

# Computerised System Records and the TMF Prepared for TMF SM V1 Initiative

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**Computerised System Records and the TMF**  
**Prepared for TMF SM V1 Initiative**

Presented by Jennifer Arters, Principal Consultant, Epista Life Sciences &  
Jennifer Peacock, Associate Director, TMF Process & Systems, Biogen

# Meet the Speakers

Jen Arters

**Title:** Clinical Principal Consultant

**Organization:** Epista Life Science

Passionate business leader with a background in system implementations, computer system validation, business process optimization, technology transformation, data migrations, operational excellence, and digital innovation.



Jen Peacock

**Title:** Associate Director, TMF Process & Systems

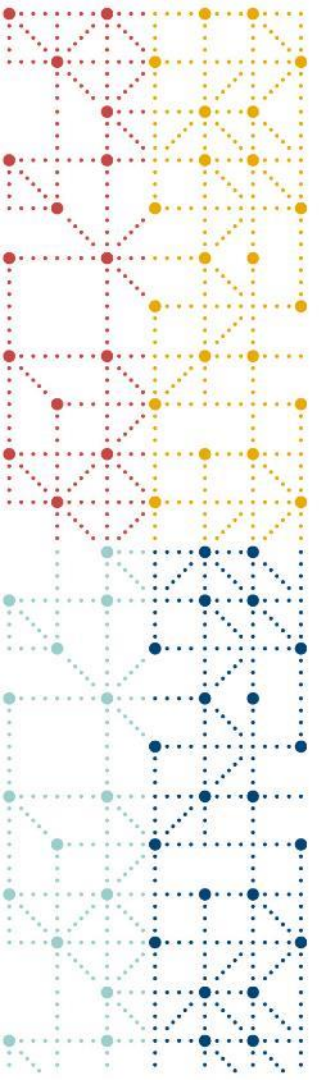
**Organization:** Biogen

Champion of process improvement with a background in life sciences, clinical trial technology, system implementations, full-scale data migrations, and business process optimization.



# 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.*



# Agenda

- Where did we start?
- The Journey
- Where are we now?
- Where do we go next?

# Word Cloud

- Mentimeter - <https://www.mentimeter.com/>
  - Code – 3283 4060







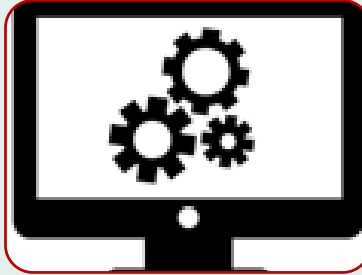
**Where did we  
start?**

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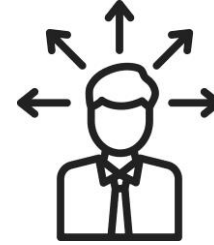
# The Problems



Not  
enough  
record  
types



System  
scope is  
limited



Insufficient  
regulatory  
and  
industry  
guidance



# What do we need?

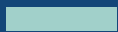
Scope  
Guidance

New Record  
Types

Metadata  
Standards

Robust  
Filing  
Framework

Systems  
Inventory  
Template



# The Journey



# Word Cloud

- Mentimeter - <https://www.mentimeter.com/>
  - Code – 5616 2341



# Round Table Discussions

## QA

- Showing control over systems and oversight throughout the trial.
- Clear definitions by record type and system type.
- Guidance for CROs and sponsors around inventory for inspections/auditors.

## TMF

- System categorization
- Might sponsor oversight change?
- Document scope goes beyond validation.
- Leverage GAMP ranking.

## Information Technology

- Systems Listing that details system details for each trial.
- Remove the silo between IT and Clinical.
- Assess other zone records to ensure no duplication.
- Trial document and not enterprise system records.

# Committee Feedback

How can we show the evidence of the record types without making the record type bucket too large? For example; when we say “executed user acceptance tests” are we placing that in an evidence category and storing the approved test case in another location?

This is a very exciting journey to have all our trial specific IT records in one location.

I like that we are defining the needs for the requirement to store system details in the eTMF.







**Where are  
we now?**



# Multiple Paths Forward

- Remove redundancy and ambiguity
- Improve searchability
- Challenge the current zone-specific paradigm

## TMF RM Structure



- Standardized list of core systems
- Owning Functional Area
- System Owner
- System Type

## Core Metadata

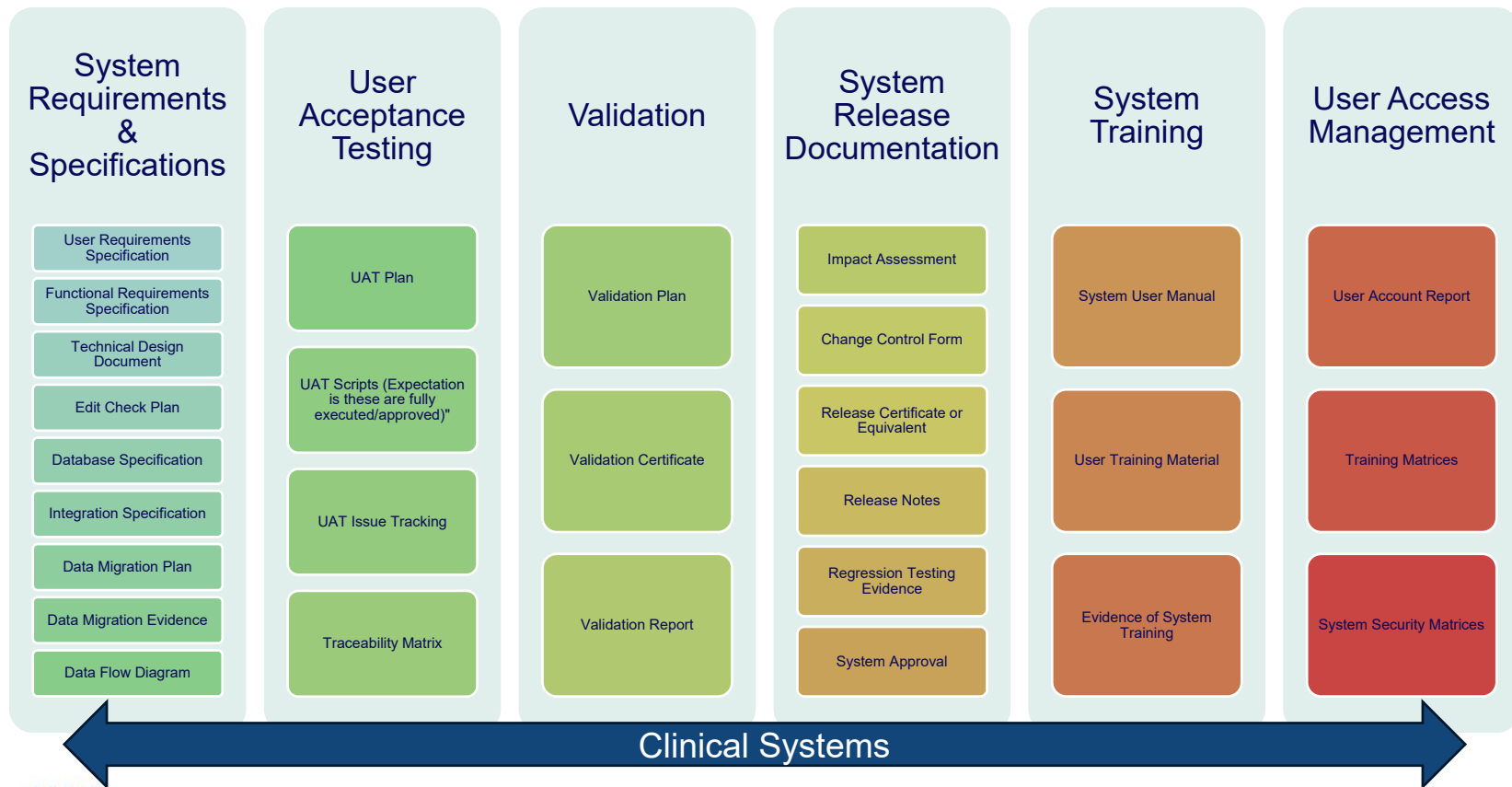


- Requirements and Specifications
- Testing and Validation
- Release Management and Change Control
- Training and User Access Management

## Proposed Collections



# Possible Record Types: An Example



A photograph of a wooden signpost pointing to the right, standing at a fork in a gravel trail. The trail splits into two paths that lead into a dense forest of evergreen trees. The scene is bright and sunny, with green grass and small plants growing along the edges of the path. The signpost is made of light-colored wood and is mounted on a vertical post. The background is filled with tall, dark green evergreen trees under a clear sky.

**Where do we  
go next?**

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# Next Steps



MEETINGS WITH  
ZONE COMMITTEES



CDISC CHANGE  
BOARD



DRAFT GUIDANCES  
AND TEMPLATES



[Volunteer | CDISC](#)

# CALL TO ACTION





# Thank You!

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