TMF Standard Model

Implementation Guide

Version 1.0

Draft

Clinical Data Interchange Standards Consortium (CDISC)

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1. Introduction

1.1 Background

The Trial Master File Standard Model (TMF SM) establishes a common language for describing, organizing, exchanging, and reviewing clinical study evidence. It represents the evolution of the TMF Reference Model into a formal Clinical Data Interchange Standards Consortium (CDISC) standard, rather than a revision of TMF Reference Model v3.3.1 alone.

Development has been guided by the need for consistent terminology, interoperability, regulatory alignment, and digital readiness. The TMF SM is intended to support ICH E6(R3), increasingly complex clinical studies, and different organizational structures, technologies, and operating models. Sponsors, service providers, technology providers, investigator sites, regulators, archivists, quality professionals, clinical operations teams, and TMF specialists have contributed to its development.

The TMF SM brings together evidence concepts for different study types such as: drug and biologic studies, medical device, in vitro diagnostic medical devices (IVDR), real-world evidence (RWE), as well as the Investigator Site File (ISF).

1.2 Purpose of the Implementation Guide

The TMF Standard Model Implementation Guide (TMFSMIG) describes the concepts, design principles, and assumptions used to create the TMF SM. TMFSMIG Version 1.0 is intended to be used with Version 1.0 of the TMF SM.

This guide is intended for organizations and individuals looking to implement the TMF SM and explains how to consistently apply the model while allowing implementation within different processes and technology environments. It does not replace applicable regulatory requirements or determine which records are required for an individual study.

1.3 Organization and Use of This Guide

The following sequence provides a progression from the model's concepts and definitions to their application:

1. Review the TMF SM workbook to become familiar with the Zones, Record Groups, Record Types, and supporting attributes. Refer to Section 1.4 for a description of the companion resources.
2. Read Sections 1–3 for the background, purpose, fundamental concepts, and relationship to other standards, regulations, and previous models. Refer to the key terms in Section 2.4 as needed.
3. Read Section 4 to understand the model architecture, design principles, Unique Identifiers, metadata framework, levels, and record relationships before applying the model.
4. Review Section 5 with the workbook to understand the Record Group and Record Type definitions, Purpose/Descriptions, metadata, and controlled terminology. Refer back to Section 4 when interpreting these definitions.
5. Read Section 6 for the general assumptions and implementation principles, including application within an eTMF, across multiple systems, and between sponsors, service providers, and investigator sites.
6. Read Section 7 when planning adoption for new, active, closed, or legacy studies. Consider the organizational approach and the role of Unique Identifiers during transition.
7. Review Sections 8 and 9 for information exchange, implementation governance, change control, and training.
8. Read Section 10 for the draft conformance considerations, including preservation of standard concepts and identification of permitted local extensions.

Readers new to the TMF SM should begin with Sections 1–4. TMF business and process owners should give particular attention to Sections 4, 6, 7, and 9; technology implementers to Sections 4, 5, 6, 8, and 10; and organizations planning adoption to Sections 7 and 9.

1.4 Key Terms

Term	Definition
Record	Evidence generated or retained as part of the planning, conduct, oversight, or management of a clinical study. *Note: Evidence includes documents, data, and other files, regardless of format, provided they meet the definition of a record.*
Zone	The highest organizational level in the three level TMF Standard Model structure.
Record Group	A grouping of related Record Types representing an enduring business activity within a Zone.
Record Type	A standardized classification identifying distinct evidence generated through a clinical study activity.
Unique Identifier (UID)	A stable identifier associated with a standard concept so that the concept can be recognized even if labels, structure, or presentation evolve.
Metadata	Structured information used to describe a record and its context.
Standard Metadata	Metadata defined for TMF SM that applies broadly across records.
Provisional Metadata	Additional metadata intended to distinguish record context in greater detail. Definitions and application guidance will be developed in a future draft; current examples are illustrative and not exhaustive.
Level	Information to describe how a record applies to study, country, site in the context of a clinical study.
Attribute	Information such as service provider, person, committee, or system that further describe where and how a record applies

2. Fundamentals of the TMF Standard Model V1

2.1 What Is the TMF Standard Model?

The TMF SM is a framework for organizing and describing evidence of how a clinical study was planned, conducted, managed, and overseen. The TMF is not simply a collection of records. It provides evidence of study conduct, decisions, risk management, oversight, and compliance, including the protection of participant safety and data integrity.

The TMF SM provides a single, globally applicable structure while allowing flexibility for different study designs and operating models. Classification of records is based on the purpose of the evidence, not solely on a record's name, format, originating system, or storage location.

2.2 From Reference Model to Standard Model

The transition from the TMF Reference Model to the TMF SM changes how clinical trial evidence is defined, organized, and described. The principal changes and their implementation implications are summarized below.

Reference Model Concept	Standard Model Approach	Implementation Implication
Zone, Section, Artifact, and Sub-artifact hierarchy	Zone, Record Group, and Record Type hierarchy	Organize evidence around enduring business activities and distinct evidence purposes; use metadata for contextual variations.
Zone terminology	Updated names, including Regulatory Authority, Institutional Oversight, Investigational Product (IP) and Ancillary Supplies, Safety, and Service Provider	Use the names and definitions in the corresponding model release to maintain consistent terminology.
General correspondence filing locations	Communications classified under the relevant Record Type	Classify a communication by the activity, decision, or oversight it demonstrates, not by its format.
Generic Note to File classification	Notes to File classified according to the evidence they provide	Keep explanatory records connected to the activities and decisions they support. Detailed metadata guidance will follow in a future update.
Core and Recommended designations	Designations removed	Determine applicability from study design, activities, regulatory requirements, responsibilities, and risks; the model is not a universal checklist.
Vendor and Contract Research Organization (CRO) terminology	Replaced with Service provider	Apply consistent terminology, aligned with ICH E6(R3), while retaining the specific responsibilities of each party.
Separate ISF, device, and RWE reference structures	Integrated evidence concepts across study contexts, including drugs, biologics, devices, IVDR, RWE, and ISF	Use shared Record Types where the evidence purpose is the same and metadata to distinguish context.
Computer System Validation (CSV) guidance Excel workbook tab	Zone 12 added – eClinical for study-specific clinical system records	Classify study-specific system implementation, configuration, testing, operation, and oversight evidence in Zone 12 where appropriate; do not redirect all system-generated records there.
No formalized metadata standard	Standard Metadata definitions, with further Provisional Metadata guidance planned	Describe context without multiplying Record Types. Potential Provisional Metadata examples are illustrative, not exhaustive.
Artifact definitions	Purpose/Description for each Record Type	Read the Purpose/Description before identifying a gap or proposing a new Record Type.

2.3 Record Type Applicability Across Study Designs

The TMF SM defines the universe of potential clinical study evidence; it does not prescribe a required set of records for every study. Determine the applicability of each Record Type from the study design, activities performed, applicable regulatory requirements, assigned responsibilities, and risks. This supports a risk-proportionate approach to TMF management and oversight.

3. Relationship to Other CDISC Standards, Regulations, and Previous Models

3.1 Other CDISC Standards

The TMF SM is intended to complement other CDISC standards through consistent terminology and standardized information across the clinical study lifecycle. Controlled terminology and CDISC conventions are used where applicable. The Unified Study Definitions Model (USDM) is an example of a complementary standard; this guide does not define a technical integration with USDM.

3.2 ICH Good Clinical Practice

ICH E6(R3) has informed the terminology and organization of the TMF SM, including its emphasis on evidence of study conduct, risk management, quality management, and oversight. Record Groups reflect these business activities while retaining terminology that is practical for implementation.

The TMF SM organizes evidence that may demonstrate these responsibilities. Use of the model does not, by itself, establish that a regulatory responsibility has been fulfilled.

3.3 Regulatory Requirements and Guidance

Applicable regulatory requirements and guidance remain the basis for determining what evidence must be created and retained. The TMF SM supports consistent classification and description of that evidence; it does not replace jurisdiction-specific requirements or an organization's assessment of those requirements.

3.4 Previous Reference Models

The TMF SM consolidates common evidence concepts from previous reference structures rather than maintaining parallel classifications. This approach introduces new Record Type names, reduces duplication, and uses metadata to distinguish context. A difference in record name, format, or originating system does not necessarily indicate a different evidence concept.

Implementation does not depend on a formal, industry-wide mapping from TMF Reference Model v3.3.1 to the TMF SM. Organizations should assess their existing classifications against the meaning of the new Record Types. Unique Identifiers support recognition of standard concepts across TMF SM releases; they should not be assumed to establish equivalence with a previous Reference Model classification without assessment.

4. TMF Standard Model V1 Architecture

4.1 Overview of the Architecture

The TMF SM uses a three-level hierarchy: Zone, Record Group, and Record Type. Zones provide the highest organizational level. Record Groups represent enduring business activities, and Record Types identify the

distinct evidence generated through those activities. This structure replaces the previous Zone, Section, Artifact, and Sub-artifact hierarchy.

Metadata describes the context of a record without creating a separate Record Type for every variation. The hierarchy and metadata should be interpreted together: the Record Type identifies the evidence purpose, while metadata distinguishes the circumstances in which that evidence was generated.

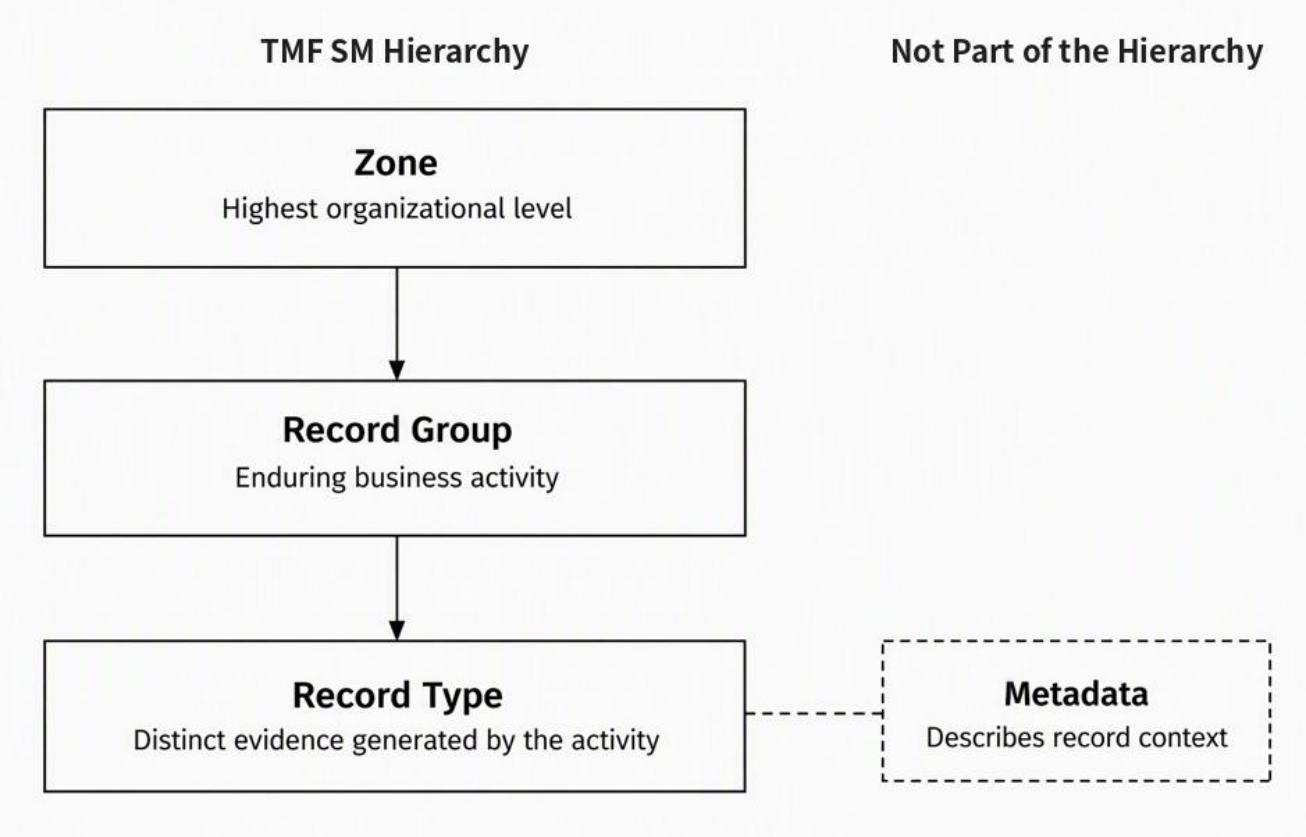


Figure 4.1. TMF Standard Model hierarchy. Metadata describes record context and is not an additional hierarchy level.

4.2 Design Principles

The following principles have guided development of the TMF SM:

- **Evidence first:** Organize records by the study activity, decision, or oversight they demonstrate, rather than as a checklist of files.
- **Consistent meaning:** Apply common names and definitions across the model and address limitations identified in the Reference Model.
- **Proportionate change:** Avoid unnecessary changes, gaps, and implementation problems.
- **Interoperability:** Support consistent interpretation and exchange across organizations and systems.
- **Digital readiness:** Accommodate increasingly technology-dependent studies and evidence maintained beyond the eTMF.
- **Regulatory alignment:** Reflect current concepts, including ICH E6(R3), while retaining practical terminology.
- **Context through metadata:** Distinguish variations without creating unnecessary Record Types.
- **Technology neutrality:** Separate the information model from a particular repository or user-interface design.

4.3 Zones

A Zone is the highest organizational level of the TMF SM and contains related Record Groups. Use the Zone names and relationships defined in the corresponding model release. A Zone provides navigation and context; classification of an individual record remains dependent on the purpose of its evidence.

4.4 Record Groups

Record Groups organize related Record Types around enduring business activities. They provide the middle level of the hierarchy and make related evidence easier to interpret together. Similar organizing concepts may occur in more than one Zone; the published model defines the applicable names and relationships.

Examples of organizing concepts considered during development include Trial Management, Quality Assurance, Risk Management, Agreements, Investigator Site Monitoring, Resources, Qualifications and Training, Tracking, and Meetings. Within each Zone, Record Groups are arranged in a logical sequence reflecting the progression of study activities rather than alphabetically. This arrangement supports navigation; it does not prescribe a required sequence of activities.

4.5 Record Types

A Record Type is the standardized classification for distinct evidence generated through a study activity. Its name identifies the concept; its Purpose/Description explains why the record exists and what evidence it represents.

A separate Record Type is appropriate only when the evidence is meaningfully different. Where records serve the same evidence purpose, use metadata to distinguish context rather than creating duplicate classifications across Zones, functions, study types, or repositories. Review the Purpose/Description before concluding that evidence is missing from the model.

Generic filing categories should not separate evidence from the activity it supports. Communications and Notes to File follow the classification principles below. Meeting records should likewise be interpreted using the applicable Record Type Purpose/Description rather than assuming that a generic category is required in every Zone.

4.5.1 Communications

The TMF SM does not provide a general correspondence filing location. Classify a communication under the Record Type for the activity, decision, or oversight it demonstrates. For example, a communication concerning a specific protocol deviation is classified under the Protocol Deviation Record Type. Additional definitions and metadata guidance for Communications will be provided in a future Provisional Metadata update.

4.5.2 Notes to File

The TMF SM does not define a generic Note to File Record Type. Classify a Note to File according to the evidence it provides so that it remains connected to the activity or decision it supports. Additional definitions and metadata guidance for Notes to File will be provided in a future Provisional Metadata update.

4.6 Unique Identifiers

Unique Identifiers (UIDs) identify standard concepts independently of display labels and local configuration. They support consistent interpretation across TMF SM releases, systems, and organizations as terminology or presentation evolves.

Retain the published UID when implementing a standard Record Type. UIDs support reporting and exchange; they do not remove the need to assess the meaning of legacy classifications during adoption.

4.7 Metadata Framework

Metadata describes a record and gives it context, supports retrieval and exchange, and helps distinguish variations within a Record Type. Incorporating metadata into the standard model aims to:

- Make record retrieval simpler and more intuitive across studies, programs, sites, CROs, and sponsors.
- Improve interoperability between organizations, processes, and systems.
- Make record uploads easier and improve their quality through standardization, including support for AI and automation.
- Make TMF transfers smoother.

The framework establishes required metadata to support implementation of the model and identifies additional metadata to guide its continued development. This approach supports initial adoption while providing a path for expanding metadata requirements in subsequent releases.

Use the definitions and guidance published with the applicable model release.

4.7.1 Standard Metadata

Standard Metadata is the required metadata defined and enforced through the V1 Standard Model. Implementations must support Standard Metadata to implement the model.

Use the definitions, data types, controlled values, and application requirements specified in the Metadata worksheet and corresponding specification for the applicable model release.

For version 1, standard metadata is limited to properties that apply to all records.

4.7.2 Provisional Metadata

Provisional Metadata is optional, suggested, and directional metadata for V1. It provides guidance on additional metadata and prepares implementers for its incorporation into the required metadata baseline in subsequent model releases.

Provisional Metadata will become Standard Metadata in a subsequent release unless community feedback identifies a need for modification. Implementing Provisional Metadata is not required to support the V1 model.

In the current October 19th draft, the Potential Provisional Metadata column illustrates where additional metadata may apply and explains certain Record Type decisions. These examples are not exhaustive and do not constitute a complete specification or create implementation requirements. Further definitions and application guidance will be provided in future drafts.

4.8 Study, Country, and Site Levels

Associate records with the applicable study, country, and site levels according to the evidence they represent. A record may apply to more than one level. Preserve sufficient context to identify where the evidence applies without creating unnecessary duplicate records.

Apply level assignments consistently to support retrieval, oversight, transfer, and inspection. Use the level definitions and attributes in the corresponding model release.

4.9 Zone 12 – eClinical

Zone 12 accommodates study-specific evidence associated with the implementation, configuration, testing, operation, and oversight of clinical systems. Its introduction recognizes that essential evidence may be generated and maintained in systems beyond the traditional eTMF.

The scope is study-specific system evidence, including relevant configuration, testing, changes, access, data handling, and oversight. Zone 12 is not a general repository for enterprise system lifecycle documentation unrelated to the study, nor for every record generated or maintained by an electronic system.

The TMF SM uses the term testing for the study-specific evidence described here. An organization may retain validation in its internal terminology; classification should follow the published Record Type and Purpose/Description rather than the local label.

5. TMF Standard Model Record Definitions

5.1 Record Group Definitions

The Record Group defines the business activity that links its Record Types. Read the definition with the associated Zone and Record Types to understand the intended grouping.

5.2 Record Type Definitions

The Record Type describes the standard classification and its associated attributes for a specific type of record. Read the UID, standard name, Purpose/Description, Record Group, applicable levels, dating conventions, metadata, and implementation notes together, where provided in the corresponding release. The Purpose/Description is the primary explanation of the evidence represented.

The following drafting conventions support consistent Purpose/Descriptions. These explain the rules for how Purpose/Description is written for each Record Type. They do not authorize local changes to published definitions:

- Describe the purpose of the record, not the appearance or contents of a document.
- Focus on the clinical study business process supported by the record, not the filing process.
- Use a standard opening pattern that immediately indicates the kind of evidence represented.
- Describe the outcome or evidence demonstrated rather than merely listing activities performed.
- Align wording, where appropriate, with ICH E6(R3) concepts such as participant safety, rights and well-being, data reliability, study integrity, risk proportionality, quality management, and oversight.
- Avoid redundant wording and unnecessary repetition.

5.3 Metadata Dictionary

The metadata dictionary should identify each element's purpose, data type, applicable records or contexts, controlled terminology or value set, and status as Standard or Provisional. Use these definitions to

distinguish a contextual metadata value from a separate Record Type. Where definitions remain under development, illustrative examples should not be treated as finalized requirements.

5.4 Controlled Terminology

Use controlled terminology where the corresponding TMF SM release defines a governed set of values. Apply the published meaning and any stated extension rules. Local values or synonyms should not replace a standard value with a different meaning.

6. Implementing the TMF Standard Model

6.1 General Assumptions and Implementation Principles

Begin implementation with the evidence generated by study activities, not with a search for filing locations. For each activity, decision, or oversight responsibility, establish the following:

1. Identify the evidence needed and the record that demonstrates it.
2. Determine who creates, reviews, approves, and files the record, and when it should exist.
3. Select the Record Type by reviewing its Purpose/Description.
4. Apply the relevant level, dating convention, and defined metadata.
5. Define how completeness, reliability, retrieval, and oversight will be assessed.

Study-specific variation should be governed and documented rather than creating a separate interpretation of the model for each study.

6.2 The Standard Model in an eTMF

An electronic TMF system may present the model through different navigation or display arrangements. Configuration should preserve the meaning of Zones, Record Groups, Record Types, UIDs, defined metadata, study/country/site context, and controlled terminology, with reporting and integrations as applicable. Local labels should remain traceable to the standard concepts.

Use metadata to distinguish context rather than recreating or duplicating Record Types. Configuration should implement the organization's evidence and process rules, not determine those rules solely from platform limitations.

6.3 Across Multiple Systems

Clinical study evidence may originate and remain in systems outside a formal eTMF system. Identify the source system, record controls, transfer arrangements, and means of access for oversight and inspection.

The TMF SM does not require all evidence to be copied into one repository. Records should remain consistently classified, controlled, and retrievable, with sufficient context to demonstrate their relationship to the study.

6.4 Sponsor-Service Provider Implementation

Sponsors and service providers should agree on Record Types, UIDs, metadata, responsibilities, transfer expectations, reconciliation, and oversight. Common identifiers and definitions reduce reliance on local naming conventions and support consistent exchange.

The sponsor should define how evidence generated by service providers will be overseen. The TMF SM supports this oversight through common classifications and metadata; it does not replace governance, review, or escalation processes.

6.5 Sponsor-Site Implementation

Use common Record Types and metadata where sponsor and investigator site records represent the same evidence concept. Distinguish each party's responsibilities and repositories, and preserve record identity, context, and traceability during exchange. Integration of ISF concepts does not remove these distinctions.

6.6 Organization-Specific Records

Before adding an organization-specific Record Type, review existing Purpose/Descriptions and determine whether metadata can represent the distinction. Add an organization-specific Record Type **only** where the evidence is meaningfully different. Use a local identifier that cannot be confused with a published TMF SM UID, document the definition and rationale, and obtain approval through organizational governance. Local metadata and terminology should extend, not overwrite, standard definitions.

If an organization-specific Record Type must be added, assign the Record Type with a 5 digit UID, beginning with number 9 (i.e. 90001). These custom UIDs should be tracked by the organization and reused where appropriate across studies. The same custom should not be assigned to multiple custom record types.

7. Adopting the TMF Standard Model

7.1 Adoption Principles

Adoption is an organizational change initiative, not simply a remapping exercise. Establish common classification and metadata rules, decision criteria for recurring evidence and exceptions, and governance for permitted variation. The objective is to reduce inconsistent interpretation while preserving the flexibility needed for different studies and operating models.

7.2 Using Unique Identifiers During Adoption

Use UIDs to retain the identity of standard concepts during configuration, reporting, and exchange. When transitioning from a previous model, assess the evidence purpose rather than relying on display names or assuming a one-to-one relationship. Document local transition decisions where needed to preserve context and traceability.

7.3 Organizational Adoption Approaches

Organizations may use full, phased, system-driven, or process-driven adoption approaches. Adoption may also align with a technology upgrade or replacement. Regardless of approach, the organization should communicate what changes, what remains the same, and who is authorized to make implementation decisions.

8. Interoperability and Information Exchange

8.1 Interoperability Principles

Interoperability is a central objective of the TMF SM. Consistent Record Types, UIDs, metadata, and terminology reduce dependency on local filing names and allow information to move more reliably among sponsors, sites, service providers, technologies, and repositories.

8.2 Role of Unique Identifiers in Interoperability

UIDs support stable identification of Record Types when display names, language, or local presentation differ. Implementations should preserve UIDs during exchange so the receiving organization or system can interpret the standard concept without relying exclusively on text labels.

8.3 Exchange Between Organizations

Information exchange should preserve the standard Record Type, UID, applicable metadata, and study context. Sponsor-CRO, sponsor-site, site-sponsor, CRO-service provider, and other exchanges should be designed so that standard identity is retained and local configuration does not obscure meaning.

8.4 Exchange Between Systems

System-to-system exchange should use standard identifiers and metadata wherever technically possible. This can support eTMF-to-eTMF transfer, eClinical-to-eTMF workflows, eISF-to-sponsor exchange, and downstream analytics. Exchange design should avoid requiring the receiving system to infer a Record Type solely from a file name or folder path.

9. Implementation Governance and Change Management

9.1 Establishing an Implementation Team

TMF SM readiness should not sit only with the TMF team. Implementation should involve the functions that create, own, configure, review, exchange, and oversee trial evidence, including TMF, Clinical Operations, Quality, Regulatory, Technology, Records Management, Data Governance, and Service Provider Management.

Education should be role-specific. Executives need to understand why standardization matters to risk, readiness, and scalability; study teams need to understand how daily activities and decisions create TMF evidence; functional owners need to understand accountability when service providers perform work; TMF teams need the structure, metadata, taxonomy, and quality implications; technology teams need configuration, integration, reporting, and transition planning; and CROs/service providers need clear expectations for record creation, transfer, metadata, and reconciliation.

9.2 Standard Versus Organizational Configuration

Organizations should distinguish CDISC-governed elements from organization-governed configuration. Standard names, definitions, UIDs, and controlled terminology should not be redefined locally. Organizations may control display labels, local metadata extensions, workflow, user-interface presentation, and other implementation details provided that they do not change the meaning of the Standard.

9.3 Change Control

Adoption of future TMF SM releases should be controlled. Organizations should assess the impact of changes to Record Types, metadata, terminology, UIDs, technology configuration, integrations, reporting, procedures, training, and service-provider expectations. UIDs should be preserved and used to help distinguish continuity of a concept from a genuinely new concept.

9.4 Training and Adoption

Training should explain the rules associated with the TMF SM vs. only teaching new filing locations. Users should understand the evidence-first approach, Record Group and Record Type concepts, the role of

metadata, UIDs, local extensions, and the relationship between the TMF SM and organizational accountability for creating and overseeing evidence.

9.5 Implementation Maturity

Implementation maturity can be viewed as a progression from adoption, to standardization, to integration, and ultimately to optimization. Early adoption establishes the structure. Standardization reduces local variation. Integration uses identifiers and metadata across systems and organizations. Optimization uses the consistent evidence model to improve oversight, analytics, digital workflows, and inspection readiness.

10. Conformance

10.1 What Does Conformance to TMF Standard Model Mean?

Conformance should reflect preservation of the meaning of the TMF SM, not visual duplication of a particular filing tree. A conformant implementation should be able to identify standard Record Types, preserve associated UIDs, use Standard Metadata and controlled terminology as defined, and distinguish permitted local customizations from standard concepts.

10.2 Record Group Conformance

Record Group implementation should preserve the standard grouping concept and relationships defined by the TMF SM. Local navigation or display may differ, but the business organization should not assign a standard Record Group name or identifier to a materially different concept.

10.3 Record Type Conformance

A standard Record Type should retain its published meaning and UID. Organizations may use local display terminology (data labels) where necessary, but the local representation should remain traceable to the standard Record Type and should not redefine its purpose.

10.4 Unique Identifier Conformance

Standard UIDs should be preserved exactly as published. A UID should not be reassigned to a different local concept. New organization-specific concepts should use local identifiers that are clearly distinguishable from CDISC Standard Model UIDs.

10.5 Metadata Conformance

Implementations should support Standard Metadata according to the published specification and should distinguish Standard, Provisional, and organization-specific metadata. Local fields should not replace or materially change the meaning of Standard Model Metadata variable.

10.6 Controlled Terminology Conformance

Where the TMF SM defines controlled terminology, implementations should use the published values or permitted extensions as specified. Local synonyms may be displayed, but exchange and machine-readable representations should retain the standard value or code where applicable.

10.7 Exchange Conformance, if applicable

Where a formal exchange specification is published, conformance should include preservation of Record Type identity, UID, required metadata, and controlled terminology during transfer. Exchange conformance should not depend on a receiving organization reproducing the sender's user interface or folder structure.

10.8 Permitted Extensions

Permitted customization may include organization-specific Record Types, metadata, terminology, workflow, and display configuration. Extensions should be governed, documented, and clearly distinguishable from Standard Model content.

10.9 Non-Conformant Changes

Examples of non-conformant changes include reusing a standard UID for a different concept, materially changing the meaning of a standard Record Type while retaining its standard identity, replacing a standard metadata concept with an incompatible local definition, or presenting a local extension as if it were part of the published CDISC Standard Model.

Appendices

Appendix A - TMF Standard Model V1 Team and Contributors

To be populated from the final CDISC contributor and governance records.

Appendix B - Glossary and Abbreviations

The final glossary should include TMF, TMF SM, Record Group, Record Type, UID, Standard Metadata, Provisional Metadata, ISF, RWE, CRO, Service Provider, eTMF, eISF, eClinical, and other terms used in the Standard Model.

Appendix C - References

References should include the final TMF SM specification, applicable CDISC terminology resources, ICH E6(R3), and other sources formally cited by the Standard Model team.

Appendix D - Revision History

The revision history should document changes to the Implementation Guide by release.