

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

February 11, 2026





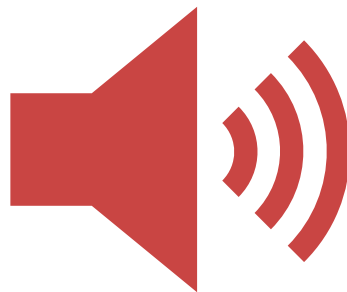
Agenda

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

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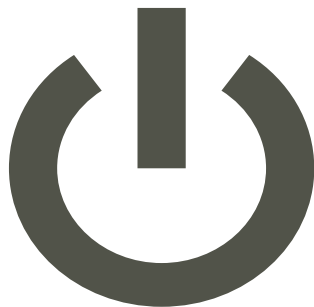
Housekeeping

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.

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Chat feature is open!

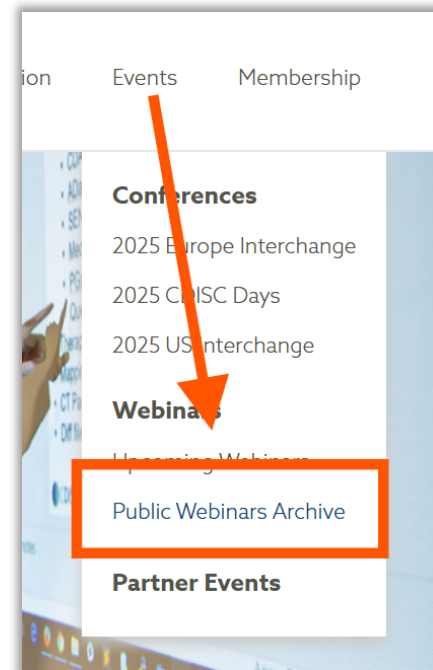
Please put your questions in the Q&A so that the speakers can see them.

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



Jamie Toth

Title: Sr. Director, Global TMF Management & Records

Organization: BeOne Medicines USA, Inc.



Aryn Knight, BS, CCRP

Title: Associate Vice President, Clinical Research

Organization: Memorial Hermann Health System

Meet the Speakers



Gagandeep Kaur

Title: Senior Project Manager, Service Delivery

Organization: Sitero, LLC



Eva Matheu

Title: Senior TMF Consultant

Organization: TransPerfect



Abbey Diaz

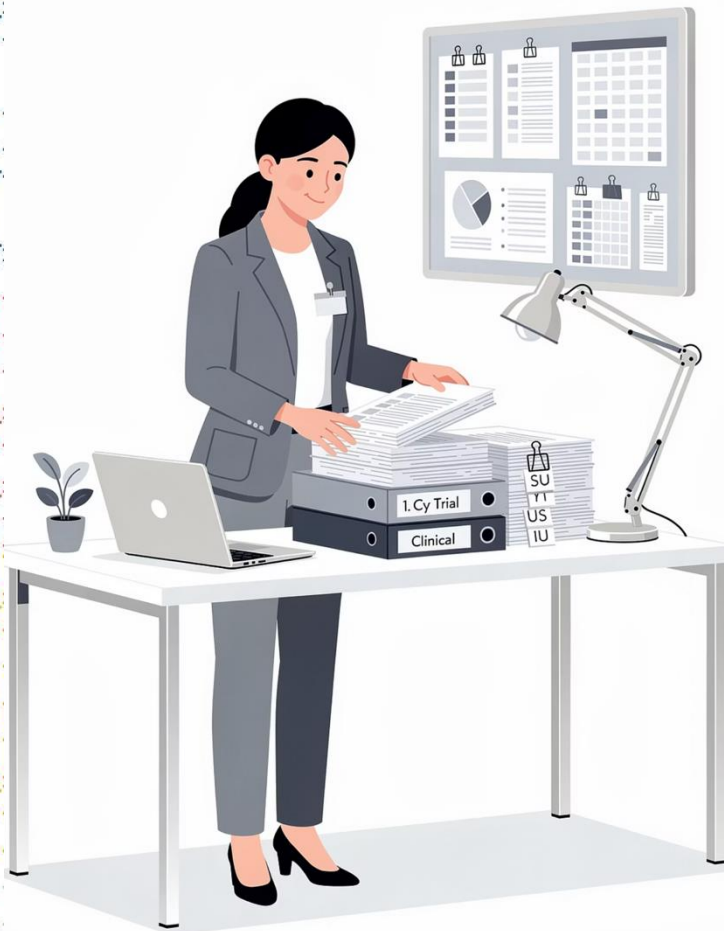
Title: Manager, Clinical Portfolio Services, Systems (TMF Operations)

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

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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

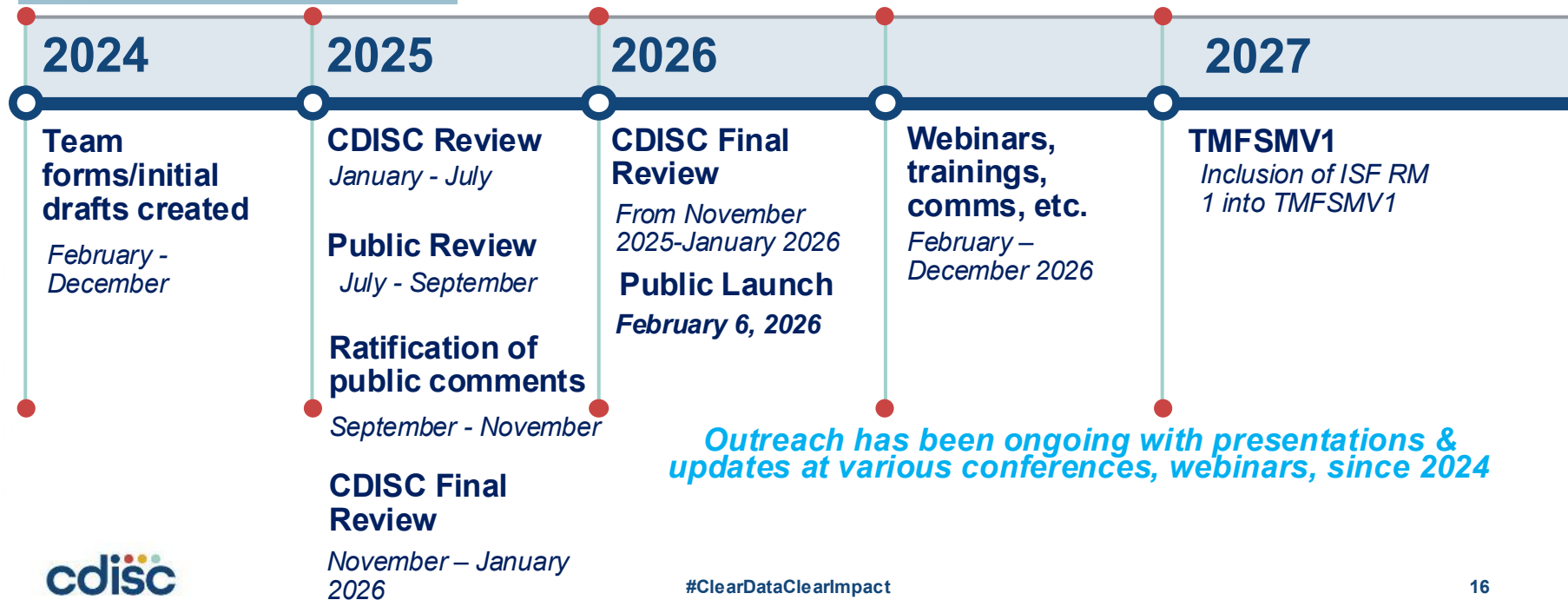
Ensure adherence to GCP and ICH guidelines which enables better ISF and TMF quality.

Facilitate inspection readiness and enable proactive risk identification.



Timeline

Two years of cross industry collaboration and work





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?

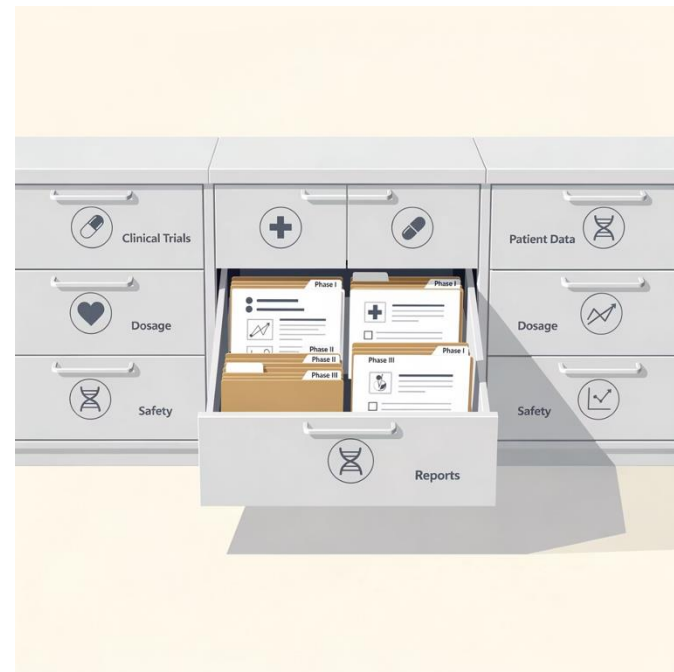
The ISF is the collection of essential records maintained by the investigator site that record and support the conduct of a clinical trial.

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



Inconsistent Practices

Filing practices vary across studies



Unclear Responsibilities Responsibilities

Confusion between sponsor and site roles



Document Location

Difficulty finding documents during inspections



Duplication of Work

Repeated training and redundant efforts

The ISF RM addresses these issues by providing a standardized structure



Consistent file names and terminology across all trials



Facilitate consistent record filing practices



Easier onboarding for new site staff



Improve preparedness for regulatory reviews



Efficient records sharing with sponsors



Align with TMF



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 Form	ISF_01.05.16	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



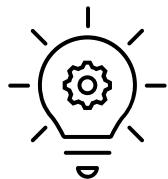
Electronic ISFs

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](https://www.cdisc.org) website

ISF RM Location



Trial Master File (TMF) is the gold standard for organizing, managing, and exchanging the essential documentation underpinning every clinical trial.

Investigator Site File (ISF) Reference Model

Version 1.0 (Provisional)

About the ISF

For many years, sponsors have relied on a harmonized framework for organizing and maintaining study related documentation: the Trial Master File (TMF) Reference Model. This reference model has driven efficiency, consistency, and transparency across the sponsor landscape. Investigator sites, however, have historically lacked an industry recognized reference model, resulting in inconsistent document organization and inefficient translation of site files into sponsor TMFs.

- A harmonized Investigator Site File (ISF) Reference Model addresses these challenges and delivers meaningful benefits to the clinical research industry, including:
 - Clear guidance on required documentation through a consistent structure and standardized naming conventions
 - Support for maintaining complete, accurate, and current site documentation
 - Reduced duplication of effort by eliminating repeated submission of the same records
 - Fewer mislabeled documents through standardized file locations
 - Reduced labeling errors due to consistent naming conventions
 - More efficient audits and inspections
 - Simplified training and onboarding for site staff

To meet this need, CDISC has developed a provisional ISF Reference Model Version 1.0. This provisional reference model provides investigator sites with a clear and consistent framework that defines where each document belongs, supports compliance with applicable regulations and guidelines, and promotes inspection readiness. At the same time, it enables improved alignment between site ISFs and sponsor TMFs, contributing to more complete, current, and accurate Trial Master Files. Additionally, it enhances communication across the industry by establishing a shared structure and common understanding among sites and sponsors.

The provisional ISF Reference Model Version 1.0 has been developed using the same methodology as the TMF Reference Model and is mapped to TMFRM v3.3.1, which affords it common artifact names and numbers with the sponsor model. This provisional version will be integrated as part of the new upcoming TMF Standard Model v1.0 and will be available as a subset of this new standard. As part of the integration effort, CDISC Controlled Terminology will be developed for ISF content. Upon completion of this integration, the status of the content in the Investigator Site File Reference Model Version 1.0 will move from provisional to final.

ISF Reference Model v1.0 (Provisional) Public Review Comments.xlsx

ISF Reference Model Version 1.0 (Provisional).xlsx

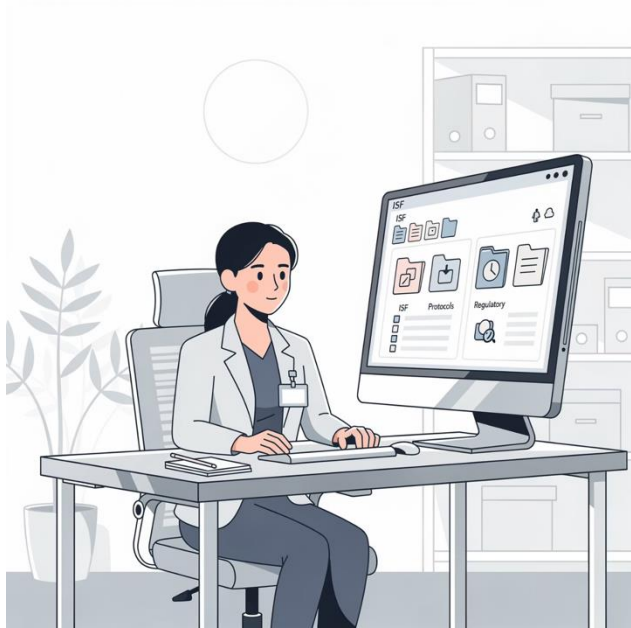


Go to the bottom of the page and click TMF Resources and select Investigator Site File - ISF



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

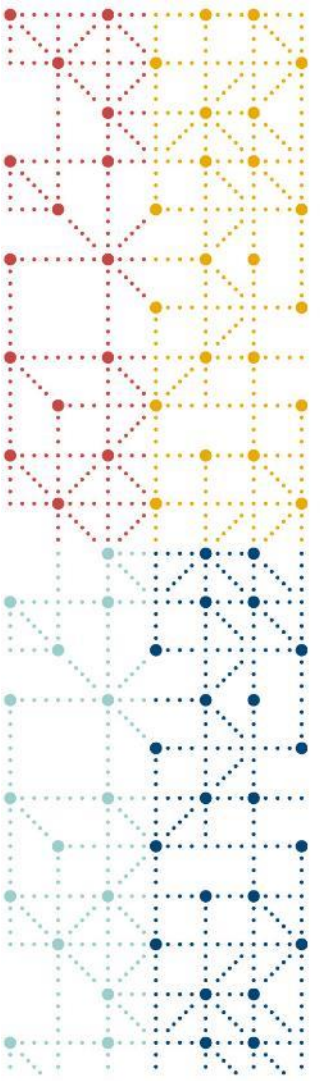
Maintain Compliance

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

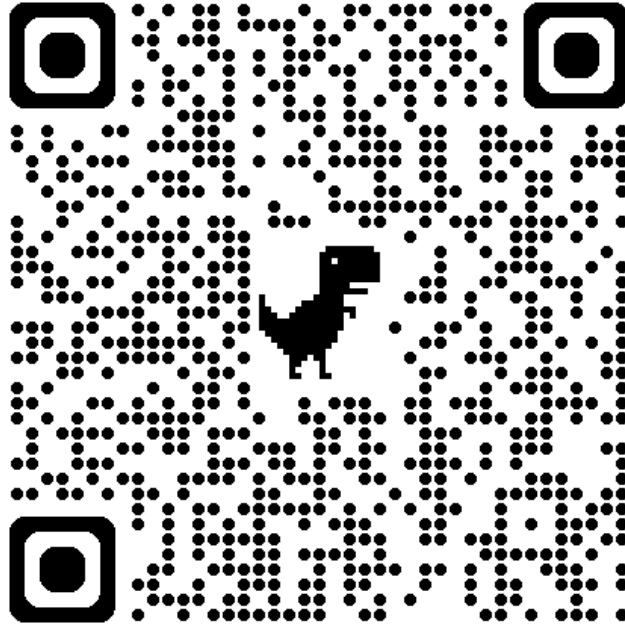


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