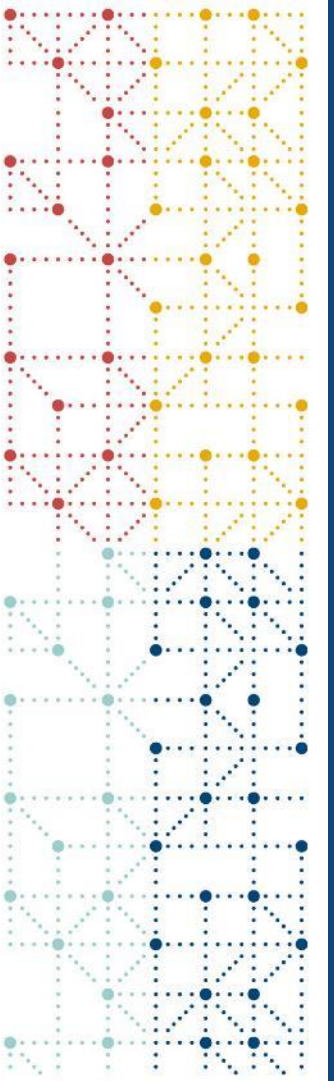
Introducing the Investigator Site File (ISF) v1 (Provisional)

February 11, 2026

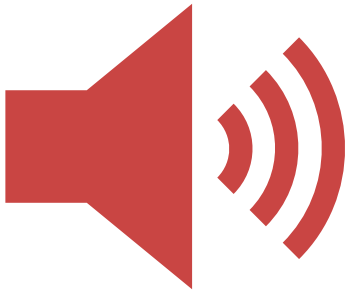
Agenda

1. Housekeeping
2. Introductions
3. Introduction to the ISF Reference Model
4. ISF Structure
5. Q & A and Closing



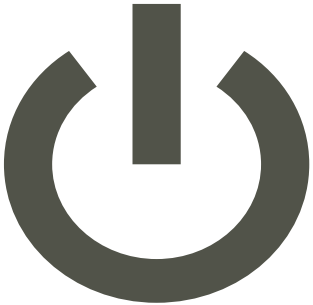
Housekeeping

Housekeeping



You will remain on **mute**

Housekeeping



Audio Issues?

First, close and restart your Teams App
Second, check your local internet connection strength

Housekeeping

Submit questions at any time via the Q&A section

If you cannot see the Q&A feature, please, change to using the Teams app instead of the browser.

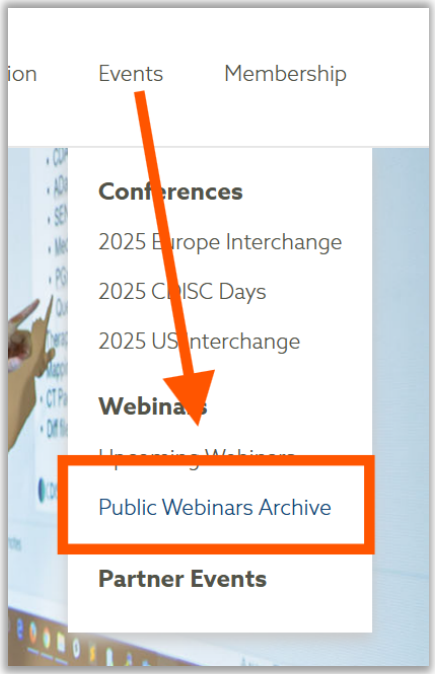
Housekeeping

Chat feature is open!

Please put your questions in the Q&A so that the speakers can see them.

Housekeeping

Webinar Recording



A recording of this webinar and a PDF of the slides will be available in the Public Webinar Archive on the CDISC website.

Meet the Speakers

Aryn Knight, BS, CCRP

Title: Associate Vice President, Clinical Research

Organization: Memorial Hermann Health System

Jamie Toth

Title: Sr. Director, Global TMF Management & Records

Organization: BeOne Medicines USA, Inc.

Abbey Diaz

Title: Manager, Clinical Portfolio Services, Systems (TMF Operations)

Organization: Alnylam Pharmaceuticals, Inc.

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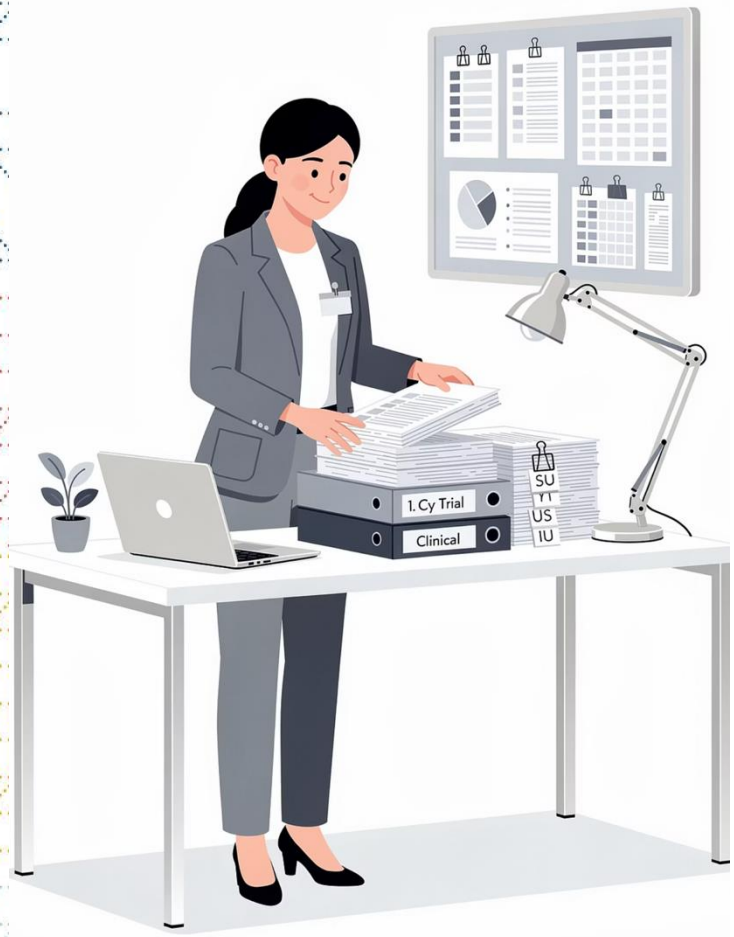


ISF Reference Model Webinar

Hosted by CDISC

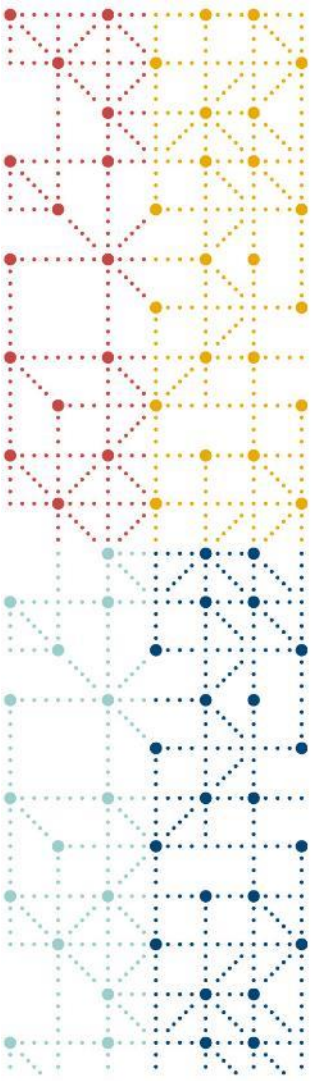
Official training on the Investigator Site File Reference Model

Inspection Readiness

Supporting compliance and standardization across clinical trial sites trial sites

Version 1.0

Provisional release establishing industry best practices



Introduction

Overview

CDISC TMF Steering Committee Liaisons:

Jamie Toth

Dawn Niccum

Co-leads:

Matt Lowery, The Pathways Grp, LLC

Aryn Knight, AVP Clinical Research, Memorial Hermann Health System

Goal:
To develop an Investigator Site File (ISF) reference model for sites to use that supplements the TMF Reference Model with the intention of standardizing ISF structure, file naming conventions, and how/where site-level essential records are filed.

Committee: ~46 members across all aspects of the industry who have an interest ***in*** and experience ***with*** ISF/TMF/regulatory including sites, sponsors, CROs, service providers/vendors, consultants.

Sub teams:

- **Evaluation**: Review of existing ISF structures
- **Standards**: Setting standards
- **Proofing**: Review of deliverables
- **Outreach**: Presentations, publications, and white papers
- **Training**: Training the industry on ISF RM

Expected Benefits

Increased Efficiency

Facilitate consistent document filing practices which reduces time spent preparing for monitoring visits, audits, or inspections.

Simplify the training process for new site staff and reduces errors in filing.

Improved Collaboration

Streamline document exchange and improved communication between sites and sponsors.

Make it easier for auditors and inspectors to locate and review documents without having to understand a unique filing system for each site.

Enhanced Compliance

Ensure adherence to GCP and ICH guidelines which enables better ISF and TMF quality.

Facilitate inspection readiness and enable proactive risk identification.

Timeline

Two years of cross industry collaboration and work

2024

Team forms/initial drafts created

February - December

2025

CDISC Review

January - July

Public Review

July - September

Ratification of public comments

September - November

CDISC Final Review

November – January 2026

2026

CDISC Final Review

From November 2025-January 2026

Public Launch

February 6, 2026

Webinars, trainings, comms, etc.

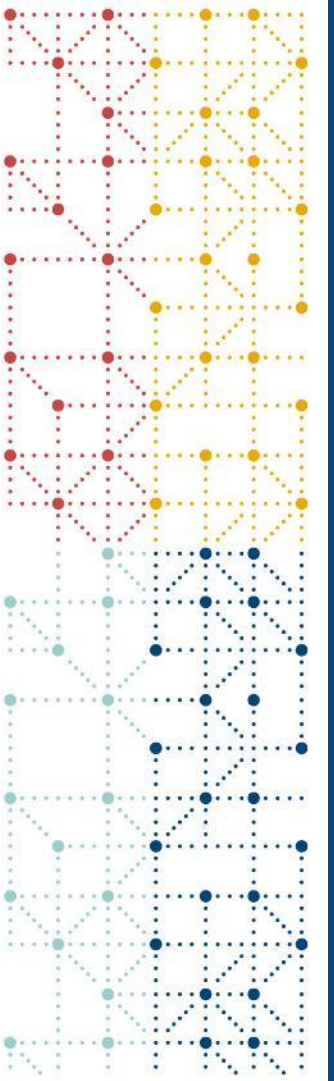
February – December 2026

2027

TMFSMV1

Inclusion of ISF RM 1 into TMFSMV1

Outreach has been ongoing with presentations & updates at various conferences, webinars, since 2024



Introduction to ISF Reference Model

OBJECTIVES

1. Describe the structure and intended use of the key sections of the ISF RM.

2. Identify the benefits of using the ISF RM by sites, sponsors, regulators, and vendors.

What Is The Investigator Site File?

The ISF is the collection of essential records maintained by the investigator site that record and support the conduct of a clinical trial.

Required to Demonstrate

- Regulatory compliance
- Good Clinical Practice (GCP)
- Participant protection

Critical For

- Audits and inspections
- Ongoing oversight

Why A Reference Model for ISF?

Challenges sites face today

The ISF RM addresses these issues by providing a standardized structure

Why The ISF Reference Model Matters

PURPOSE

Standardize Structure

Consistent file names and terminology across all trials trials

Reduce Errors

Facilitate consistent record filing practices

Simplify Training

Easier onboarding for new site staff

Inspection Ready

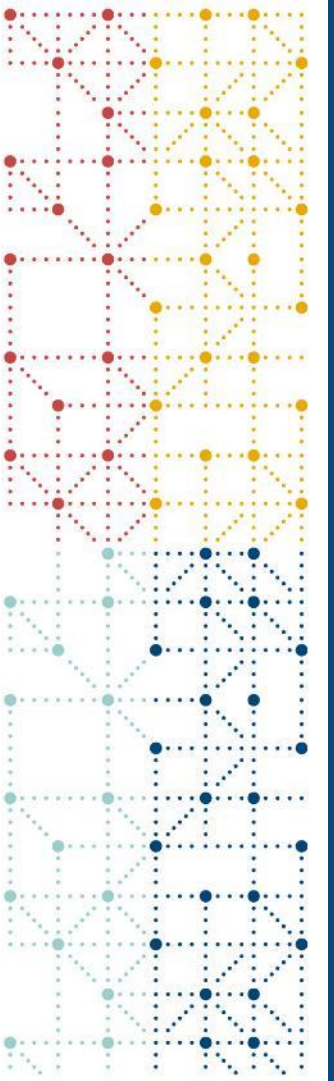
Improve preparedness for regulatory reviews

Streamline Exchange

Efficient record sharing with sponsors

Align with TMF

Connect site records with sponsor practices



ISF Structure

ISF RM Release 1.0

ISF Structure Overview

The ISF Zone Map visually represents the **14 zones** of the ISF structure, supporting comprehensive trial management.
Currently 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
Grand Total	**126**

126 Artifacts
- 89 Core
- 37 Recommended

ISF Reference Model-Structure Overview


Zones


Section

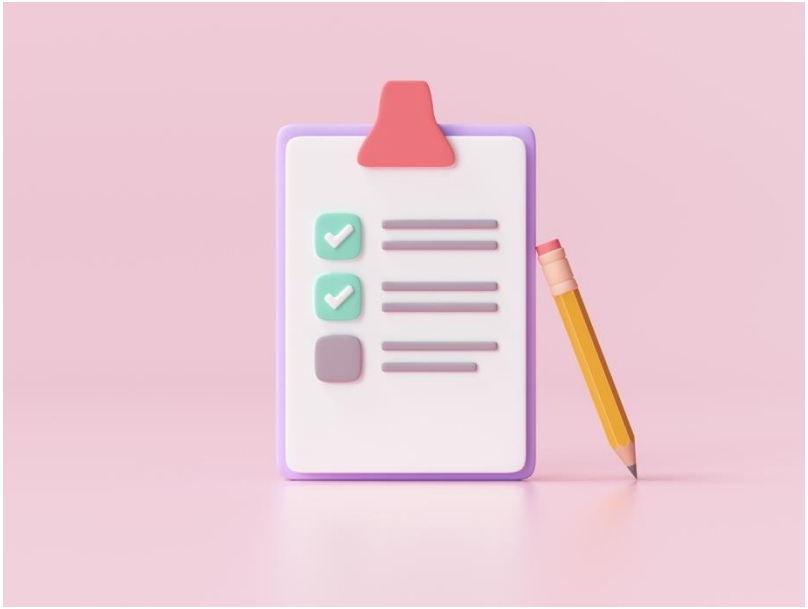

Artifacts


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

Let's Hear From You



Which type of ISF do you currently use?

A. 100% Paper ISF
B. 100% Electronic ISF
C. Combination of Paper and Electronic ISF (hybrid)
D. I don't handle regulatory so, I have yet to use an ISF
E. Not sure

How ISF Reference Model Is Delivered

Excel Spreadsheet Format Format

Delivered as a comprehensive Excel workbook

Powerful Functionality

- Searching
- Sorting
- Filtering
- Pivoting

Flexible Implementation

- Paper ISFs
- Electronic ISFs (eISF systems)

ISF Reference Model

	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 Fo	Saved to this PC	Sample Case Report Form

Key Benefits of ISF-TMF Alignments

Shared Structure

Common terminology across all stakeholders

Easier Exchange

Streamlined document sharing processes

Fewer Issues

Reduced reconciliation problems

Clear Expectations

Better monitoring and inspection outcomes

Improved Communication

Enhanced industry-wide collaboration

Flexible Implementation

The ISF RM supports implementation across different environments

Paper ISFs

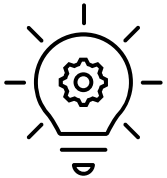
Traditional physical document management

Electronic ISFs

Digital eISF system implementation

Hybrid Environments Environments

Mixed paper and electronic systems



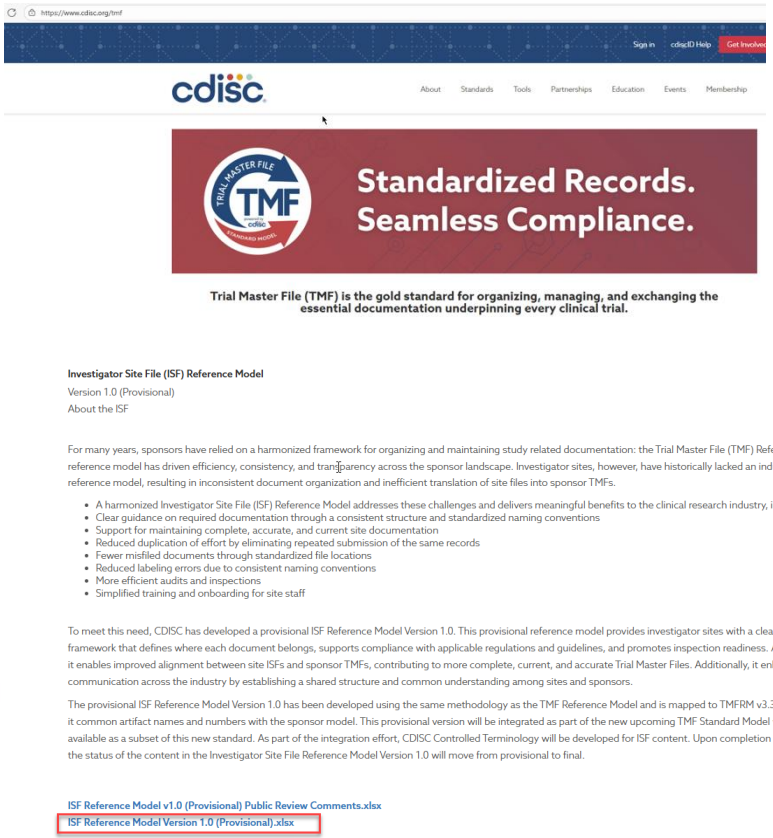
Follow the ISF RM in the order outlined to support completeness and inspection readiness

Putting the ISF RM into Motion

Become familiar with the ISF RM and consider start using it

The ISF RM V1 is located on the CDISC.org website

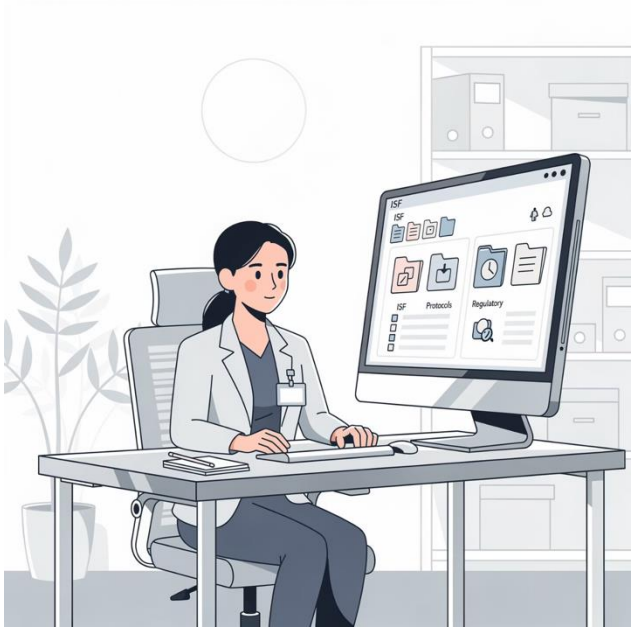
ISF RM Location



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.**

Implementing the ISF RM



Getting Started

The ISF RM is designed for both paper and electronic ISFs and should be followed in the outlined order.

1

Develop ISF Plan

Define how the ISF will be created, maintained, and controlled throughout the trial lifecycle

2

Create ISF Index

Derive study-specific index from ISF RM, graying out non-applicable artifacts

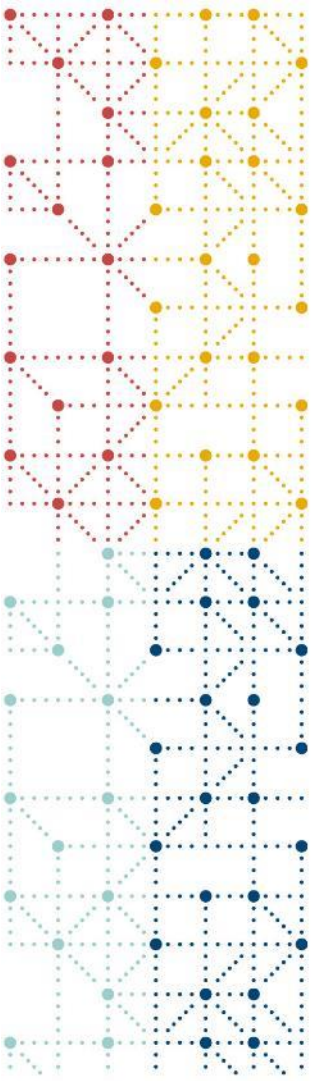
3

Maintain Compliance

Ensure ISF remains complete, accurate, and inspection-ready per ICH GCP

Stay Tuned: What's Next for ISF RM

- ISF User/Implementation Guide
- ISF Reference Model v2 planned to be released with TMF Standard Model v1 in early 2027
- More comprehensive training in the model is been planned!



Let’s Open the Floor

Audience Questions

We’d love to hear from you — Please add your questions or comments in the Q&A window

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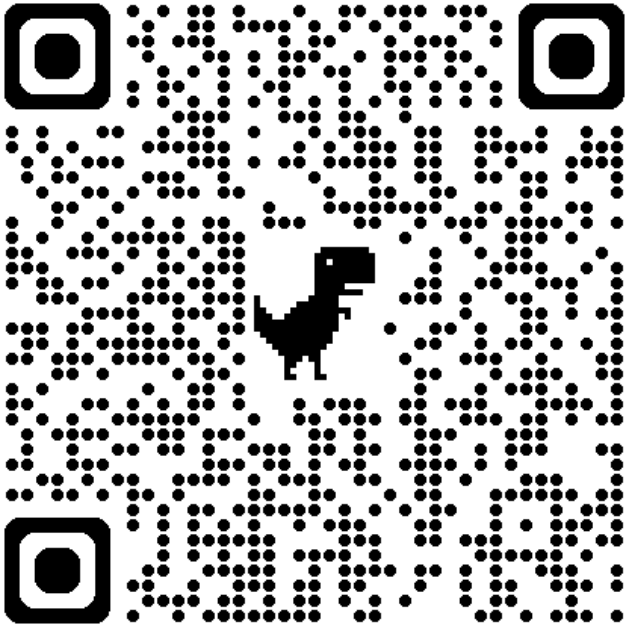

Thank You!