

# 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.

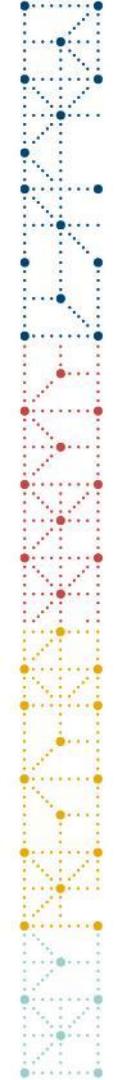


## Jen Peacock

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

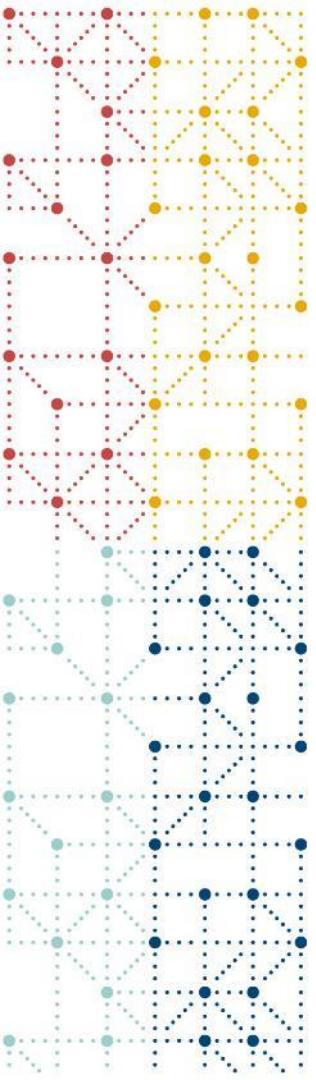
**Organization:** Biogen

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

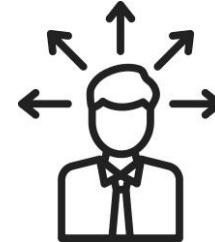
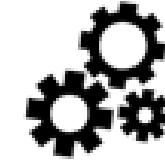




# Where did we start?

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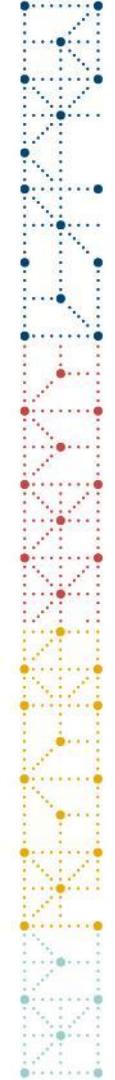
# The Problems



Not  
enough  
record  
types

System  
scope is  
limited

Insufficient  
regulatory  
and  
industry  
guidance



# What do we need?

Scope  
Guidance

New Record  
Types

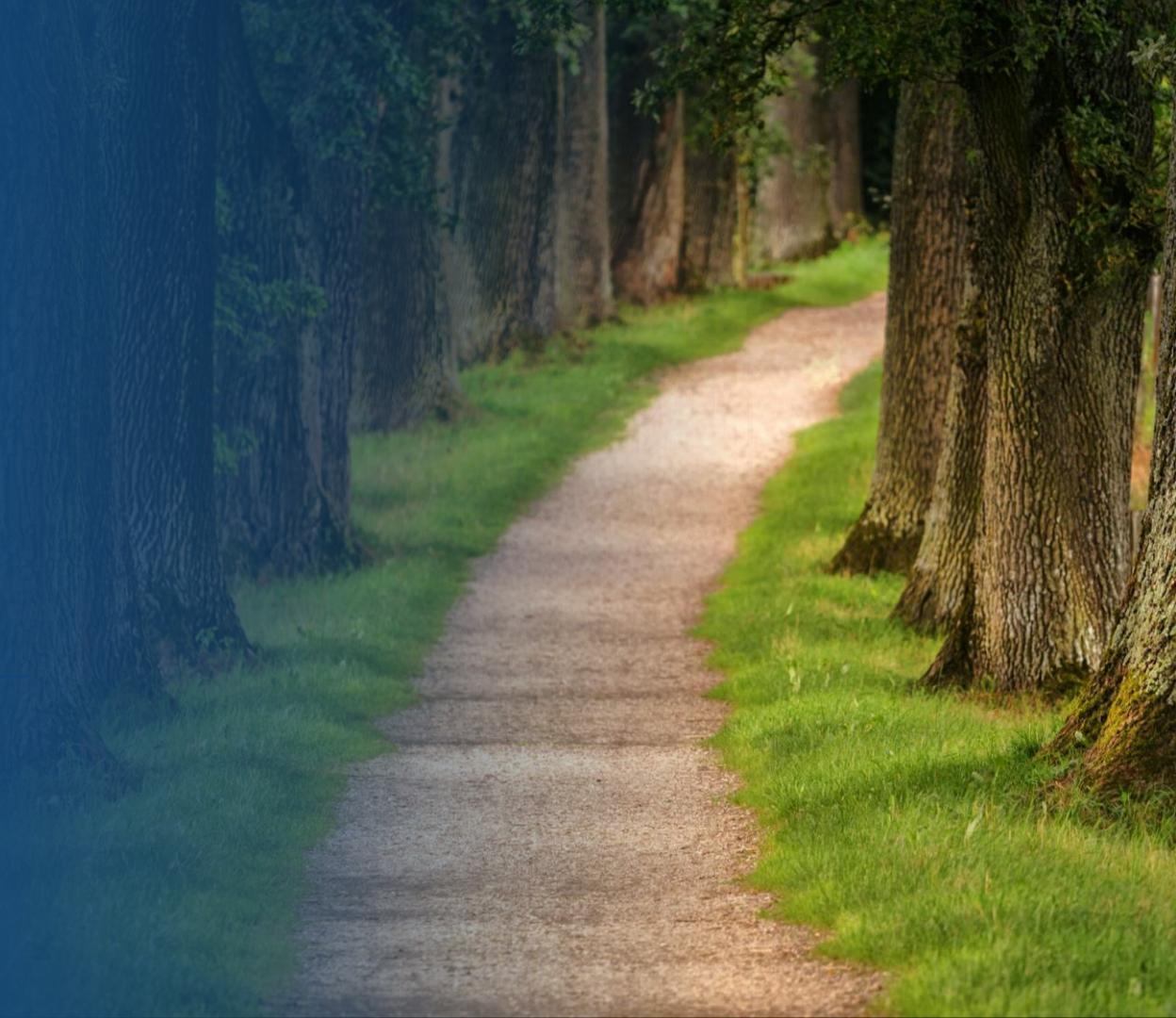
Metadata  
Standards

Robust  
Filing  
Framework

Systems  
Inventory  
Template



# The Journey



# Word Cloud

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



# Round Table Discussions

## QA

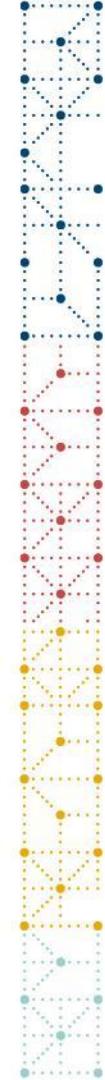
- Showing control over systems and oversight throughout the trial.
- Clear definitions by record type and system type.
- Guidance for CROs and sponsors around inventory for inspections/auditors.

## 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.

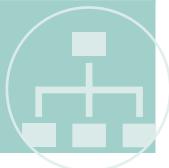


Where are  
we now?

# 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

## System Requirements & Specifications

- User Requirements Specification
- Functional Requirements Specification
- Technical Design Document
- Edit Check Plan
- Database Specification
- Integration Specification
- Data Migration Plan
- Data Migration Evidence
- Data Flow Diagram

## User Acceptance Testing

### UAT Plan

UAT Scripts (Expectation is these are fully executed/approved)"

### UAT Issue Tracking

### Traceability Matrix

## Validation

### Validation Plan

### Validation Certificate

### Validation Report

## System Release Documentation

- Impact Assessment
- Change Control Form
- Release Certificate or Equivalent
- Release Notes
- Regression Testing Evidence
- System Approval

## System Training

### System User Manual

### User Training Material

### Evidence of System Training

## User Access Management

### User Account Report

### Training Matrices

### System Security Matrices

Clinical Systems



# Where do we go next?

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# Next Steps



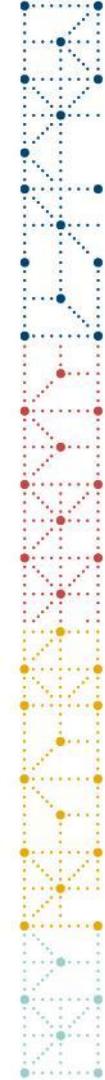
MEETINGS WITH  
ZONE COMMITTEES



CDISC CHANGE  
BOARD



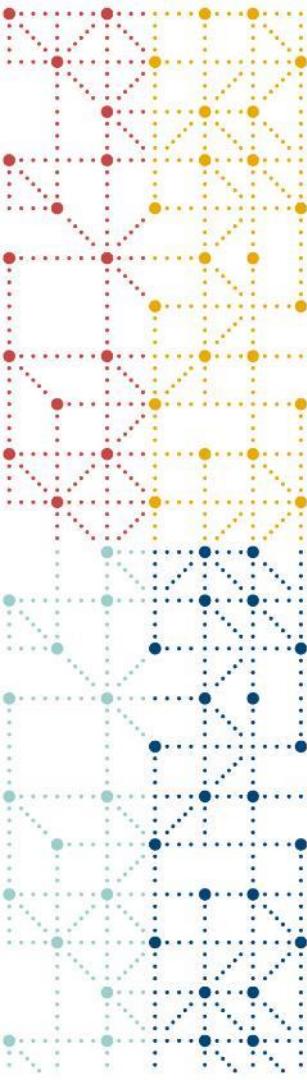
DRAFT GUIDANCES  
AND TEMPLATES



Volunteer | CDISC

# CALL TO ACTION





# Thank You!

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