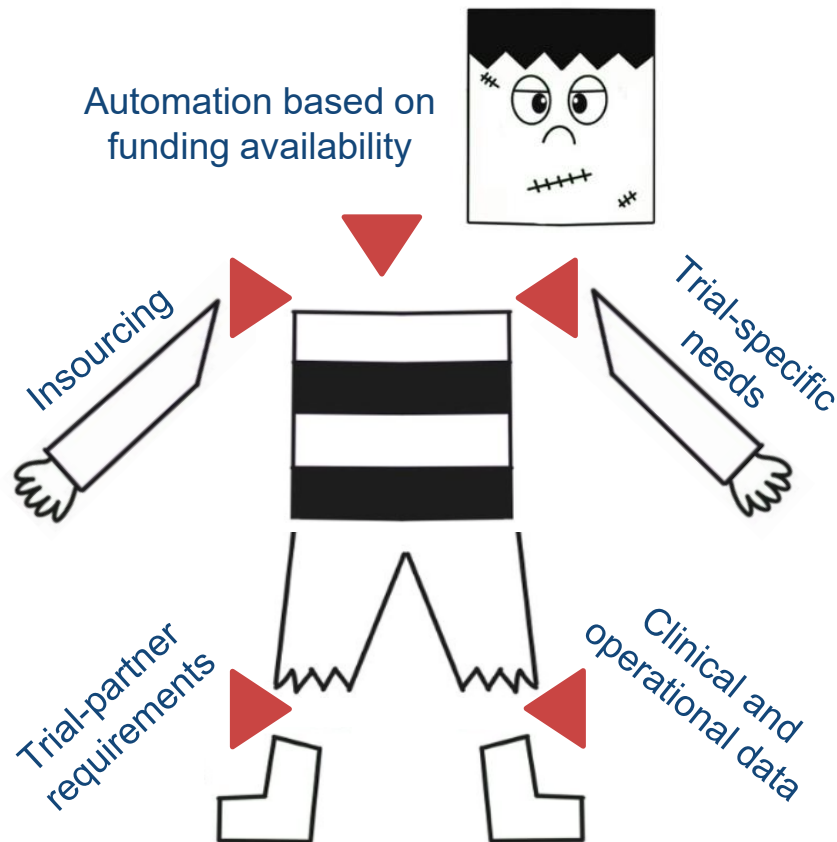
Reduce the number of systems and silos used for TMF management

# Reshaping the Product Development Environment

## History of “Franken-System”:

- Grew from various systems over time
- Built systems for specific, fit-for-purpose needs
- Switched between in-house and outsourced clinical trials
- Required complex point-to-point integrations
- Included 20+ year old systems (end-of-life)

**To operate at the speed of science, we need an integrated data and digital ecosystem.**



# Adapting to New Ways of Working



Educate teams  
to drive  
communication  
and collaboration



Understand risk  
metrics and  
apply risk-based  
thinking



Allow TMF system  
to drive process  
for entering trial  
events

# 50+

core and cross-  
functional members of  
CDOS team

# Setting the Foundation with CDISC TMF RM

## Foundation

**Simplifying 800+ document types based on TMF Reference model**

- Transitioning the TMF from a passive to proactive model
- Understanding the value of TMF metadata
- Revisiting TMF health metrics and enhancements

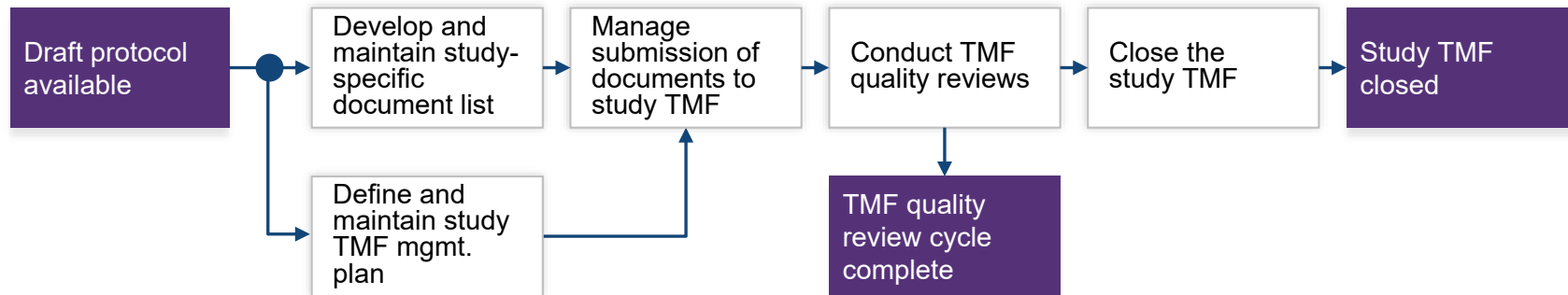
## People

**Connecting data to document with accountability**

- Moving toward holistic study planning
- Focusing on collaboration for a successful unified ecosystem
- Elevating the concept of data stewardship at organizational-level

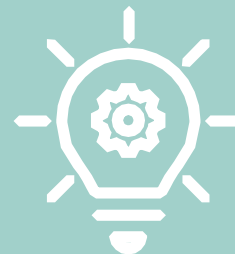
# Identifying Gaps and Areas to Simplify

## Example Process Map:



# Next Steps in TMF Transformation

- **Implementation planning**  
including identifying additional ways to streamline site document exchange
- **Maturing the TMF function**  
including increasing processes within the system
- **Elevating the value of TMF**  
across the organization
- **Sharing Knowledge**  
as a community helps us work smarter



## Takeaway:

Fully leveraging technology and TMF process improvements can save critical site time and ultimately enable us to serve our patients better.

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Questions?





**Thank You!**

