



# cdisc® 2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



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## Bridging the Gap Between TMF & the ISF

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## Speakers



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## Objective

- Understand key ISF-only components and how they differ from the TMF, plus structure updates to prepare for ISF adoption.
- Update on ISF Initiative from the CDISC subteam.
- Hear the Site Perspective
- Plans for TMF SM V1 and ISF Version 2.0.



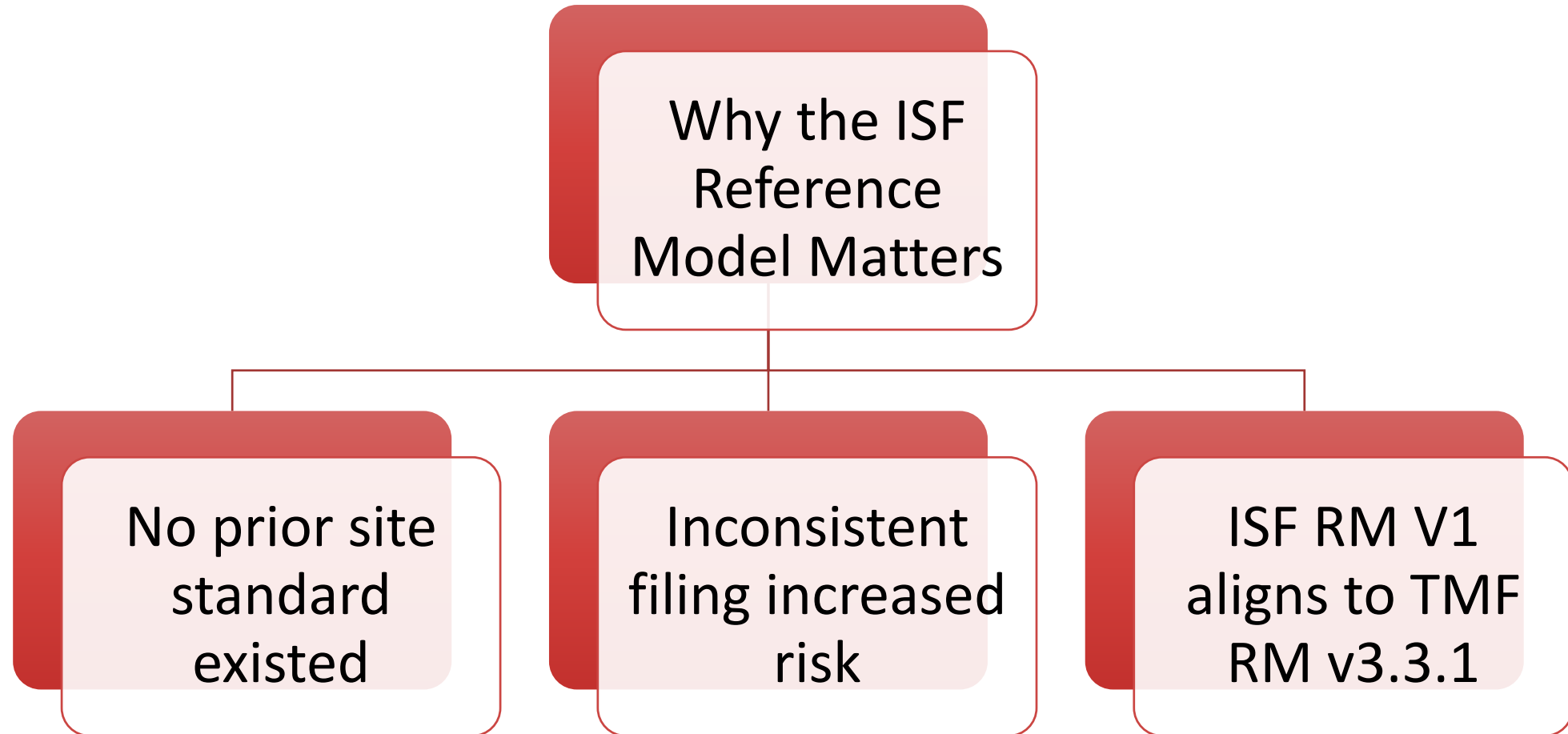


## TMF vs. ISF

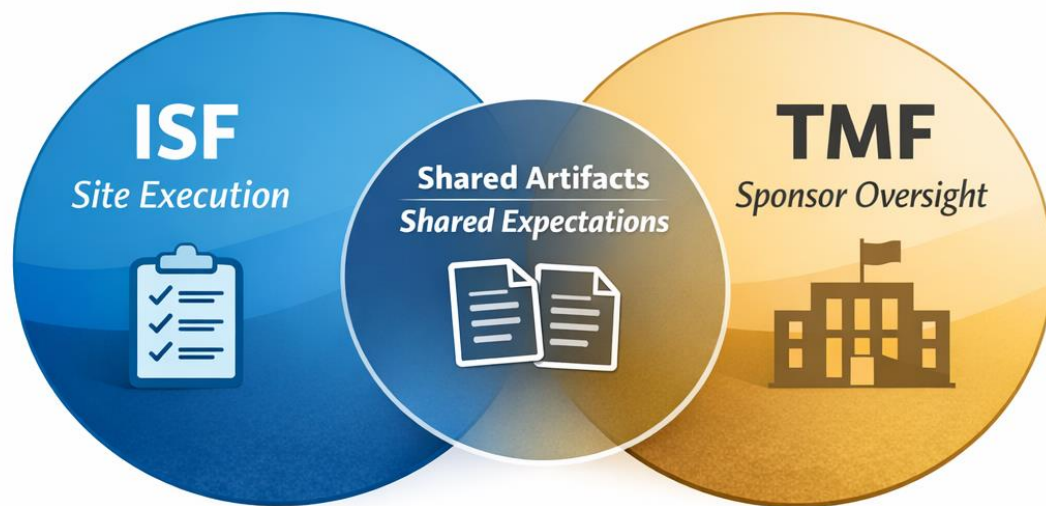
| ISF                             | TMF                           |
|---------------------------------|-------------------------------|
| Site-owned                      | Sponsor-owned                 |
| Proves what happened locally    | Proves what happened globally |
| Daily operational use/execution | Oversight and submission      |

*Distinct but  
Connected*

# Why CDISC Created the ISF RM



# Overlap without Duplication



*Same standards. Different owners. One inspection story.*

- *Some artifacts shared*
- *Some site-only by design*

# ISF RM Release 1.0 - Overview

## ISF Structure Overview

The ISF Zone Map visually represents the **14 zones** of the ISF structure, supporting comprehensive trial management.

*Available now as an Excel File with columns A – L.*

## Structured ISF Zones

14 zones cover various documentation categories such as planning, regulatory, and site materials.



| ISF Zone Combined #/Name                      | Count of ISF Artifact Type |
|-----------------------------------------------|----------------------------|
| ISF_01_Planning and Procedures                | 23                         |
| ISF_02_Study Library                          | 12                         |
| ISF_03_Participant Materials                  | 7                          |
| ISF_04_Regulatory Submissions                 | 3                          |
| ISF_05_IRB or IEC                             | 7                          |
| ISF_06_Other Committees                       | 3                          |
| ISF_07_Site Documentation                     | 21                         |
| ISF_08_IP or Device Documentation             | 16                         |
| ISF_09_Trial Supply Documentation             | 4                          |
| ISF_10_Testing Facility Documentation         | 10                         |
| ISF_11_Monitoring Logs and Reports            | 6                          |
| ISF_12_Safety Events, Logs, and Reports       | 6                          |
| ISF_13_Study and/or Participant Data and Logs | 6                          |
| ISF_14_Correspondence and Notes to File       | 2                          |
| <b>Grand Total</b>                            | <b>126</b>                 |

126 Artifacts

- 89 Core
- 37 Recommended

# ISF RM Release 1.0 - Overview

|    | A                              | B               | C                       | D                                       | E                  | F                             | G                                                   | H                   | I                                      |
|----|--------------------------------|-----------------|-------------------------|-----------------------------------------|--------------------|-------------------------------|-----------------------------------------------------|---------------------|----------------------------------------|
| 1  | ISF Zone Combined #/Name       | ISF Zone Number | ISF Zone Name           | ISF Section Combined #/Name             | ISF Section Number | ISF Section Name              | ISF Artifact Combined #/Name                        | ISF Artifact Number | ISF Artifact Type                      |
| 2  | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.01_ISF Plan                      | ISF_01.01          | ISF Plan                      | ISF_01.01.01_ISF/eISF Index                         | ISF_01.01.01        | ISF/eISF Index                         |
| 3  | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.02_Feasibility                   | ISF_01.02          | Feasibility                   | ISF_01.02.01_Feasibility Documentation              | ISF_01.02.01        | Feasibility Documentation              |
| 4  | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.03_Site Selection and Activation | ISF_01.03          | Site Selection and Activation | ISF_01.03.01_Site Activation Document               | ISF_01.03.01        | Site Activation Document               |
| 5  | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.04_Recruitment                   | ISF_01.04          | Recruitment                   | ISF_01.04.01_Recruitment Plan                       | ISF_01.04.01        | Recruitment Plan                       |
| 6  | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.05_Guidance Documentation        | ISF_01.05          | Guidance Documentation        | ISF_01.05.01_Informed Consent Plan                  | ISF_01.05.01        | Informed Consent Plan                  |
| 7  | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.05_Guidance Documentation        | ISF_01.05          | Guidance Documentation        | ISF_01.05.02_IP or Device Instructions for Handling | ISF_01.05.02        | IP or Device Instructions for Handling |
| 8  | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.05_Guidance Documentation        | ISF_01.05          | Guidance Documentation        | ISF_01.05.03_IP or Device Labeling Plan             | ISF_01.05.03        | IP or Device Labeling Plan             |
| 9  | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.05_Guidance Documentation        | ISF_01.05          | Guidance Documentation        | ISF_01.05.04_IP or Device Transfer Documentation    | ISF_01.05.04        | IP or Device Transfer Documentation    |
| 10 | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.05_Guidance Documentation        | ISF_01.05          | Guidance Documentation        | ISF_01.05.05_IP or Device Recall Plan               | ISF_01.05.05        | IP or Device Recall Plan               |
| 11 | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.05_Guidance Documentation        | ISF_01.05          | Guidance Documentation        | ISF_01.05.06_Unblinding Plan                        | ISF_01.05.06        | Unblinding Plan                        |
| 12 | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.05_Guidance Documentation        | ISF_01.05          | Guidance Documentation        | ISF_01.05.07_IRT User Manual                        | ISF_01.05.07        | IRT User Manual                        |
| 13 | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.05_Guidance Documentation        | ISF_01.05          | Guidance Documentation        | ISF_01.05.08_Trial Supply Plan                      | ISF_01.05.08        | Trial Supply Plan                      |
| 14 | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.05_Guidance Documentation        | ISF_01.05          | Guidance Documentation        | ISF_01.05.09_Operational Procedure Manual           | ISF_01.05.09        | Operational Procedure Manual           |
| 15 | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.05_Guidance Documentation        | ISF_01.05          | Guidance Documentation        | ISF_01.05.10_Other Plan                             | ISF_01.05.10        | Other Plan                             |
| 16 | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.05_Guidance Documentation        | ISF_01.05          | Guidance Documentation        | ISF_01.05.11_Safety Manual                          | ISF_01.05.11        | Safety Manual                          |
| 17 | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.05_Guidance Documentation        | ISF_01.05          | Guidance Documentation        | ISF_01.05.12_Site Policies or Procedures            | ISF_01.05.12        | Site Policies or Procedures            |
| 18 | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.05_Guidance Documentation        | ISF_01.05          | Guidance Documentation        | ISF_01.05.12_Site Policies or Procedures            | ISF_01.05.12        | Site Policies or Procedures            |
| 19 | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.05_Guidance Documentation        | ISF_01.05          | Guidance Documentation        | ISF_01.05.13_Manual                                 | ISF_01.05.13        | Manual                                 |
| 20 | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.05_Guidance Documentation        | ISF_01.05          | Guidance Documentation        | ISF_01.05.14_Source Data Agreement                  | ISF_01.05.14        | Source Data Agreement                  |
| 21 | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.05_Guidance Documentation        | ISF_01.05          | Guidance Documentation        | ISF_01.05.15_Data Entry Guideline                   | ISF_01.05.15        | Data Entry Guideline                   |
| 22 | ISF_01_Planning and Procedures | ISF_01          | Planning and Procedures | ISF_01.05_Guidance Documentation        | ISF_01.05          | Guidance Documentation        | ISF_01.05.16_Sample Case Report Form                | ISF_01.05.16        | Sample Case Report Form                |

# ISF RM Release 1.0 - Overview



Zones



Section



Artifacts



Subartifacts



## ISF RM Metadata (12 columns)

- A. ISF Zone Combined #/Name
- B. ISF Zone Number
- C. ISF Zone Name
- D. ISF Section Combined #/Name
- E. ISF Section Number
- F. ISF Section Name
- G. ISF Artifact Combined #/NameISF
- H. Artifact Number
- I. ISF Artifact Type
- J. ISF Subartifact Name
- K. TMF Artifact Group
- L. ISF Inclusion

# ISF RM Release 1.0 - Overview

| SUMMARY                                     |     |
|---------------------------------------------|-----|
| Total ISF Artifacts                         | 126 |
| Artifacts with TMF Alignment (has TMF code) | 113 |
| Artifacts with No TMF Equivalent (n/a)      | 12  |
| Artifacts with Varied TMF Mapping           | 2   |
| Core Artifacts                              | 86  |
| Recommended Artifacts                       | 40  |

## NOTABLE NAMING & TERMINOLOGY DIFFERENCES

*These items align conceptually but have naming or structural differences between ISF and TMF*

| ISF Section                             | ISF Artifact Type                 | TMF Artifact Group                     | Key Naming Difference     | ISF Term              | Impact                                                   |
|-----------------------------------------|-----------------------------------|----------------------------------------|---------------------------|-----------------------|----------------------------------------------------------|
| ISF_01.03_Site Selection and Activation | Site Activation Document          | 05.02.17 IP Site Release Documentation | Different focus           | Site Activation       | TMF emphasizes IP release; ISF emphasizes site readiness |
| ISF_01.05_Guidance Documentation        | IP or Device Labeling Plan        | 06.01.07 IP Re-labeling Documentation  | Plan vs Documentation     | Labeling Plan         | ISF captures planning; TMF captures executed relabeling  |
| ISF_01.05_Guidance Documentation        | Source Data Agreement             | 05.04.02 Source Data Verification      | Agreement vs Verification | Source Data Agreement | Different aspects of source data management              |
| ISF_01.06_System Compliance Information | System Compliance Document        | 10.04.03 Validation Documentation      | Compliance vs Validation  | System Compliance     | ISF broader scope; TMF more technical                    |
| ISF_03.01_Participant Logs              | Participant Identification Log    | 05.04.10 Subject Identification Log    | Participant vs Subject    | Participant           | ISF uses modern inclusive terminology                    |
| ISF_03.01_Participant Logs              | Participant Log                   | 05.04.01 Subject Log                   | Participant vs Subject    | Participant           | ISF uses modern inclusive terminology                    |
| ISF_03.02_Participant Consent           | Signed ICF                        | 05.04.11 Source Data                   | ICF vs Source Data        | Signed ICF            | TMF classifies consent as source data                    |
| ISF_03.03_Blank Forms                   | Blank ICF                         | 02.02.03 Informed Consent Form         | Blank vs Template         | Blank ICF             | ISF specifies blank version explicitly                   |
| ISF_03.03_Blank Forms                   | Participant Reported Outcome Data | 02.02.01 Subject Diary                 | PRO vs Diary              | PRO Data              | ISF uses broader PRO terminology                         |
| ISF_07.07_Site Training Evidence        | Site Evidence of Training         | 05.02.03 Site Evidence of Training     | No difference             | Same                  | Good alignment example                                   |

## ***The Site Perspective***

**Vincenzo Mercurio, PhD**

1. *ISF experience :*
  - a. *# of trials/studies*
  - b. *Variations in ISF structure experienced*



## *The Site Perspective*

**Vincenzo Mercurio, PhD**

- c. Usage of Paper vs. Electronic ISF*
- d. Challenges today*



## *The Site Perspective*

**Vincenzo Mercurio, PhD**

2. *What happens when you are:*
  - a. *Audited (internal/external)?*
  - b. *Inspected?*
3. *What are your expectations for the future?*





## *Ask the Audience*

*What can you do now at your organization for site adoption of ISF RM?*





## ***What can you do now at your organization for site adoption of ISF RM?***

- 1. Get familiar with the ISF structure now*
- 2. Consider adopting ISF RM V1 provisional as part of your TMF Index today!*
- 3. Engage with sites! Ask them their opinion!*
- 4. Pilot usage of the ISF RM on a few small studies*
- 5. Spread the word*

*From Guidance to Practice*

## ISF RM V1 Future

1. Launch of User Guide and a simple ISF Plan or Checklist
2. More comprehensive training
3. ISF RM V2 planned to be released with TMF Standard Model V1 in early 2027
4. Ongoing engagement with eISF vendors as part of TMF SM V1 vendor workstream



## Key Takeaways

- TMF + ISF alignment reduces inspection findings without adding burden
- Clear ownership and proportional documentation are the path to inspection readiness
- Use it, give feedback, and help shape ISF RM v2.0

*The ISF RM makes structure a Site reality*

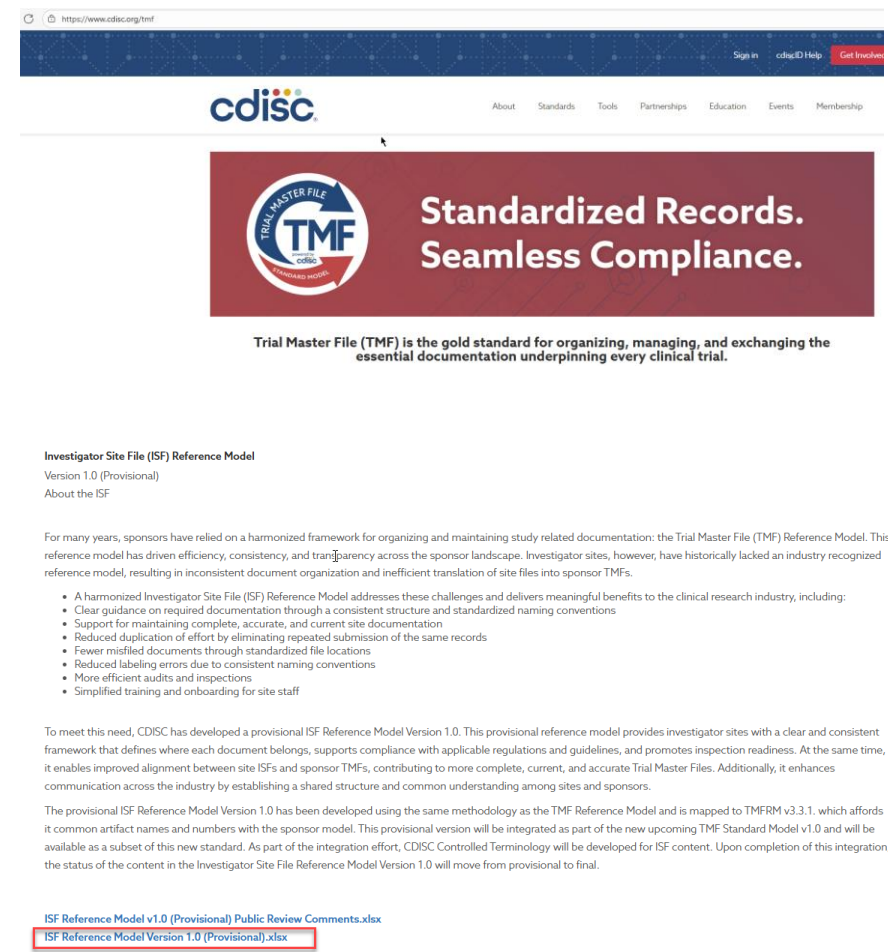
**Questions?**



**Grazie mille!**



# ISF RM V1 is located on the [CDISC.org](https://www.cdisc.org) website



Go to the bottom of the page and click TMF Resources and select Investigator Site File - ISF



The ISF Page will display. The model is available **via a link at the bottom of the page.**