

# Changing Operating Models for Simplicity and Connectivity

Leila Canlas  
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**Guide your vision by  
thinking outside of  
the box.**

# Understanding Pfizer's Clinical Transformation Initiative

## Seagen Acquisition Offers an Opportunity

### Takeaway:

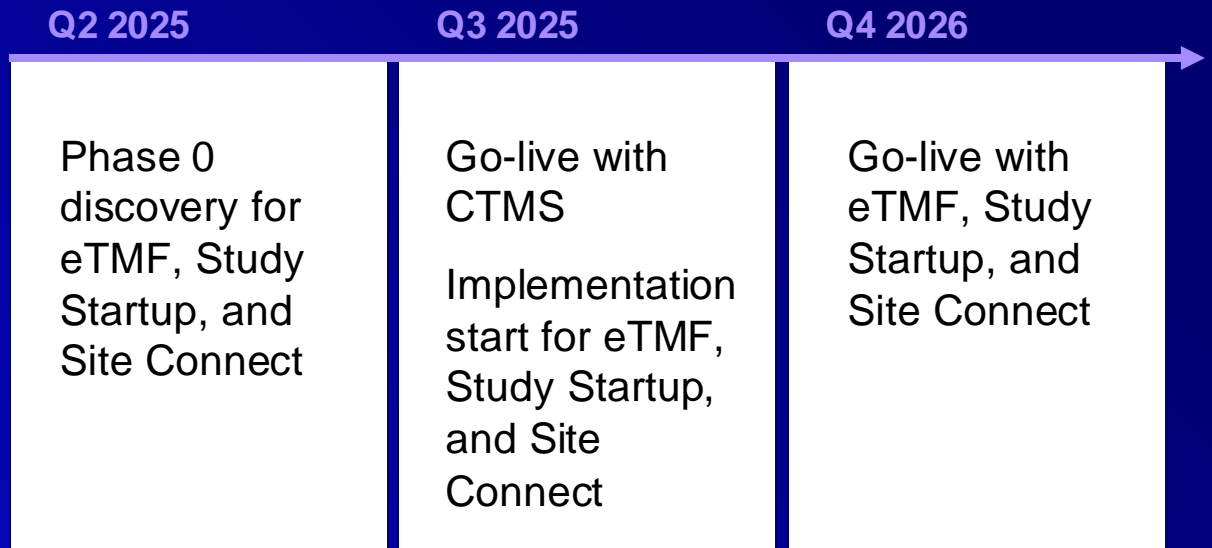
An acquired company can identify opportunities for efficiency and simplicity.



# Clinical Transformation Is Underway

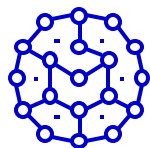
## Expected Outcomes:

- **Landscape simplification:**  
50% reduction in systems and 80% reduction in integrations
- **Effort reduction:**  
70% reduction in documents filed manually
- **Improved site engagement:**  
one system for sites and Pfizer, including streamlined document exchange



# How TMF Shapes the Initiative

# Pfizer's TMF Team Manages 400+ Studies



## Unified

TMF operating  
model  
*with CROs working in  
Pfizer system*



## 100+

TMF staff



## 400+

ongoing studies,  
including 50+ from  
acquisition

# Key Drivers for TMF Transformation

## Expected Outcomes:

- **75% reduction**  
in hours spent filling documents manually
- **15% reduction**  
in hours spent on QC
- **Improved collaboration**  
visibility, and real-time access
- **Increased in-system processes**  
including collaborative authoring of project, study, and clinical monitoring plans
- **Standardized approach**  
between Seagen's legacy, mixed-model studies and Pfizer's ongoing studies

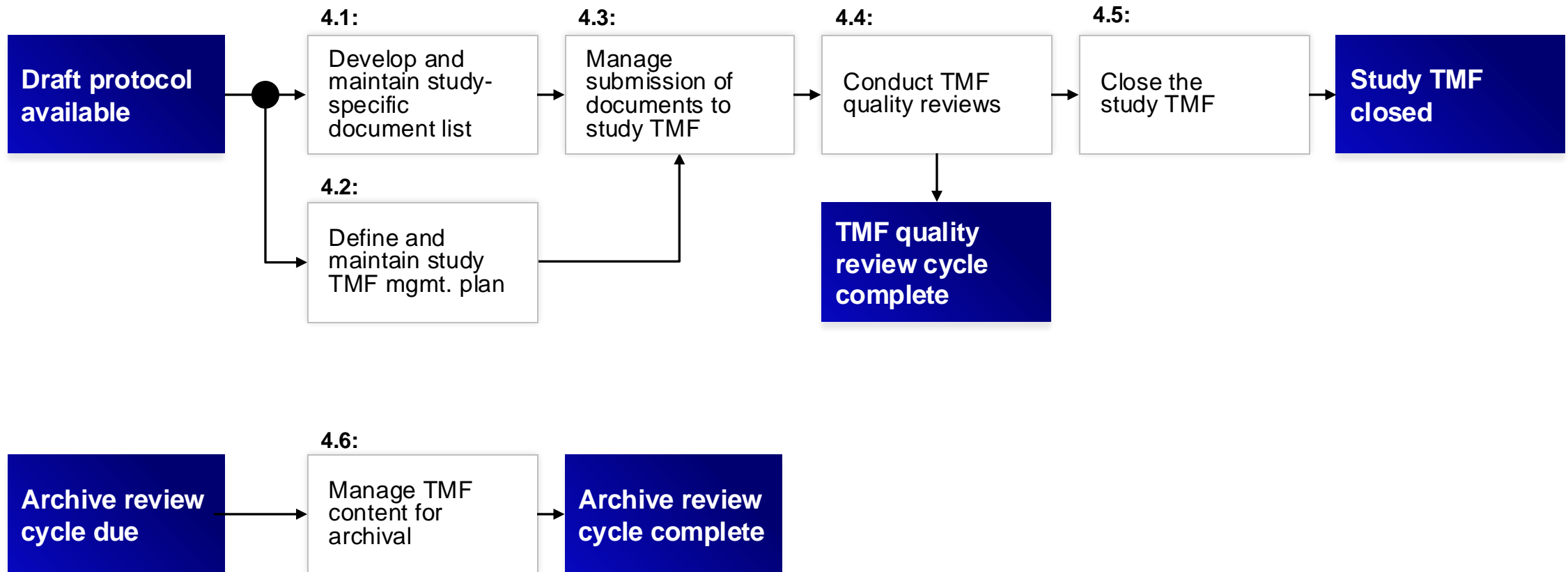
## Takeaway:

We have an opportunity to standardize across the portfolio, leverage new automation, and increase active TMF processes.



# 1. Identifying Gaps and Areas To Simplify With Process Mapping

## Example Process Map:



## 2. Using the TMF Reference Model V4 to Influence Change

### The revised TMF Reference Model supports:

- **Reducing 600+ legacy document types**
- **Encouraging increased adoption of risk-based processes,**  
including explicitly in SOPs

### Takeaway:

We are evolving our operating model with the backing of industry standards to increase strategic TMF decision-making.

### 3. Encouraging a Team Mindset Among TMF Leaders

Insights from recent trip to Wuhan, China:

1

**Take opportunities to socialize concepts with global leaders**, including the TMF Reference Model and innovative risk-based approaches.

2

**Invest in relationships between TMF business process and IT leaders** for a shared understanding of engineering systems to meet industry regulations.

3

**Recognize that fostering a healthy team dynamic across time zones requires proactivity.**

# Next Steps

# 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

## Takeaway:

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

# Tips to Increase TMF Influence at Your Organization

**1**

**Participate in the TMF Community**

**2**

**Stay up-to-date on industry best practices and inspection expectations**

**3**

**Embrace continuous learning**

**4**

**Know the key leaders and their functions**

**5**

**Remember who's on the other side – OUR PATIENTS!**

# Thank You

