



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

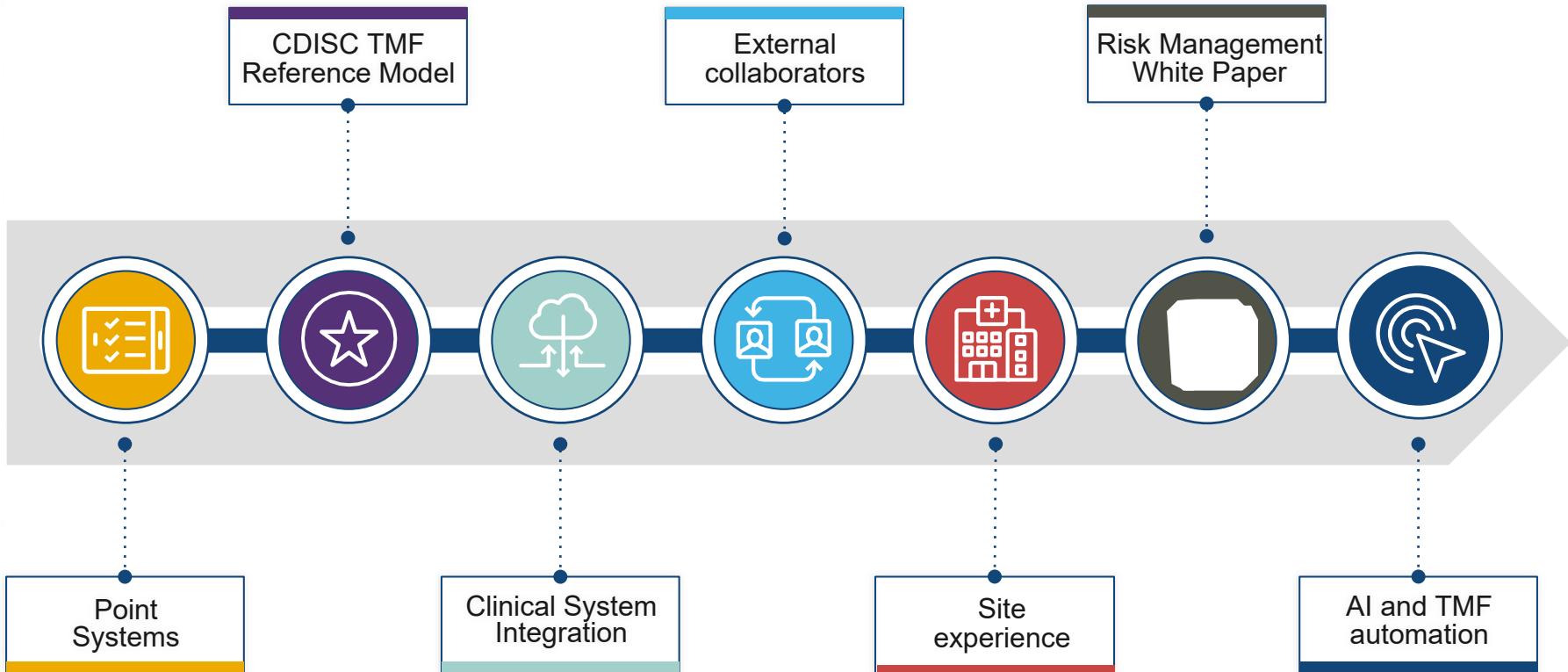
Title: Manager, Customer Success, Clinical Operations

Organization: Veeva Systems

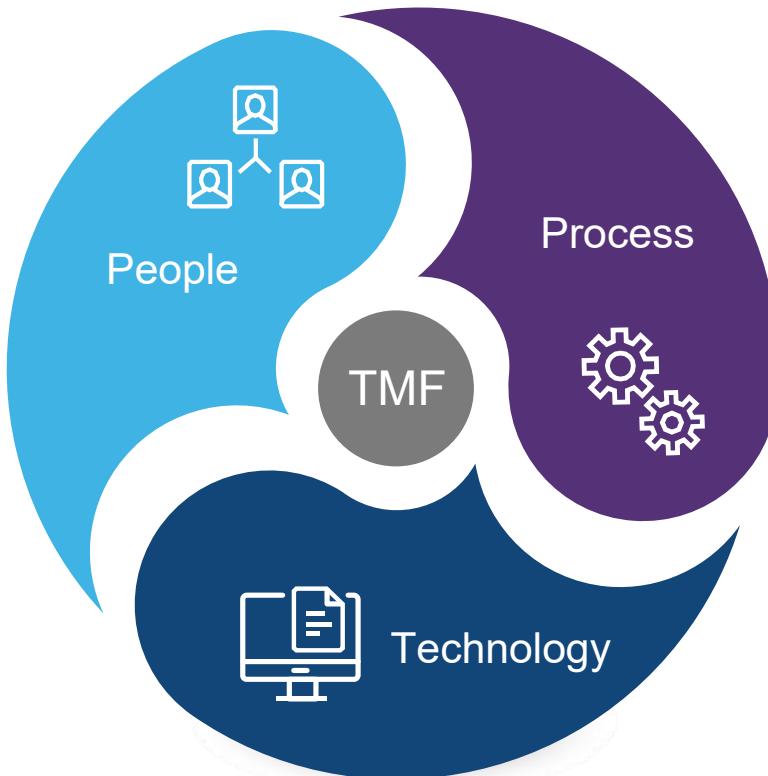
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Evolution of the TMF Industry and Technology



Everyone Plays a Role in Improving TMF



An Integrated Approach to TMF Transformation

> People

Create ideas and drive innovation

> Process

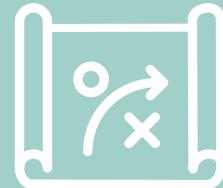
Improve efficiency through collaboration

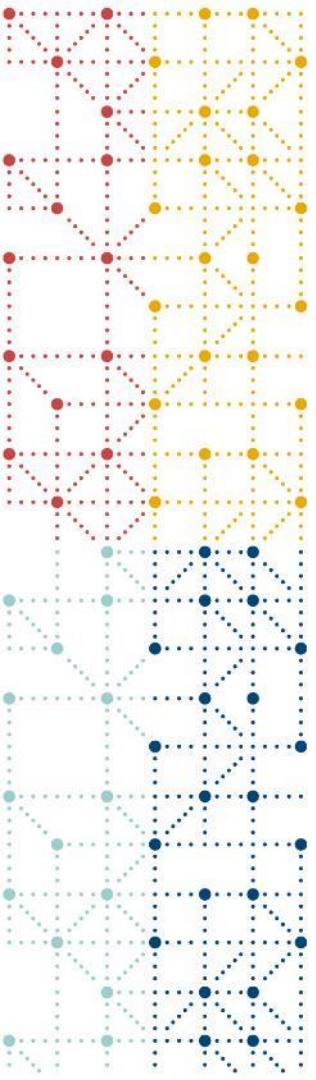
> Technology

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+

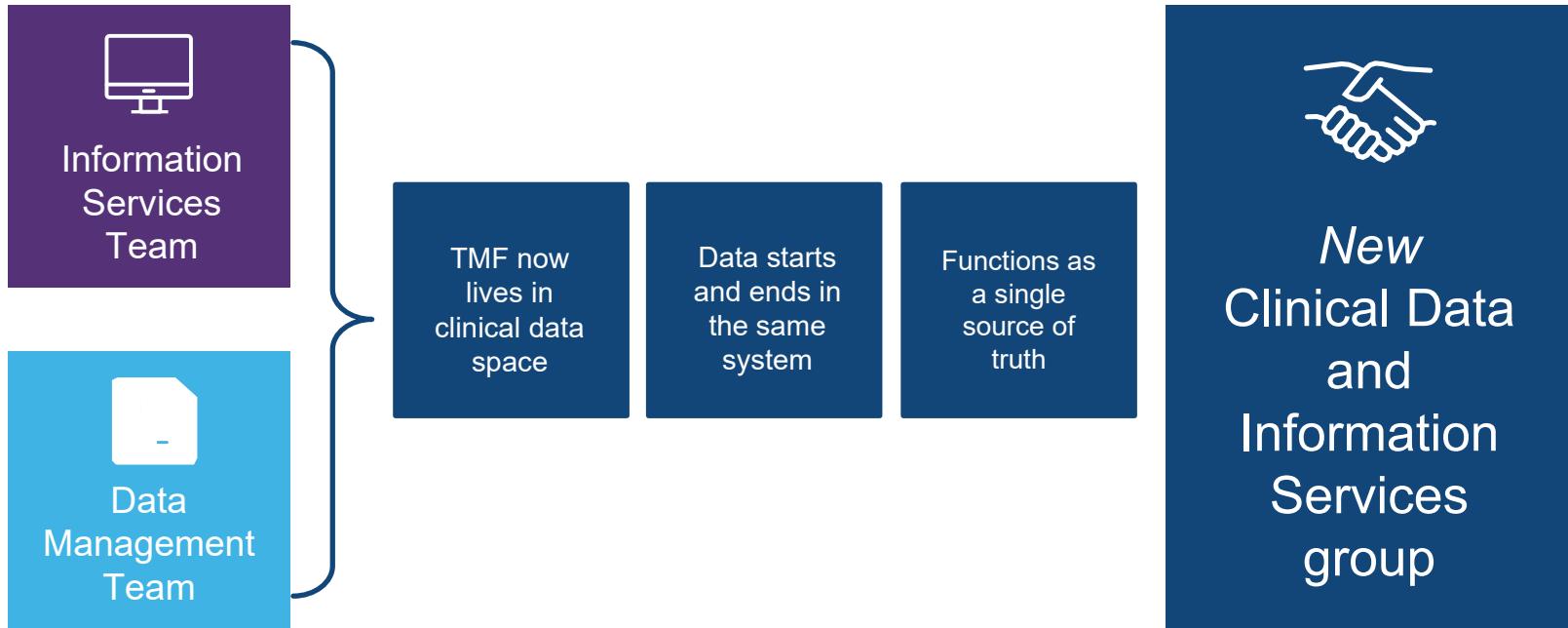
TMF staff

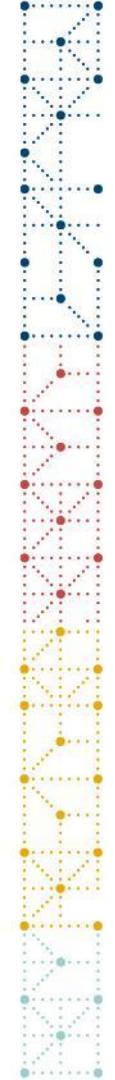


400+

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

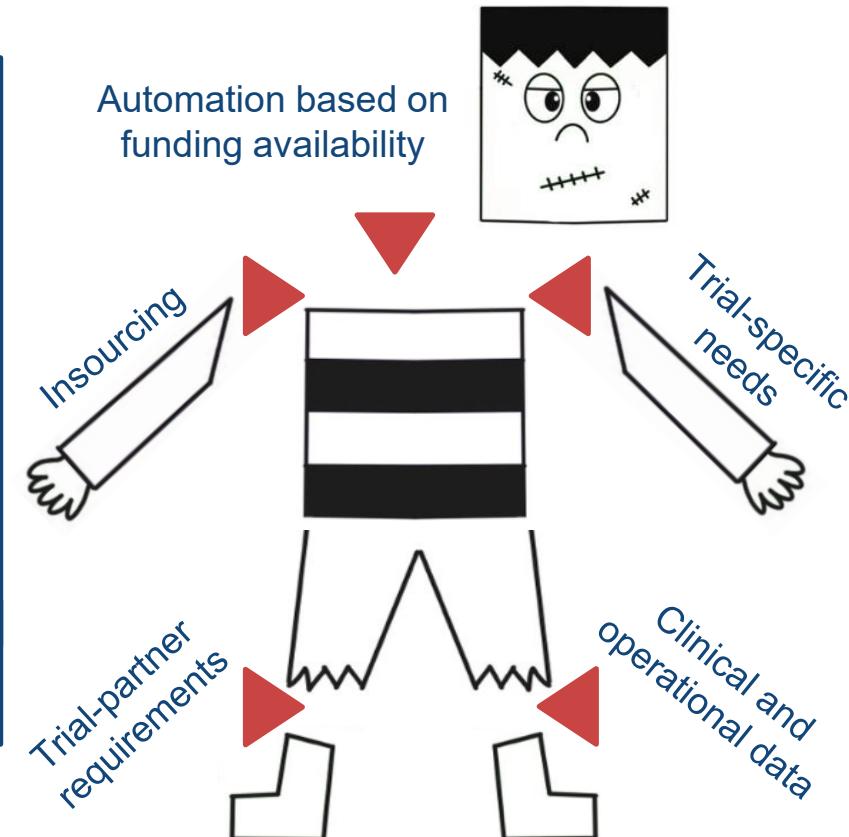
Reshaping the Product Development Environment

History of “Franken-System”:

- Grew from various systems over time
- Built systems for specific, fit-for-purple 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.

Automation based on funding availability



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

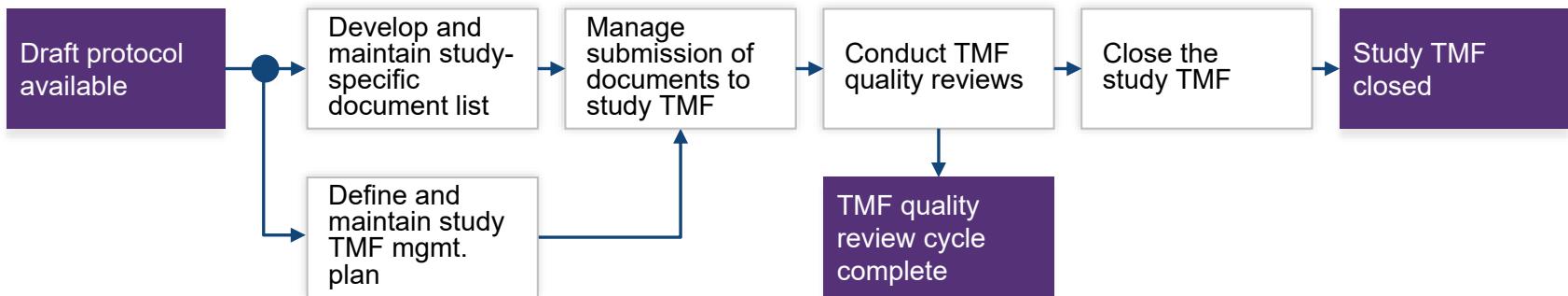
People

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:



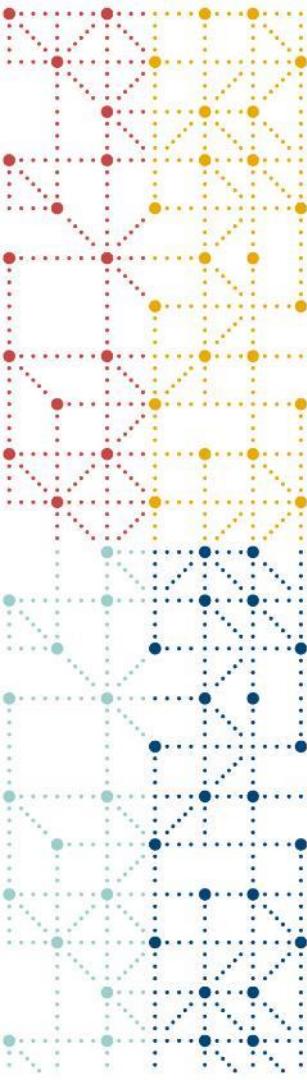
Next Steps in TMF Transformation

- › **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

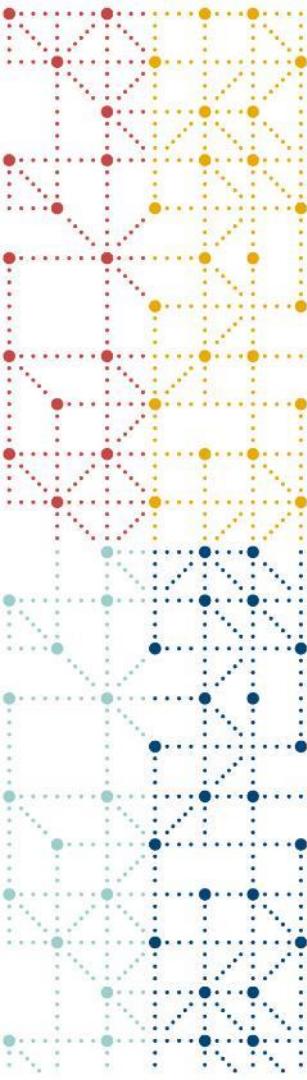


Takeaway:

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



Questions?



Thank You!

