



2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

eClinical Systems Has Entered the Chat

Jennifer Peacock, Assoc. Dir., TMF Systems and Process, Biogen

Agenda

1. Introduction
2. Structure
3. Metadata
4. Next Steps

Speaker



Jennifer Peacock is the Associate Director of TMF Systems & Process at Biogen, with extensive experience driving innovation and compliance in clinical trial documentation. With a strong background in Trial Master File (TMF) strategy and clinical trial systems implementation and optimization, she plays a key role in shaping efficient, inspection-ready TMF processes. Outside of her career, she enjoys a good book, strong coffee, and camping with her husband, two kids, and dog.

Jennifer Peacock

Assoc. Director, TMF Systems and Process
Biogen



Disclaimer

The content of this presentation reflects my personal views and does not represent the official position of my employer, its affiliates, or its stakeholders.



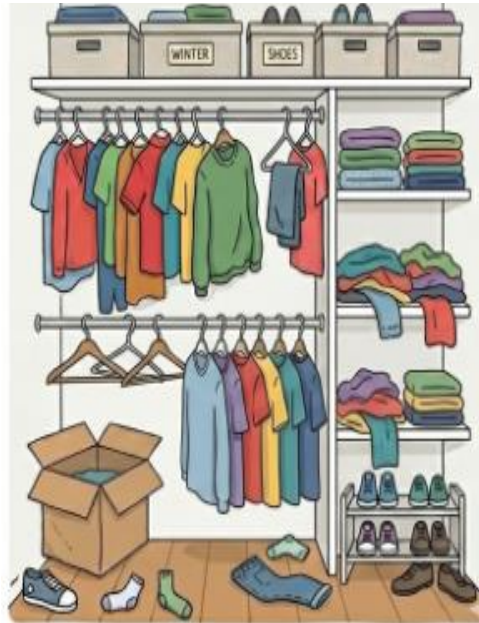
Introduction

The Why

Best Laid Plans...



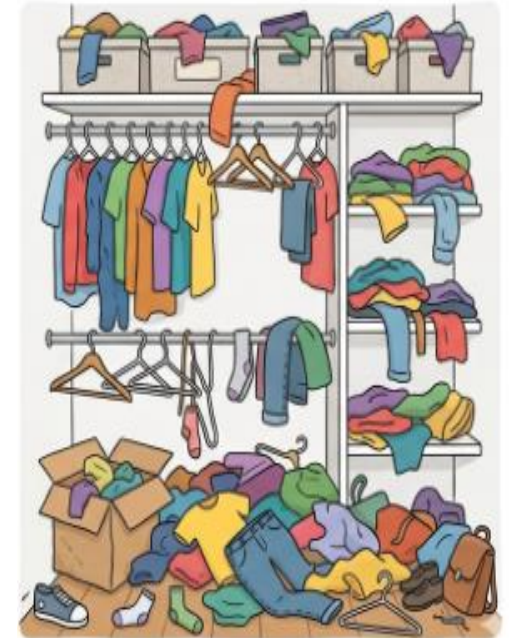
The Vision



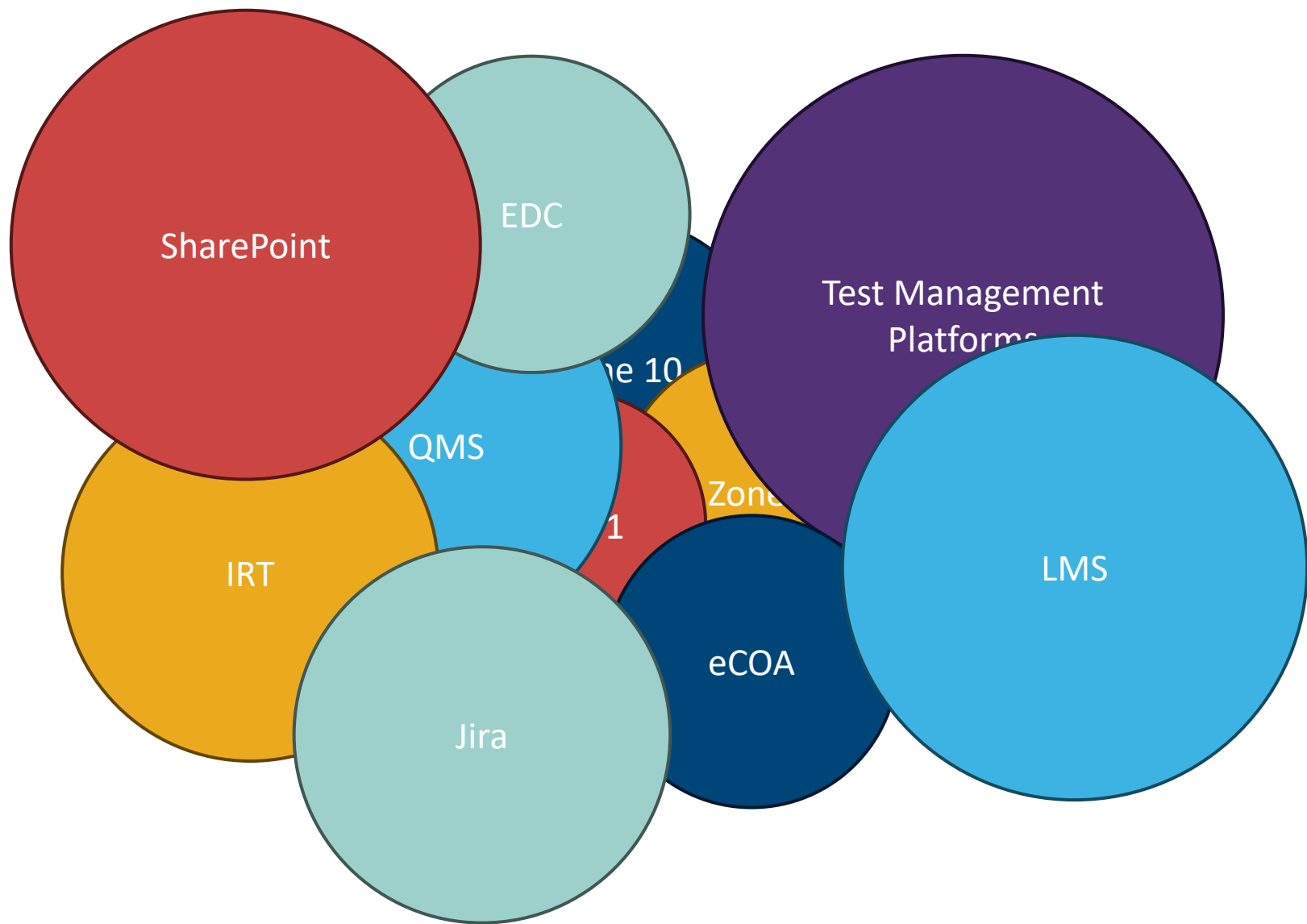
Then a few things happen



... and a few more



How it turns out





The Forgotten Pillar: eClinical Systems

- **Siloed Organizational Responsibilities**
- **Traditional Paper-Based Legacy**
- **Focus on Content over System Controls**
- **Vendor vs. Sponsor Responsibility Gap**
- **Lack of Explicit eTMF Reference Model Mapping**
- **Complexity of Digital Network**

Zone 12: eClinical Systems

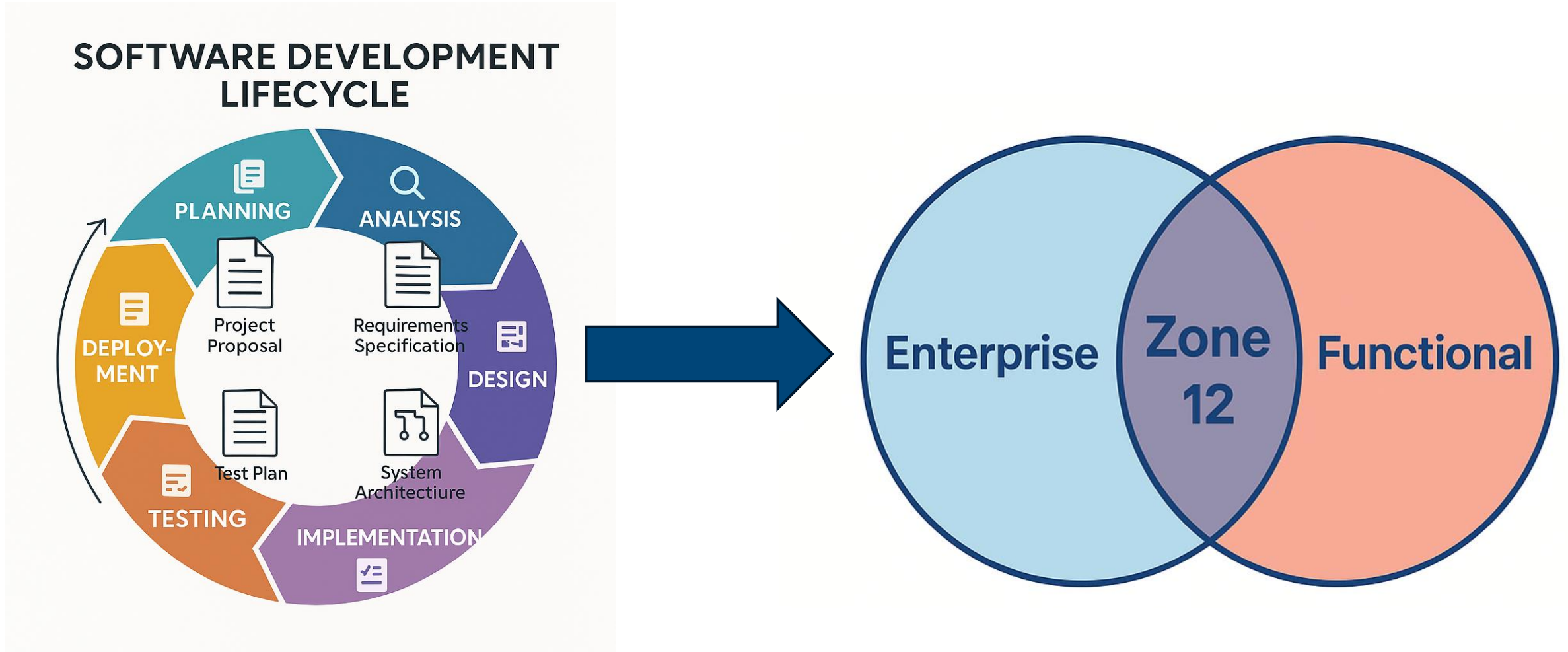




Structure

The What

To be in Zone 12 or not to be in Zone 12...



Record Groups



SYSTEM REQUIREMENTS
AND SPECIFICATIONS



VALIDATION



SYSTEM MAINTENANCE



SYSTEM TRAINING

Zone 12 Record Groups and Record Types

System Requirements and Specifications

- Plan
- Specification / Requirements
- Technical Description
- Traceability Matrix
- Test Scripts
- Test Evidence

Validation

- Validation Risk Assessment
- Report
- Certificate of Validation
- Oversight Evidence
- Audit Trail
- Audit Trail Review
- System Inventory

System Maintenance

- Change Control

System Training

- User Manual
- System Training
- Training Evidence

Putting the FUN in FUNctional

- Is your document an output of the SDLC?
- Is your document trial-specific?
- Is your document a function-specific output?





Metadata

The How

Much Ado About Metadata



- Classification
 - F(indable)AIR
 - A(tributable) LCOA+
- Traceability
 - System Lineage
 - Integrations
- Transparency
 - Change Control
 - Oversight

Metadata Examples

System Type

- EDC
- IRT
- CTMS
- ePRO
- DCT
- Wearables
- Integration

Plan Type

- Design
- IQ/OQ
- UAT
- Data Migration
- Integration
- Validation

Specification/ Requirements Type

- Design
- Installation
- Functional
- Non-Functional
- User Requirements



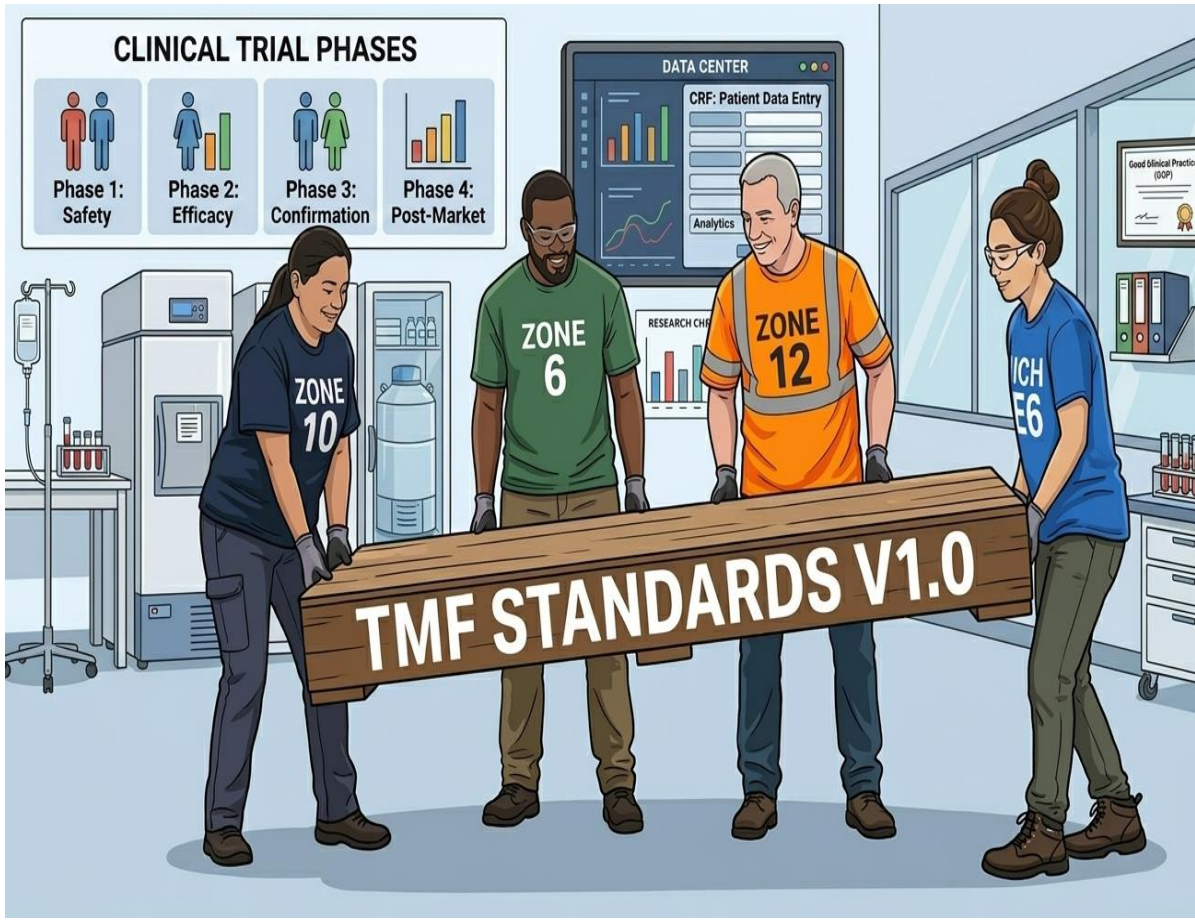
Next Steps

Next Steps

- Establishing the "Golden" Values
- Harmonization with SM v1.0
- System Integration Mapping
- Governance & Stewardship
- The Blueprint for Scale



It Takes a Village



- Zone 10
- Zone 6
- ICH E6 R3



Thank You!

Jennifer Arters
Lori Braun
Cat Hall
Nick Hargaden
Tara Morris
Paige Mucha
Curran Murphy
Hugh O'Neill

Jennifer Peacock
Olga Radyushkina
Chad Scribner
Chris Shea
David Weinstein
Clare Whitehouse
Shiva Yadlapalli



Questions?

