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# 2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

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## Shaping Zone 10 for Tomorrow's Data Governance
## A Collaborative Approach to TMF Standard v1.0

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# Speakers

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# Agenda

1. The Team and the Journey
2. Why Zone 10 needed a change
3. The game changer: the eCLinical System zone
4. Data-related vs Systems-related records
5. How we are reshaping Zone 10
6. Benefits, challenges and lessons learned
7. Next steps and community feedback

# The team & the journey

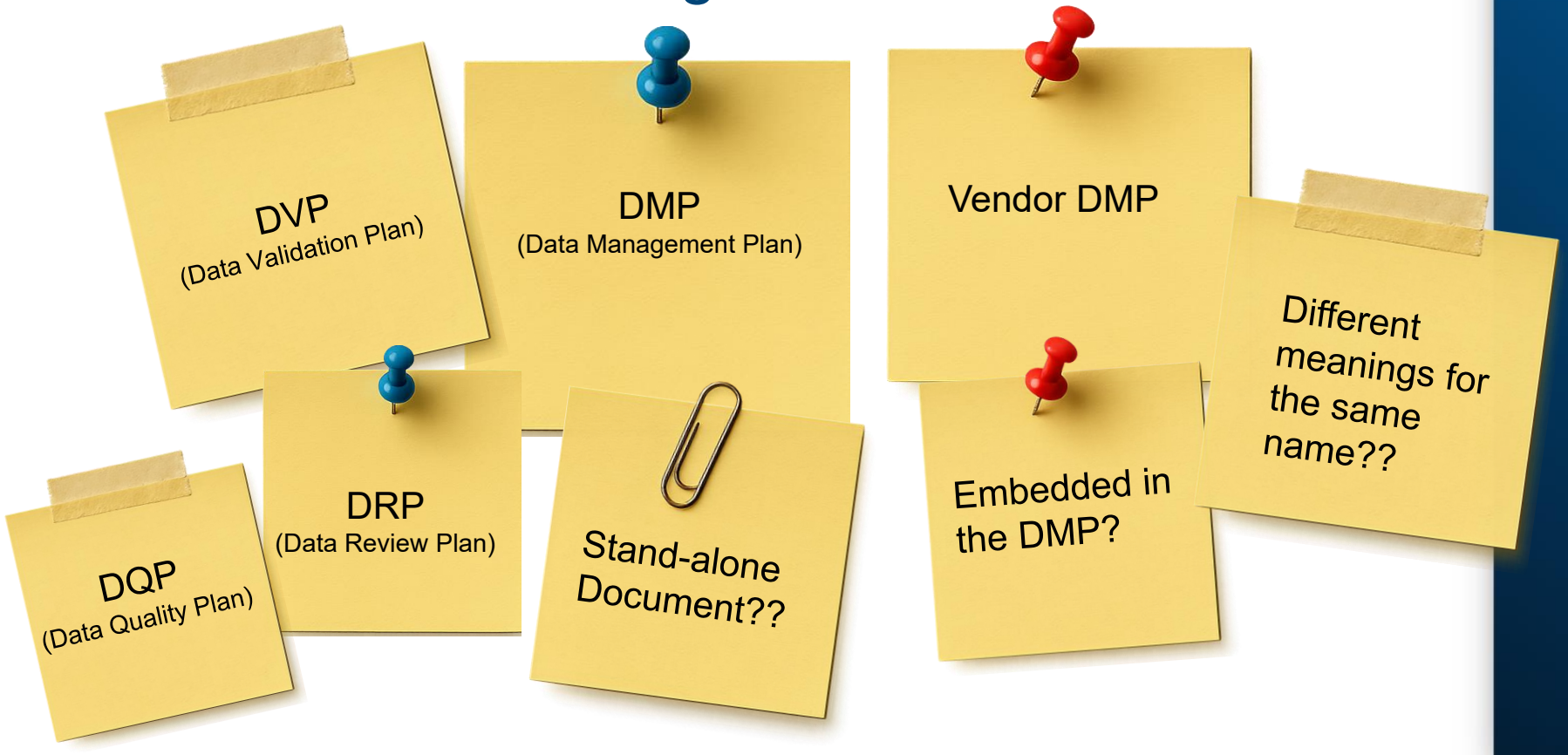
## The team behind the reshaping of Zone 10

- Highly motivated and engaged professionals
- Diverse backgrounds and experiences across companies
- Strong Data Management expertise, combined with solid TMF knowledge
- A shared willingness to challenge the status quo
- Lively discussions leading always to a shared, improved vision

A common goal:
**Improving how we work, not just updating a standard**

# The «Simplest» record group..

## 10.01.01 – Data Management Plan



# The core problems

**Terminology Confusion**

**Same idea, but different names at different companies**

Data Review Plan

**Some terms used interchangeably**

EDC, eCRF, Database

**Outdated or ambiguous record types**

**Not used anymore**

(Data Entry Guidelines (Paper))

**Too generic**

(Other Validation Documents)

**Misleading**

(Database Requirements)

**Missing Record types**

**New regulatory requirements**

(User access review, Audit trail review)

**New flows**

(No paper, system integration, data flow become more complex)

*If the standard doesn't reflect reality, companies will invent their own solutions.*

# The Game Changer: Introducing the eClinical System Zone

## Background

- Increasing number of system-related documents
- Regulatory expectations growing over time
- No dedicated place in the TMF RM

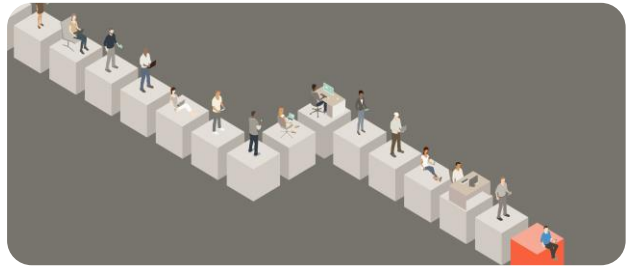
## The actual situation

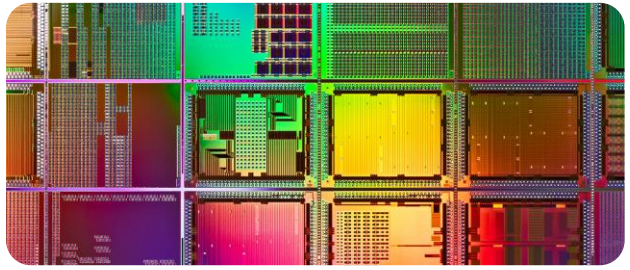
- System documents ended up in Zone 10
- Different interpretations across companies
- Same document filed in different places
- Unclear ownership and accountability

## The future

- A dedicated zone for eClinical System records
- Consistent approach across organizations

# “Data-related” vs “system-related” records





**Data records**

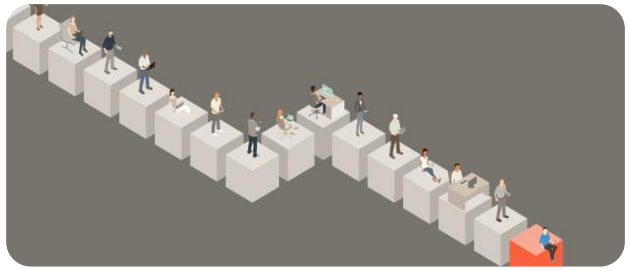
- How data are collected
- How data are handled and processed
- How data are transferred between systems
- How data are reviewed, cleaned, and verified
- How data integrity is ensured across the study lifecycle

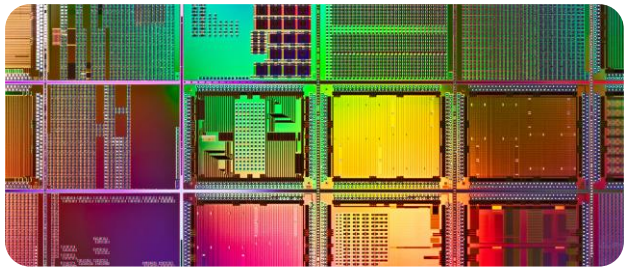
**System records**

- Study-specific system validation activities
- System maintenance
- System training

*The key question was not where to file documents, but what they are really about.*

# From Zone 10 to Zone 12: practical examples





**Zone 10**

- Data Management Plan
- Data Validation and Data Review documentation
- Data cleaning and reconciliation records
- Annotated CRFs
- Data transfer specifications
- Final subject data documentation

**Zone 12**

- eCRF Validation Plan and reports
- eCRF User and Functional Requirements
- eCRF Change control records

Zone 10 is about the data journey...

… Zone 12 is about the system enabling that journey.

*Two zones: two purposes, one continuous story and responsibility*

# Data-related vs System-related Records

## • Benefits

**Clear accountability for Data Management in zone 10**
Data Managers can clearly own and explain data processes and related documentation in zone 10.

**A coherent story for Zone 10**
Zone 10 tells the full data lifecycle story: from data creation, to handling and cleaning, through reconciliation, up to final archiving.

**Reduced ambiguity and interpretation**
Clear boundaries help harmonize practices across organizations.

## • Trade-off

**More complex accountabilities in Zone 12**
The separation highlights the real, cross-functional ownership of system-related records (IT, Data Management, vendors, clinical).
This improves alignment with reality, but increases coordination and governance complexity.

## • Challenges

**Borderline records still exist**
Some documents sit at the intersection between data and systems. (Examples of grey areas: documents related to Data Transfer flow).

**Ongoing need for cross-functional dialogue**
Clear principles help, but collaboration remains essential.

*The complexity was always there.*
*The new model simply makes it visible.*

# How we are reshaping Zone 10

**Before**

**24 artifacts**

Overlapping purposes

Unclear ownership

Mixed data & system records

Artifacts no longer used

**After**

**15 data-focused record groups**

Clear purpose for each group

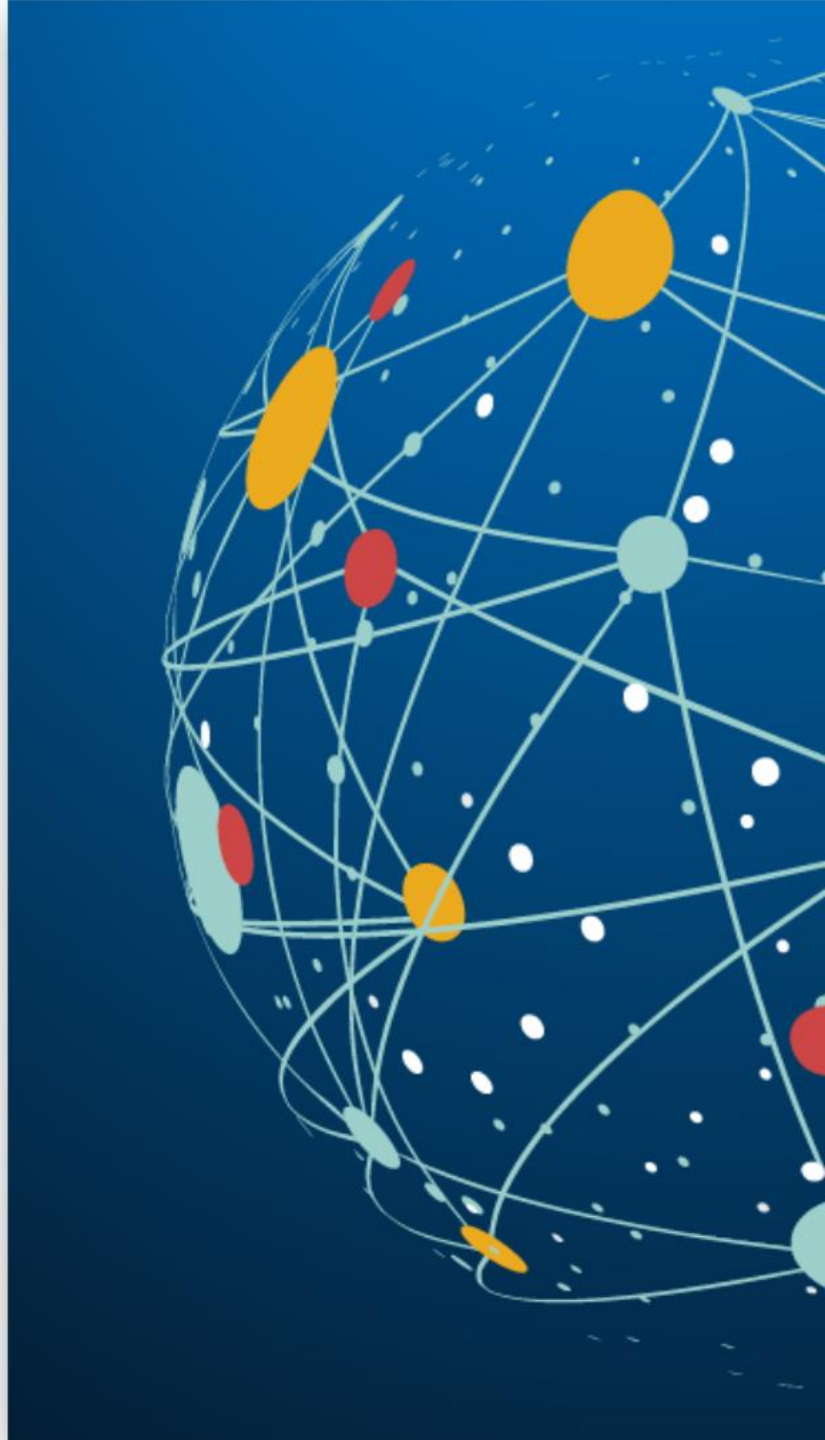
Aligned terminology

Stronger Zone 10 story

| New Proposed Record Groups |
|---|
| Data Management Plan |
| CRF Completion Requirements |
| Annotated CRF |
| Documentation of Corrections to Entered Data |
| Final Subject Data |
| Approval for Database Activation |
| External Data Transfer Specifications |
| SAE Reconciliation |
| Dictionary Coding |
| Data Review Documentation |
| Database Lock and Unlock Approval |
| Relevant Communications |
| Tracking Information |
| Meeting Material |
| Filenote |

# Lessons Learned

- The community plays a crucial role: diverse backgrounds and experiences across companies enable meaningful change.
- Discussions are also open regarding records that may be filed outside the eTMF, though these remain important for the TMF storytelling.
- Employing a shared, recognized terminology is vital to speak the same language and prevent misunderstandings.
- All areas of the TMF are closely interconnected. Collaboration and consultation across the entire community are essential for success.



# What's ongoing and next

## Clarifying Record Types

Refining purpose-based definitions

## Cross-zone collaboration

Active consultation with other zones ensuring consistency across the TMF RM

## Enabling consistency through metadata

Using metadata to support filing, retrieval and metrics

## Prompt to change!!

*This is not a timeline, but a continuos effort!*

## Community Feedback

Do you like this approach?
The distinction between Data and System is clear?

# References


- *ICH - Guideline For Good Clinical Practice E6(R3) (January 2025)*
- *Clinical Trials Regulation (EU) No 536/2014, (January 2022)*
- *EMA - Guideline on computerised systems and electronic data in clinical trials (March 2023)*
- *MHRA GXP Data Integrity Guidance and Definitions; Revision 1 (March 2018)*
- *US FDA - 21 CFR Part 11: Electronic Records; Electronic Signatures (1997)*
- *US FDA - Electronic Systems, Records, and Signatures in Clinical Investigations - Question & Answer (2024)*

# Questions?

# Thank You!