

cdisc 2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



One Standard, Multiple Subsets

How TMF Standard Model V1 unifies Drug/Biologic, RWE, Medical Device, IVDR and ISF without losing domain specificity

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Why One Standard Matters…

Fragmentation creates friction exactly where clinical evidence needs continuity.

Different vocabularies
Equivalent evidence can be named, grouped and interpreted differently.

Duplicate maintenance
Separate models create parallel updates, mappings, training and governance.

Broken interoperability
Transfers and analytics require repeated translation between structures.

A single governed foundation

Consistent terminology
Shared record types
Common identifiers and attributes
One change-control pathway
Technology-neutral implementation

The objective is not uniformity of every study. It is consistency in how evidence is defined and exchanged.

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The Subset Landscape

Five perspectives. One underlying information model.



COMMON TMF STANDARD MODEL V1 FOUNDATION

Subset affiliation identifies applicability. It does not create a separate model or isolated hierarchy.

How harmonization was achieved

Domain expertise was integrated into the standard, not bolted on afterward.

1. **SUBTEAM INPUT**
   ISF, RWE, Device and IVDR specialists reviewed applicability, terminology and gaps.
2. **CROSS-MODEL MAPPING**
   Teams compared overlapping concepts and traced unique content to the common structure.
3. **TERMINOLOGY RESOLUTION**
   Names and descriptions were broadened where needed to work across study types.
4. **EXCEPTION DISCIPLINE**
   A new Record Type was created only when an existing one could not reasonably accommodate the evidence.
5. **INTEGRATED REVIEW**
   The combined draft was reviewed again from each subset perspective.

The result is a shared language that preserves the intent of each contributing domain.

The Governing Design Principle

Reuse first. Extend only when the evidence is genuinely different.

COMMON RECORD TYPE

Can the existing Record Type name and Purpose/Description encompass the evidence across relevant study types?

YES

Use the shared Record Type and assign subset affiliation

NO

Create a new Record Type within an existing group and zone

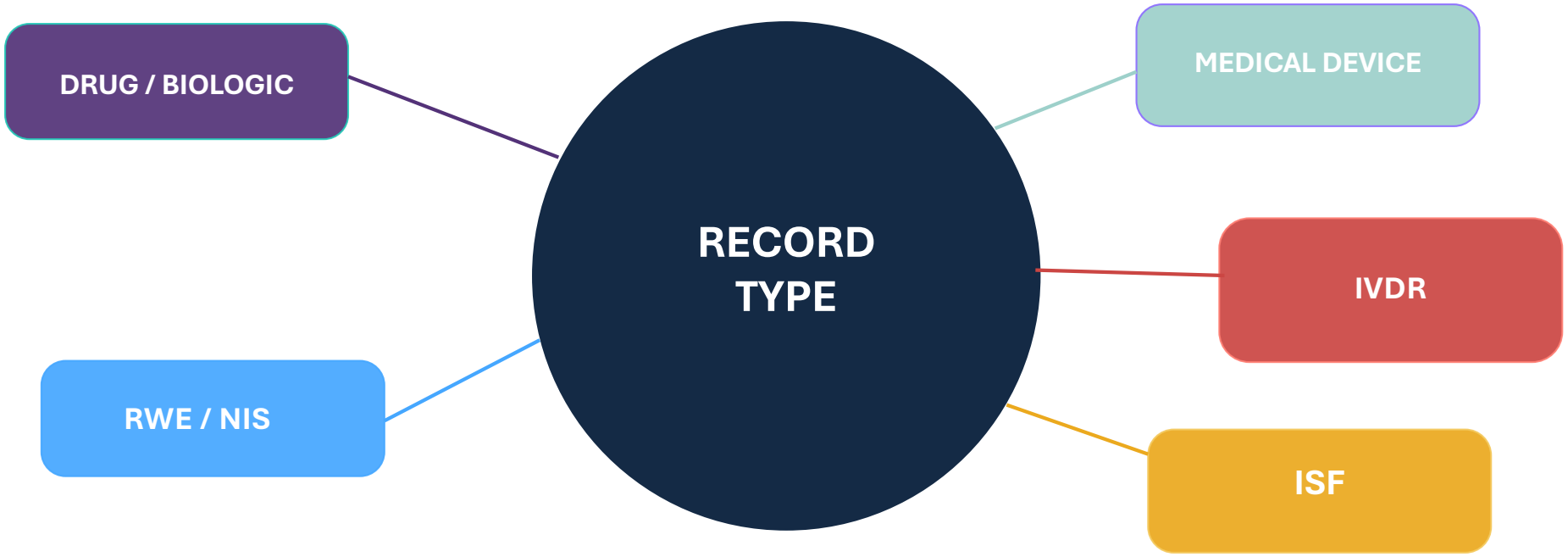
OUTCOME

Less duplication
Fewer competing definitions
Cleaner implementation
Clearer change control
Better machine readability

Subset-specificity is expressed through the model's attributes, not by reproducing the whole taxonomy.

Metadata Makes Subsets Composable

A Record Type can affiliate to more than one subset at the same time.



Subset Affiliation = controlled attribute(s) assigned to the Record Type

Harmonization Approach

- We had to agree on a harmonized terminology set
  - Trial became **Study**
  - Patient or Subject became **Participant**
  - Vendor became **Service Provider**

- Record Type names were simplified in some instances
- Record Groups are common across all subsets
- Definitions were made inclusive of the applicable subsets

The Benefits Compound Across the Ecosystem

The value of one standard increases as more participants and systems use the same foundation.

SPONSORS & CROs

Simpler study setup, oversight, transfer and cross-study comparability.

INVESTIGATOR SITES

A consistent site-facing structure with cleaner translation to the sponsor TMF.

TECHNOLOGY PROVIDERS

One implementation target for taxonomy, attributes and controlled terminology.

INSPECTORS

More consistent organization and retrieval of evidence across domains.

STANDARDS COMMUNITY

One governance process and a clearer path for controlled evolution.

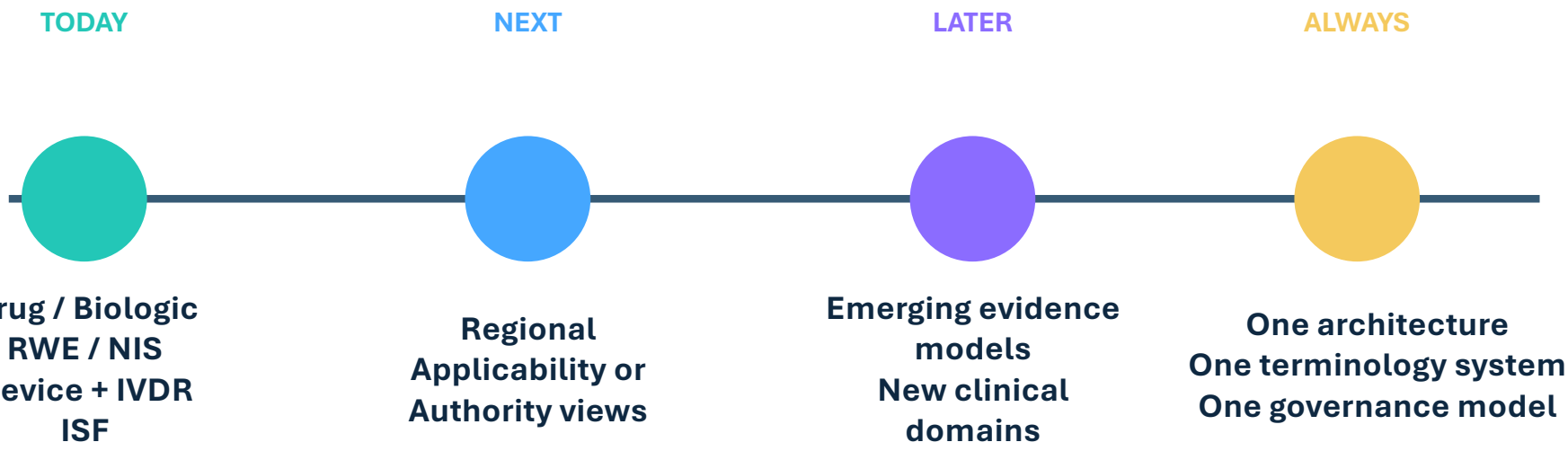
DATA & AI

More structured, machine-readable inputs for automation and analytics.

A standard becomes strategic when it supports both human understanding and digital interoperability.

Built to Expand without Breaking

Future subsets can be introduced as governed views over the same model.



Extensibility is a design feature: add affiliations and controlled context before adding parallel structures.

The Take Away

One standard gives us a common language. Subsets make that language useful in context.

1

UNIFY

Maintain one authoritative foundation for clinical evidence.

2

HARMONIZE

Resolve terminology with domain experts across contributing subteams.

3

COMPOSE

Use metadata attributes so multiple subsets can apply simultaneously.

4

EVOLVE

Add new domain or regional subsets through governed extension.

ONE STANDARD | MANY VALID STUDY CONTEXTS