
# A Risk Based Approach for Determining How to Manage the TMF for Different Types of Studies

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# Meet the Speakers

## Rebecca Halbur

Title: Assoc. Director, TMF Records Management

Organization: Moderna

Rebecca Halbur: Rebecca Halbur is the Associate Director of TMF Process at Moderna. Her 14+ years of TMF experience spans both sponsor and CRO and includes various TMF models and oversight including document processing, people management, and systems. She has also setup and navigated the complex global TMF environment of implementing and migrating new systems, training global teams, and implementing bespoke QC processes. She has participated in inspections with several regulatory agencies including MHRA, FDA, Health Canada, EMA and PMDA. She holds a BSc in Biology from North Carolina State University and Master of Liberal Arts in Sustainability from the Harvard Extension School.

## Rebecca Reel

Title: Senior Manager, TMF and Records Management

Organization: Biogen

Rebecca Reel is a Senior Manager in TMF and Records Management at Biogen. Her 10 years in biotechnology have included roles in biotech library and research services, IT, and TMF. She has implemented and validated a new eTMF system, planned and managed data migrations, and designed new processes and system configurations for a variety of types of TMFs. She holds an MSIS in Information Studies from the University of Texas at Austin.

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- *The views and opinions expressed in this presentation are solely those of the authors and do not necessarily reflect the official policy or position of CDISC or of their organizations*

- *The author(s) have no real or apparent conflicts of interest to report.*

# Agenda

1. Identify and define what types of TMF could follow a risk-based approach
2. Document and configure
3. Socializing your risk-based TMF setup

# Planning for the unplanned

How do you define what types of studies go into your eTMF system?

How can you be agile in your resourcing and processes when unplanned work comes to you?

# From the National Institute of Health (NIH)

## Does Your Human Subjects Research Study Meet the NIH Definition of a Clinical Trial?

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Learn more

**Answer the following four questions to determine if your study is a clinical trial:**

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

**Your study is considered to meet the NIH definition of a clinical trial even if:**

- Your study uses healthy participants, or does not include a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study utilizes a behavioral intervention
- Your study uses an intervention for the purposes of understanding fundamental aspects of a phenomenon (See more information about Basic Experimental Studies with Humans).

**Your study is NOT considered to meet the NIH definition of a clinical trial if:**

- Your study is intended solely to refine measures.
- Your study involves secondary research with biological specimens or health information.

# Where might you find some of these gray areas?

- Epidemiological Studies
- Post Authorization Safety Studies
- Expanded Access Programs
- Translational Research Studies
- Pregnancy Registries

# It’s probably time for some landscaping…

- How does your quality group define what constitutes a TMF?
- How do your functions define a TMF?
- How does your team define it?
- How does your record management group define it?

- How do **you** as a TMF professional define it?

# Two technology roads…

## Validated Repository

- Pros
  - Fit for purpose
  - Less resource required for system config.
  - More flexibility around variations with documentation
- Cons:
  - Inconsistent filing methodologies
  - You may need to acquire one

## Existing eTMF System

- Pros:
  - You may already have one if you're sitting here
  - More familiar user base
  - May be more comfortable with your quality group
- Cons:
  - Need to create special configs, or work with existing configs which may be cumbersome
  - Some resource burden may still sit with TMF team
  - Could impact your metrics with irrelevant data
  - More complicated system for what is needed (i.e. not fit for purpose)

# So, you've cut your grass… what's next?

Understand your options

Formulate a plan

# Example Approach to Implementation

- Analysis:
  - Internal TMF team researched industry and regulatory information about ‘non-standard’ studies
  - Formed position on what could be done with existing resources, both system configurations and personnel
- Socialization:
  - Presented ideas to departmental leadership and proposed a pilot approach with two TMFs
  - Developed rapport with study management team and pitched the idea
- Configuration:
  - Updated SOP and system set up options
  - Continually documenting and finding the consistent areas in inconsistent study design

# How do you move forward?

- Define your process in your SOP
  - Create WI around it, but try not to overengineer – you're creating classifications for these studies based on their risk level and so you shouldn't have to accommodate every nuance
  - Consider a decision tree
  - Avoid using organizations/departments to define your criteria
- Get your stakeholders on board
  - Continue the change management.
  - Share your logic and plans and understand how this might impact them.
  - Consult with them prior to rollout.
- Use internal audits to your benefit for improved quality

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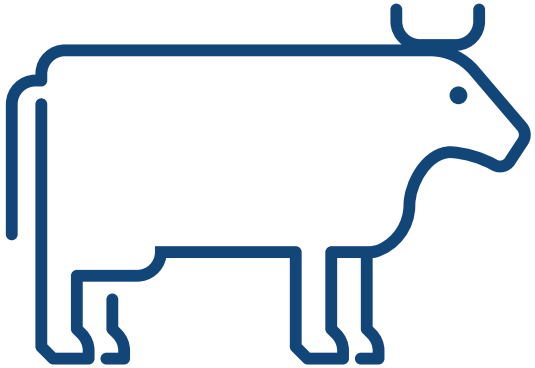
# What if I don’t?



- You spend precious resources doing non-value add work to check a box
- People don’t know what they’re doing
- Functions point to processes for the standard that they can’t possibly fulfill
- Paving the cow paths

# Remember…

- Be flexible and create a space to do something that makes sense
- Technology is allowing trials to continuously evolve and they're not always going to fit a perfect mold
- Outline your logic and document your process

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# Thank You!