



cdisc[®] 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

Status of CDISC TMF Standard Model

Paul Carter
Chair CDISC TMF SM
CEO Montrium Inc.



Speakers

Speaker biography can go here if you have one to share.

Name

Title

Company

What is V1?

- A Formal Standard Model for identifying essential records (evidence)
- Defined by over 500 active industry volunteers
- Provides more structure and granularity than the previous versions of the TMF RM
- Multi-dimensional (2D -> 3D)
- Aligned with ICH E6 (R3)
- Built for different subsets of clinical investigations
- Designed with digital records in mind

TMF Standard Model Architecture



RECORD INSTANCE METADATA LAYER



RECORD TYPE METADATA LAYER



STRUCTURE LAYER

TMF Standard Model Hierarchy

From high-level structure to granular records and metadata

Grouping by high-level functional area

ZONES (12)

∞

Cross-Zone grouping of Record Types by procedural area

RECORD GROUPS (50+)

1

1

Evidence based Record Types

RECORD TYPES (2000+)

1

∞

Record specific metadata values

METADATA (30++)

1

Counts are indicative and evolving with the standard



What is 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 also be retired...



Record Type Metadata

The Definition Layer

What they are: Predefined values assigned to *Record Types*

Key Characteristics:

- Fixed and controlled (managed through change control)
- Define structural elements of the model

Examples

- Dimensional (Study, Country, Site, Zone, Record Group)
- Identifiers (UID, Record Number)
- Definitions
- Sub-Set Affiliation

Record Instance Metadata

The Instance Layer



What they are: User-assigned values applied to Record Instances

Key Characteristics:

- Provide record-specific context
- Are more flexible and configurable
- Can be based on standard lists of values or user defined values

Examples:

- Identify a **record affiliation** (Site Number, Investigator, Country etc.)
- Assign a **record characteristic** (approval date, Record Owner etc.)
- Provide **context** specific information (ICF Type, eClinical System Type etc.)

From Record Type to Record Instance

Record Type

Financial Disclosures (05.02.10)

Defines the metadata structure for all Financial Disclosure forms across studies.

Type Metadata

Level: Site

Zone: 05 Site Management

Section: 05.02 Site Set-up

Record UID: 00427

Dating Convention: Date of the Signature

Instance Metadata

Country: ISO-3166 Country Code

Site: String

Name: String

Date: Date



Instances created
using this blueprint



Multiple Record Instances — each shares the same metadata blueprint.

Components of the TMF Standard Model v1



ZONES

- Existing Zones retained
- Additional Zone introduced: **Zone 12 – eClinical Systems**

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**, **RWE**, **ISF**)
- Standardized using **industry-recognized terminology**

METADATA

- Initial release includes a **core identification dataset**
- Designed for progressive expansion over time
- Aligned, where applicable, with **USDM**
- Metadata fields systematically linked to Record Types

Components of the TMF Standard Model v1



UID (UNIQUE IDENTIFIER)

- **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

MODEL SUB-SETS

- Defined groupings of Record Types for **specific domains**
- **Current Sub-Sets** include:
 - Drug / Biologic
 - Medical Device
 - RWE / NIS
 - 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 and Site** level have been **maintained**
- **Cross study** (program) records would be filed at the **Study level**
- **Investigator** records would be filed at the **site 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**

Controlled Terminology

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**

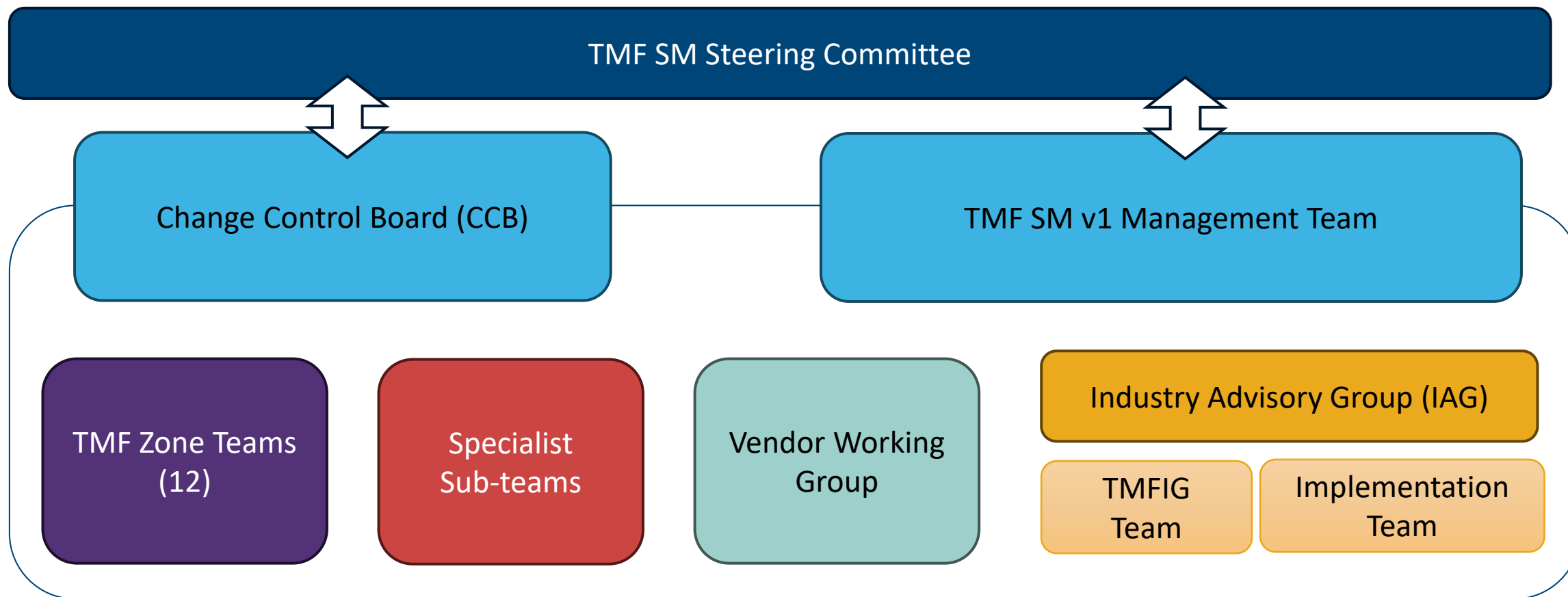


TMF Implementation Guide (TMFIG)

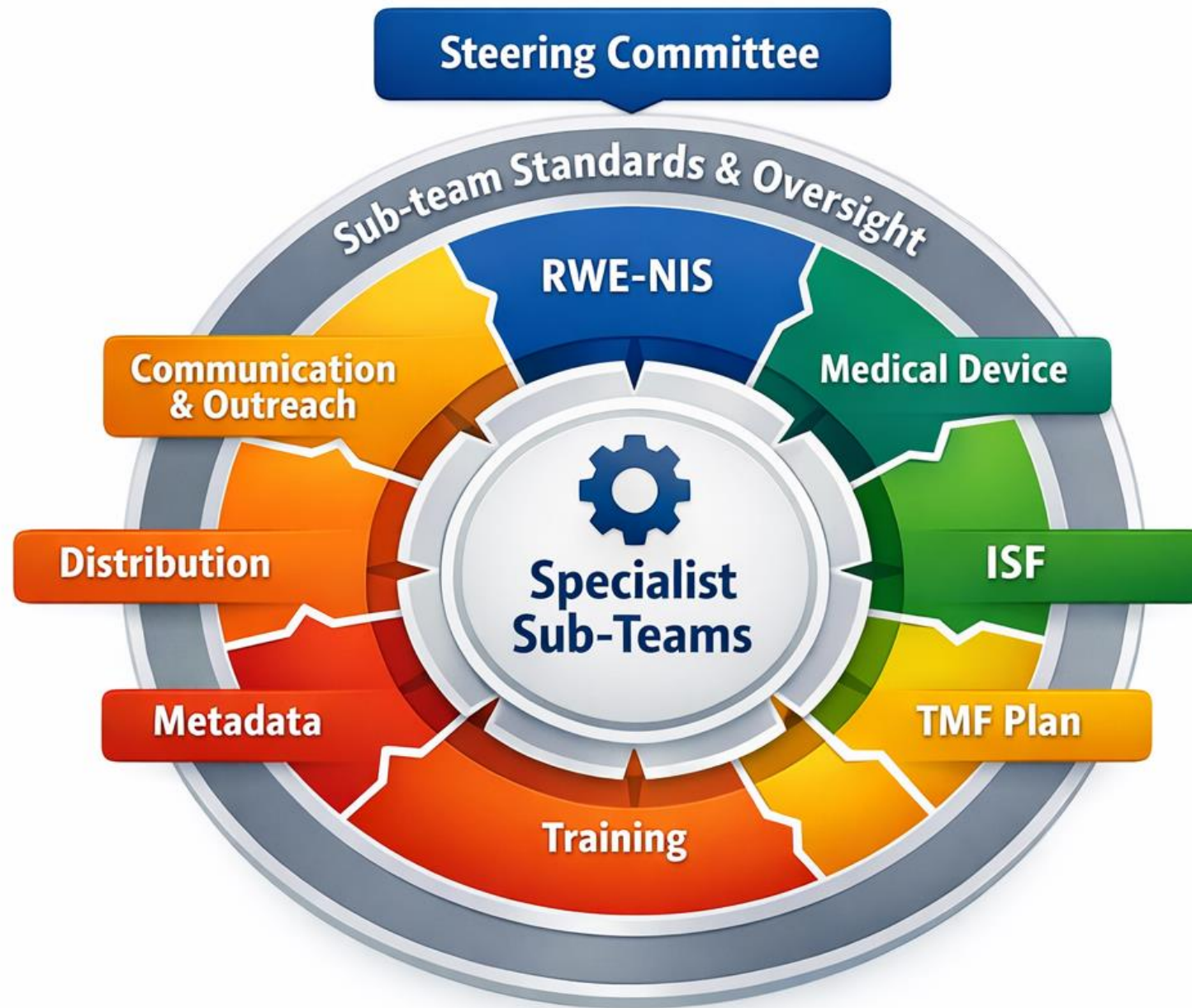
- The TMFIG is a **formal document** that governs the standard and how it is to be used
- It encapsulates all of the **governing principles and rules** that have been defined for the standard
- It provides **specifications and criteria** for each element of the standard
- It provides **guidance** on how the standard should be used
- It is **governed by the change control board**
- Each new version of the standard will have a corresponding TMFIG version



TMFSM Organizational Structure



Specialist Sub-teams





Industry Advisory Board (IAB)

Composition ~10 senior industry experts

Core Mandate

The IAB supports both the **technical** and **practical adoption** of the TMF Standard Model

Technical Implementation

- TMF Implementation Guide (TMFIG)
- Distribution tools and access mechanisms

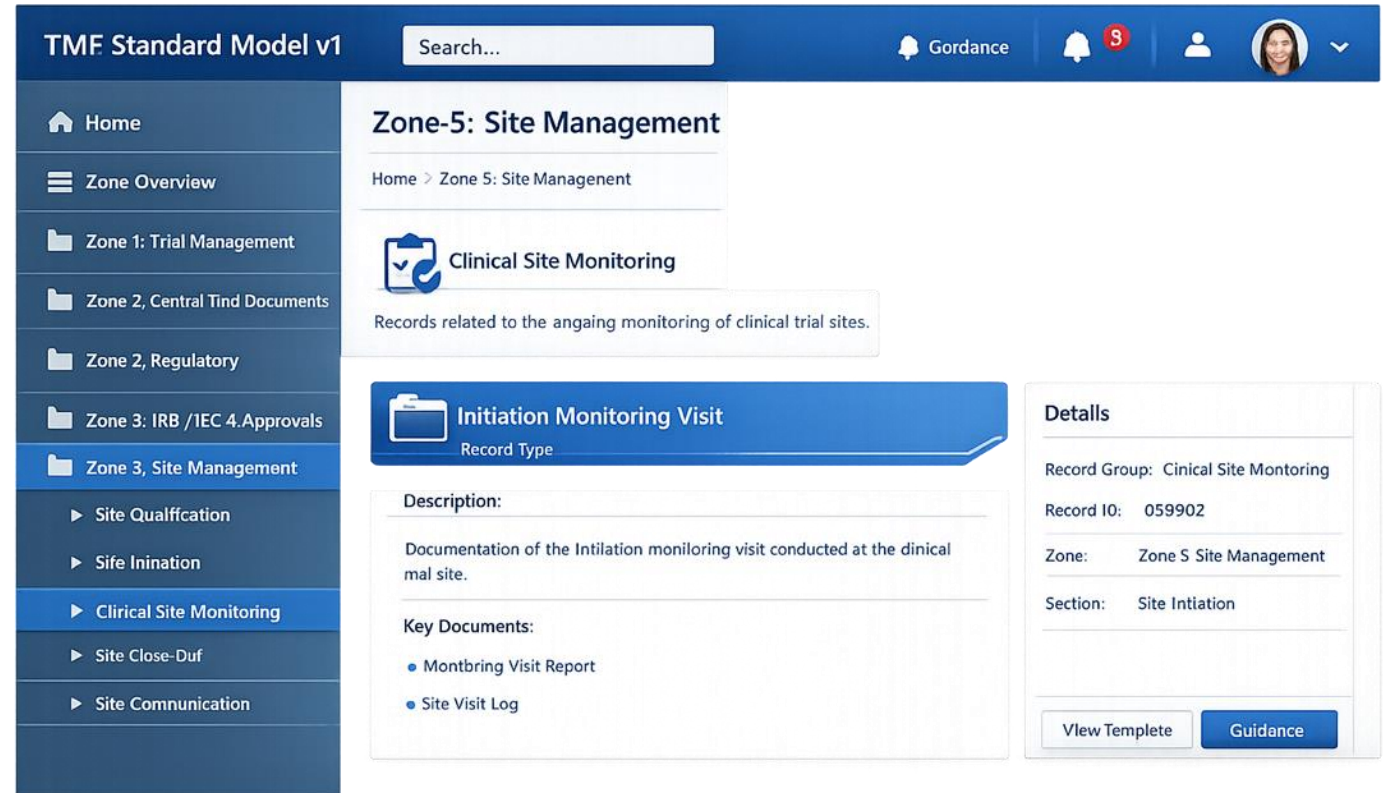
Practical Implementation

- Change management and adoption strategy
- Webinars and industry engagement
- Quick-reference materials (cheat sheets)
- Training and enablement

Ongoing Role: Provides continuous feedback to support the evolution of the standard

Distribution of the New Standard

- Setting up a working group to **develop an app** for the **distribution** of the standard
- Will be **mobile app** and **web based**
- Will allow the community to **consult and easily search** for record types based on attributes
- **Excel version** will also be available



Vendor Working Group

- A vendor working group has been **active since the start** of the development of v1
- Majority of **mainstream vendors** are represented on the group
- Vendors have been **consulted and provided input** on each decision
- Vendors will receive a **preview** of the **draft standard** prior to public review
- **Dialog** with the group is key to ensuring **vendor buy-in** and readiness



Change Control Board

- **New Charter** being put in place for TMF CCB
- **Members** will now be **elected** each year to a 13 strong board for a **3-year term**.
- Elections are on a **revolving cycle**
- The **CCB Chair** will be **elected** by the board
- There are **clear roles and responsibilities** for the different sub-teams and zone teams
- CCB will take over the **governance of the standard** and the TMFIG once it is released



Volunteers and Workgroup Management



Volunteer Coordination

Implementation of a more **structured approach** to sourcing and placing volunteers

Workgroup Organization

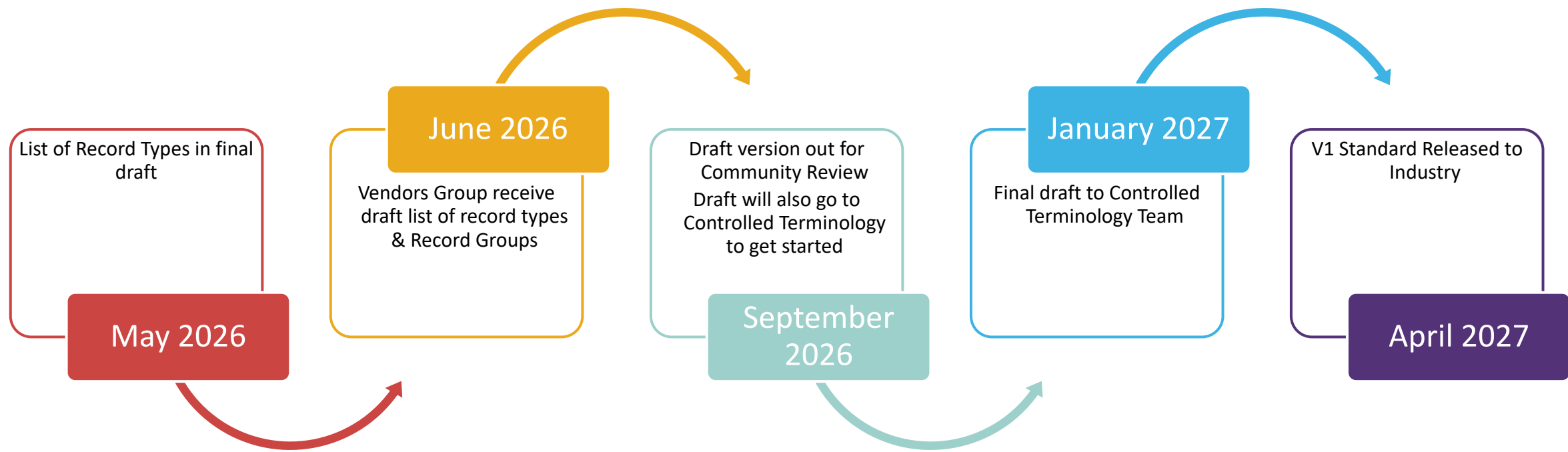
Ensuring that all **workgroups function in the same way** using the same standard processes and deliverables

Tools

Development of **templates and management tools/trackers** to better manage initiatives



Timeline





Thank You!

pcarter@montrium.com

