

cdisc®

2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



TMF Standard Model V1: Understanding the Architecture

Gill Gittens, TransPerfect Life Sciences

Speaker



Gill Gittens
Senior Director, eClinical Strategy and Solutions
TransPerfect Life Sciences

Over 25 years in the life sciences industry, specializing in TMF operations, inspection readiness and clinical trial regulatory standards.
Member of the CDISC TMF Steering Committee and TMF Standard Model V1 Management Committee.

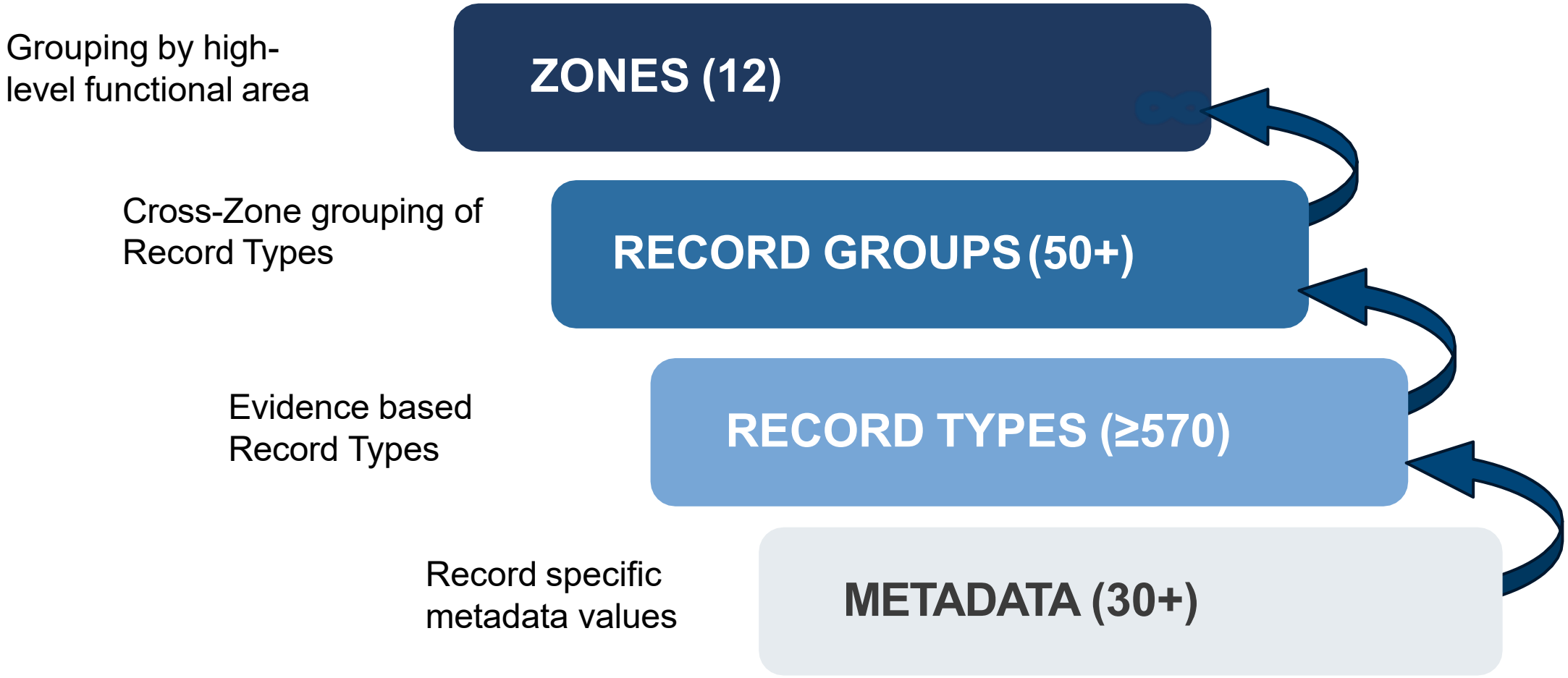
Agenda

1. The structural architecture
2. What's going
3. Metadata and relationships
4. Consistency across organizations and systems
5. Navigating the model for adoption

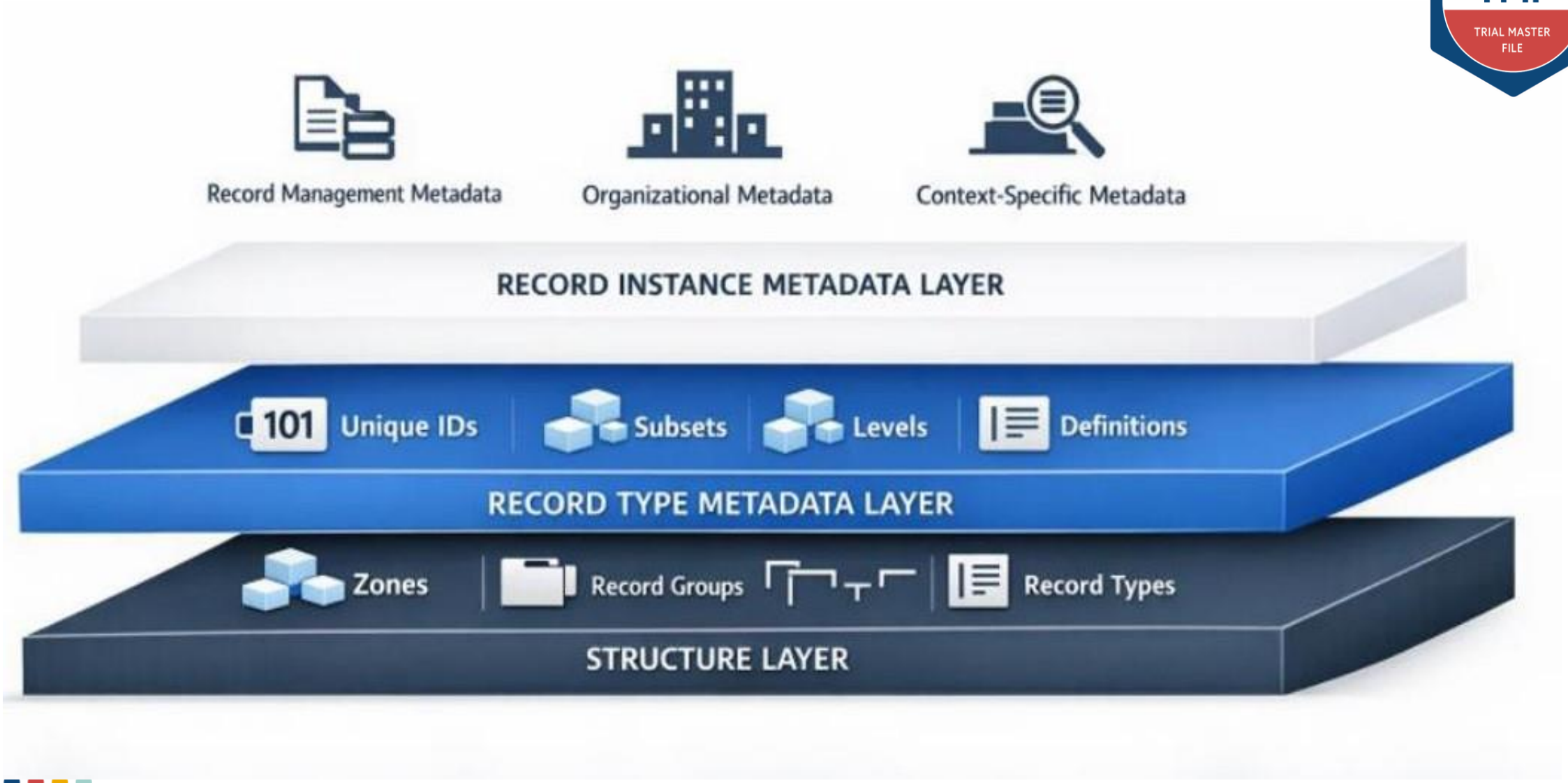
What's going…

- **Sections:** now replaced by **Record Groups**
- **Artifacts:** now replaced by **Record Groups** and **Record Types**
- **Sub-Artifacts:** replaced by **Record Types**
- **Core and Recommended:** no longer relevant
- Other attributes of TMF RM 3.3.1. may not be included in V1 of the TMF SM and may even be retired…

TMF Standard Model Architecture



Architecture



How the Architecture Fits Together

ZONES

- Existing Zones retained Additional Zone: **Zone 12: eClinical**

RECORD GROUPS

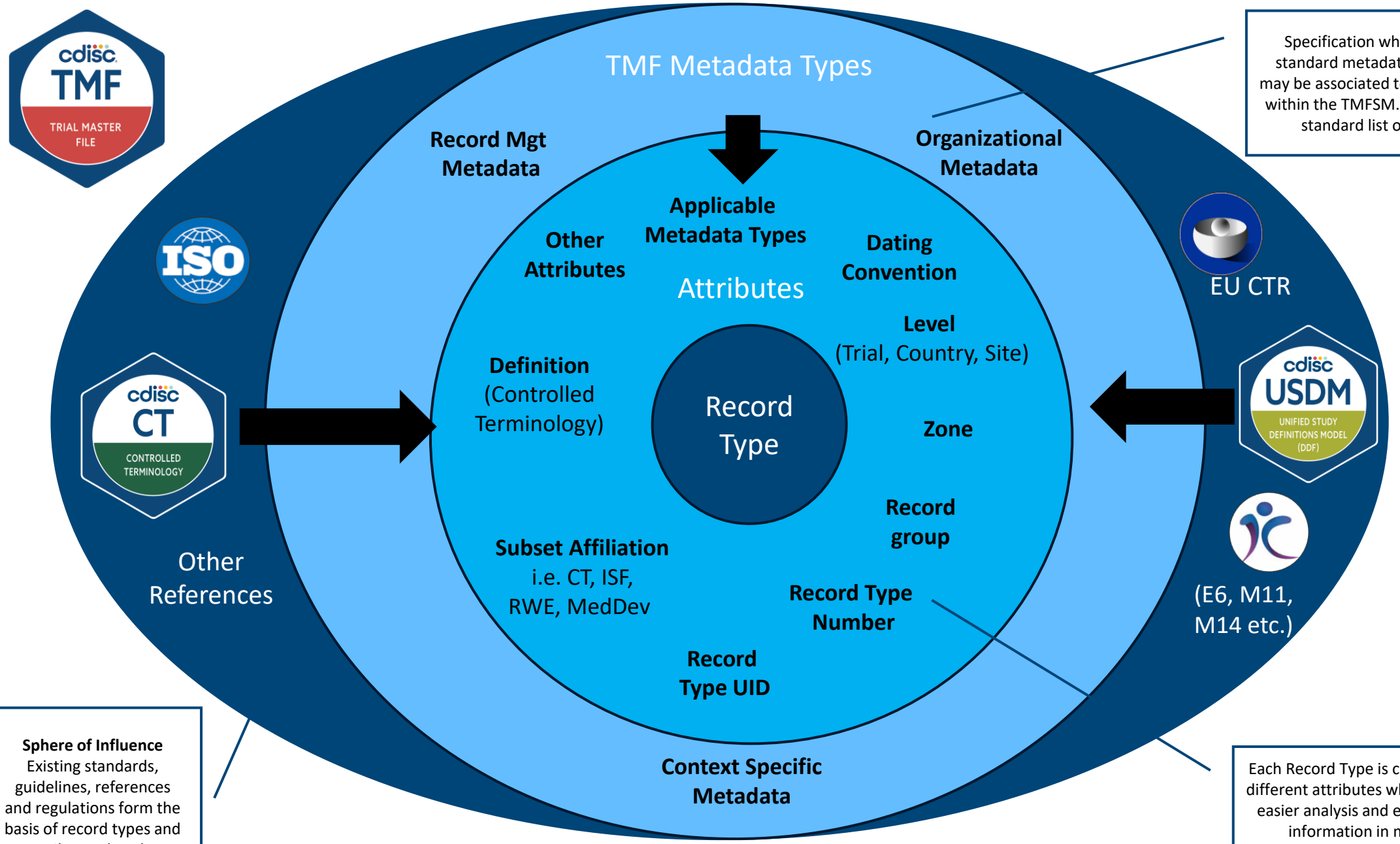
- Structured in alignment with **ICH E6 (R3)**
- Enable cross-zone grouping of related records
- Replace legacy **Sections and Artifacts**

RECORD TYPES

- Derived from existing **Artifacts and Sub-artifacts**
- Expanded through:
  - Industry feedback
  - Zone team reviews
  - Specialized workstreams (**ICH E6 (R3), EU CTR, Medical Device, IVDR, RWE, ISF, eClinical**)
- Standardized using **industry-recognized terminology**

METADATA

- Initial release includes a **core identification dataset and provisional**
- Designed for progressive expansion over time
- Aligned, where applicable, with **the Unified Study Definitions Model (USDM)**
- Metadata fields systematically linked to Record Types and subsets



Specification which defines standard metadata fields that may be associated to record types within the TMFSM. Also includes standard list of values.

Sphere of Influence
Existing standards, guidelines, references and regulations form the basis of record types and attributes that the TMFSM is composed of.

Each Record Type is classified with different attributes which allow for easier analysis and extraction of information in multiple dimensions.

Components of TMF Standard Model V1

UID

- **5-digit identifier** uniquely assigned to each Record Type
- Legacy **3-digit UIDs retained** where applicable
- New UIDs **assigned sequentially**
- **9#### range** reserved for **user-defined** Record Types
- **Stable key** across organizations, systems and versions

MODEL SUB-SETS

- Defined groupings of Record Types for **specific domains**
- **Current Sub-Sets** include:
  - Drug/Biologic
  - Medical Device
  - IVDR
  - RWE
  - Investigator Site File (ISF)
- **Record Types** may be:
  - **Shared** across Sub-Sets
  - **Specific** to a single Sub-Set
- Additional Sub-Sets expected over time

LEVELS

- Levels are **dimensions** at which records are created or **organized by**
- **Study, Country-Region and Site** levels have been **maintained**
- **Cross study** (program) records would be filed at the **Study level**

OTHER ATTRIBUTES

- Additional attributes provide further **structure and context**
- Examples include:
  - Dating conventions
  - Process-related classifications
- **Full set** of attributes for V1 is still **evolving**

One Record Type, End to End

ZONE	**02 Central Study Documents**
RECORD GROUP	**Participant Information** *also used in Zones 5 and 6*
RECORD TYPE	**ICF** *UID assigned at release*
SUB-SETS	*Drug/Biologic, Medical Device, IVDR, RWE and ISF*
LEVEL	**Study, Country and Site** *Milestones: Study, 01 First Country RA Approval. Country and Site, 03 Site Live / Ready / Open for Enrollment*
METADATA	**Purpose:** to provide evidence of the informed consent information approved for use and provided to participants **Dating convention:** Version Date **Instance metadata:** Type of ICF

ASSIGNED TO EACH RECORD (INSTANCE LAYER)

RECORD INSTANCE	**Main study ICF, Site 202 (Nashville), United States** Version date 15 March 2025. Inherits every fixed value above.

The UID

The stable key

- **Constant** when names, labels or navigation change
- **The same** in every organization and every system, so records can be exchanged, reconciled and compared
- **Carried** from the record type onto every instance (Unique TMF records of the Same RT will have the same UID)
- **Legacy TMF RM 3-digit UIDs retained** where applicable, so mapping from 3.3.1 starts from the UID. New UID would be 00001
- **9#### range reserved** for user-defined record types

One Record Group, Three Zones

Participant Information

ZONE 02 Central Study Documents	**ZONE 05** Site Management	**ZONE 06** IP and Ancillary Supplies
• ICF • ICF Review and Approval • ICF QC Checklist • ICF Summary of Changes • ICF Distribution • Participant Information Sheet • Participant Information Sheet Summary of Changes • Participation Card • Other Information Given to Participants	• Personal Data Consent	• Participant Directions for IP Use • Participant Directions for IP Handling

Why this matters: Record Groups group records by process, so the same group appears wherever that process touches the study. The group travels; the zone tells you where the record sits.

Consistency Across Organizations and Systems



Standardized Encoding Across the Model

- All **Record Types**, **Attributes**, and **Metadata** will be encoded using **controlled terminology**
- Ensures **consistency**, **interoperability**, and **machine-readability** across systems

Centralized Governance

- Controlled terms will be published within the **CDISC Controlled Terminology (CT) library**
- Developed in collaboration with **NCI Enterprise Vocabulary Services (NCI-EVS)**

Ongoing Curation

- Managed by the **TMF Controlled Terminology Sub-team**
- Continuously expanded and maintained through **formal change control processes**

Why it matters

Controlled terminology plus the UID mean two organizations classify the same record the same way, in any system.

cdisc

Navigating the Model for Adoption

1 SUB-SET	2 LEVEL	3 ZONE	4 RECORD GROUP	5 RECORD TYPE
Which domain? Drug / Biologic, Medical Device, IVDR, RWE or ISF	**Where is it created?** Study, Country or Site	**Which functional area?** One of 12 zones	**Which process?** Procedural grouping that can span zones	**Which record?** Identified by its UID, the stable key

Mapping from TMF RM 3.3.1

- **Start from the UID.** Legacy 3-digit UIDs are retained where applicable
- **Sections** become Record Groups
- **Artifacts and Sub-Artifacts** become Record Groups and Record Types
- **Core and Recommended** no longer apply

Local needs without breaking the standard

- **9#### range** reserved for user-defined record types
- **Standard UIDs stay untouched,** so local additions never collide with the model
- **Consistent across systems:** the same UID means the same record type wherever it is used

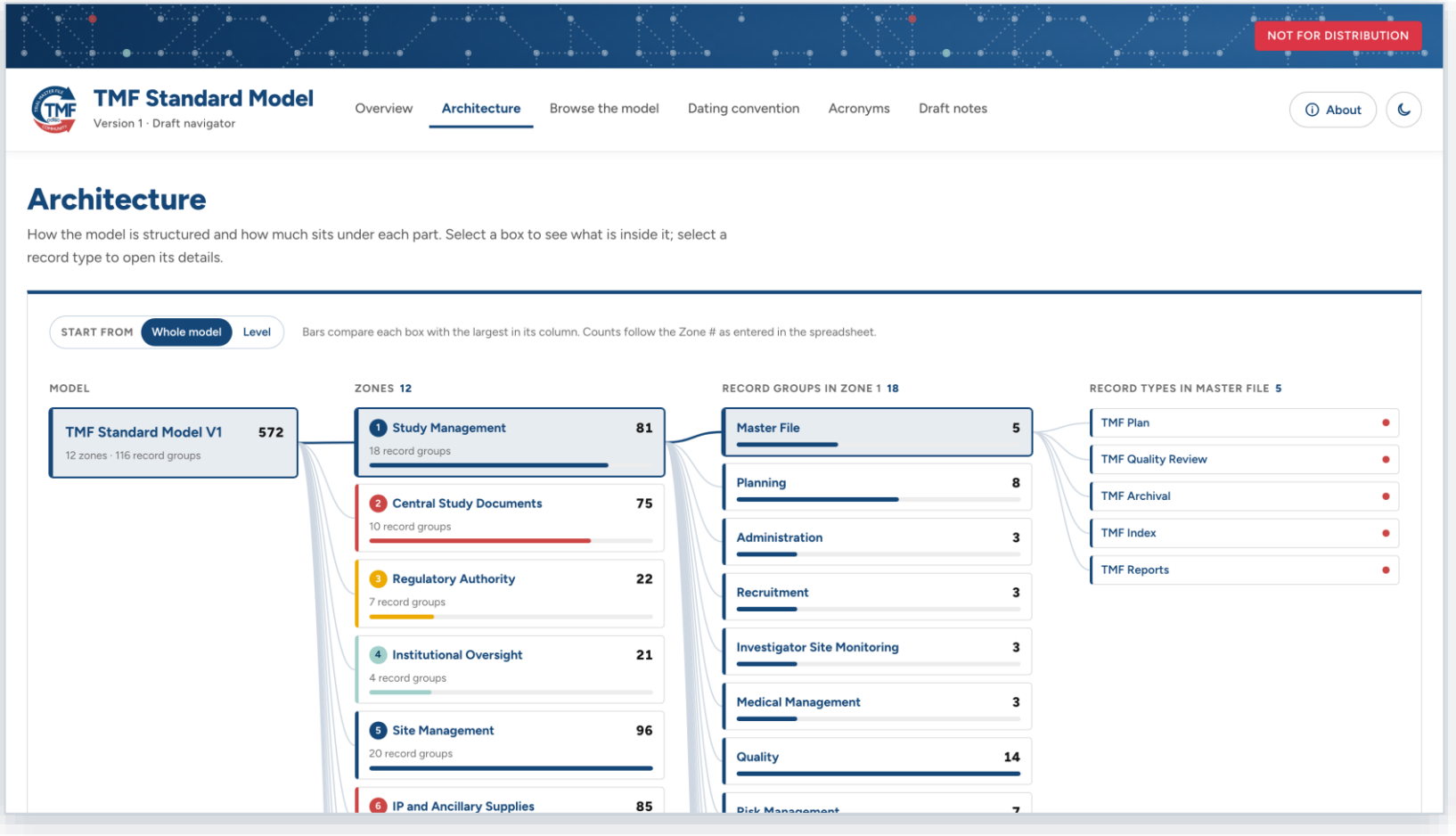
TMF Standard Model Navigator

An offline, interactive tool for exploring the TMF Standard Model V1 draft and capturing review feedback.

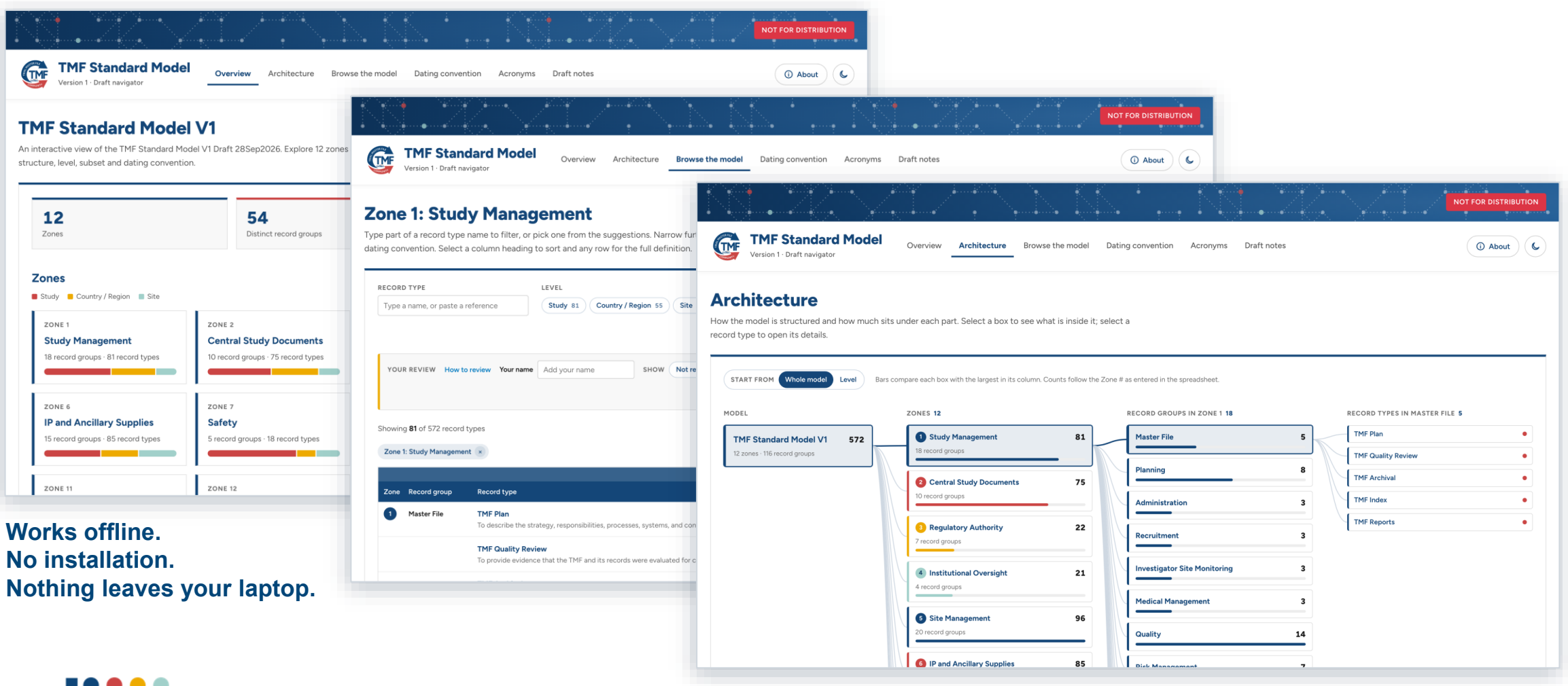
- **Architecture:** see how much sits under each zone and record group
- **Browse:** filter 572 record types by zone, level and subset
- **Review:** record verdicts and notes, then export to Excel



Rob Jones
Clinical Business Partner
Arithmos Tech
TMF Community Steering Committee member



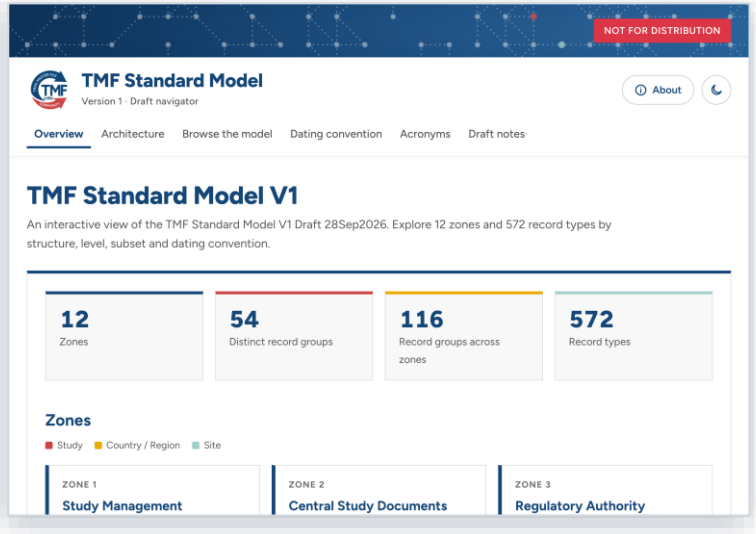
One file. The whole draft.



Works offline.
No installation.
Nothing leaves your laptop.

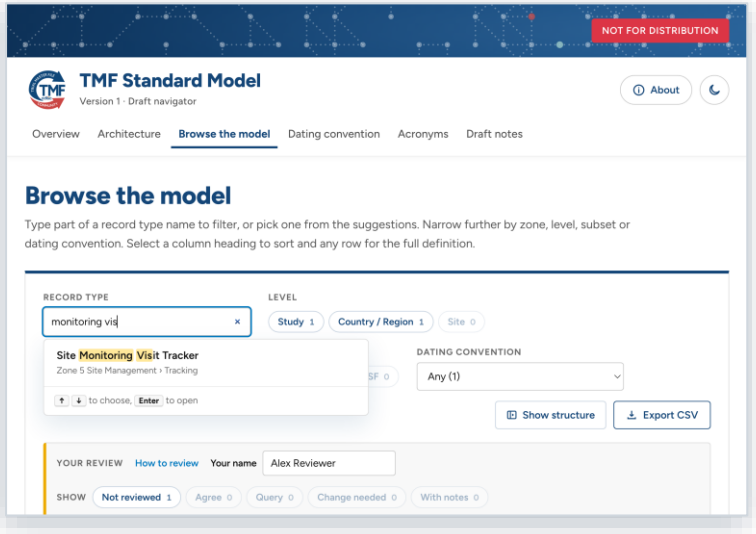
cdisc®

Explore the draft your way



The model at a glance

Zones, record groups and record types, with every count a click away.



Find any record type in seconds

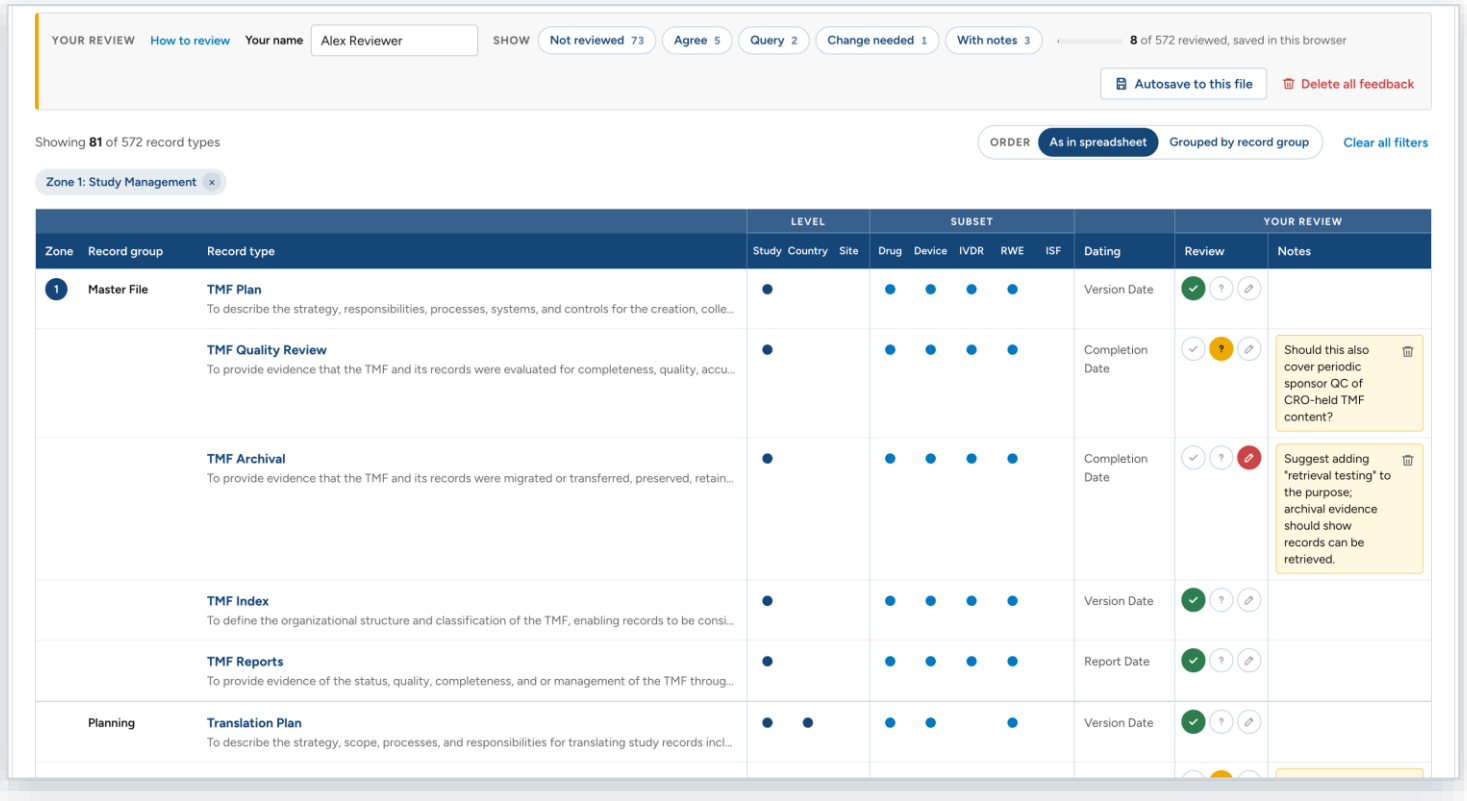
Type-ahead search, with filters for level, subset and dating convention.



Every detail in one panel

Purpose, levels, subsets, dating convention and ICH E6(R3) mapping.

Review it, record by record



One-click verdicts

Agree, Query or Change needed on every record type.

Notes as you go

Comments save as you type.

Saves into the file

Your review travels with the file you send back.

Export to Excel

Row numbers match the draft spreadsheet.

Questions?



Thank You!

