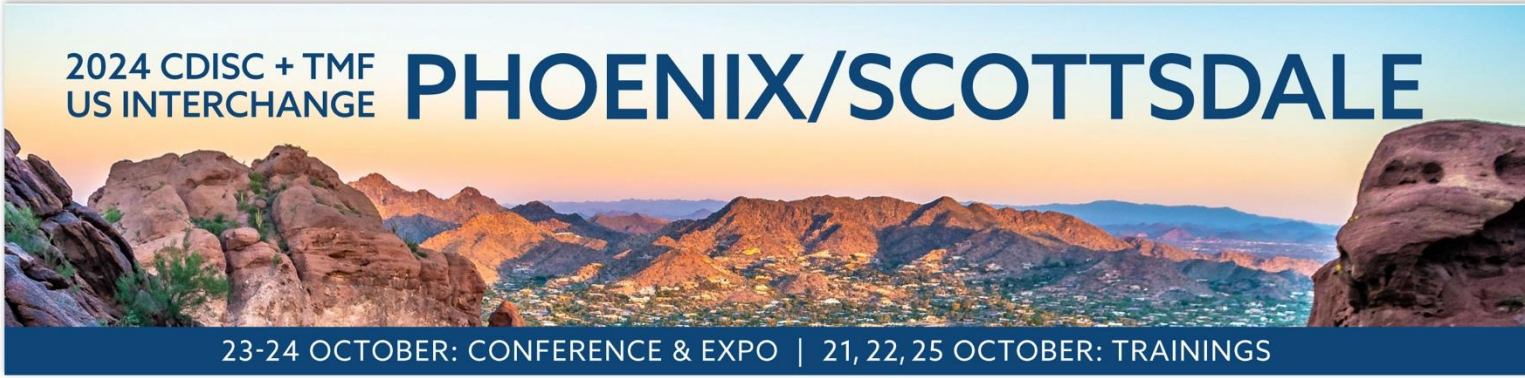


CDISC ISF Initiative

Jamie Toth, CDISC TMF RM SC Member
Matt Lowery, CEO / Principal Consultant, The Pathways Group
Anna Fehr, CEO, One of a Kind Clinical Research Center
Nikki Jundt, Assistant Regulatory Specialist, One of a Kind Clinical Research Center

Meet the Speakers

Anna Fehr
CEO
One of a Kind Clinical Research Center

Nikki Jundt
Assistant Regulatory Specialist
One of a Kind Clinical Research Center

Matt Lowery
(Recorded Message)
ISF Initiative Co-Lead

Jamie Toth
CDISC TMF Reference Model Liaison to the ISF Initiative

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- The views and opinions expressed in the following slides are those of the individual presenter and should not be attributed to the company the presenter works for, nor the associations the presenter is affiliated with.

Agenda

1. What is the ISF RM
2. Why is the ISF RM Needed
3. Progress to Date
4. Feedback from Sites

What is the ISF RM?

ISF Initiative Co-Leads

Matt Lowery

CEO / Principal Consultant
The Pathways Group

Aryn Knight, BS, CCRP

Associate Vice President
Clinical Innovation and Research Institute
Memorial Hermann Health System
Society of Clinical Research Associates (SoCRA), Houston Chapter Chair

What is the ISF Initiative?

Goal: To create a vendor-agnostic ISF reference model for sites to use that mirrors the TMF Reference Model.

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

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.

Why is the ISF RM Needed?

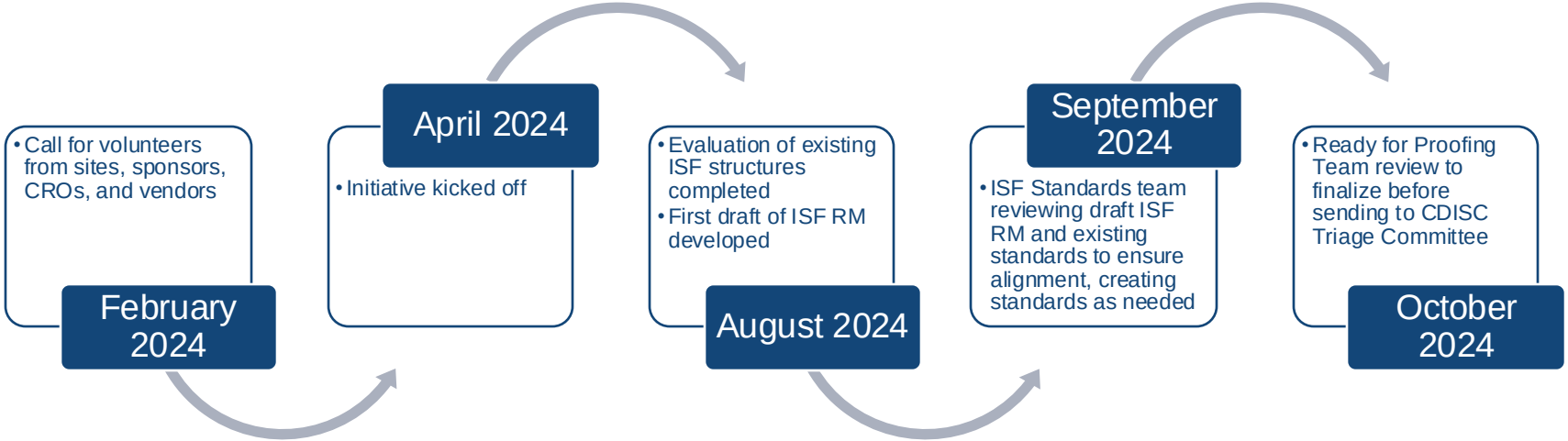
Why is the ISF RM needed?

- Standardizes ISF structure, file naming conventions, terminology, etc.
- Helps sites have healthy, complete, and up to date ISFs which would help sponsors/CROs have healthy, complete, and up to date TMFs.
- Decreases duplication of work due to sponsors/CROs contacting multiple people at the site multiple times for the same record.
- Prevents misfiled records since file locations would be the same (or at least not completely different).
- Decrease mislabeling errors since naming conventions would be the same (or at least not completely different).
- Make audits easier and hopefully increase the frequency of audits.

Let’s hear from Matt, Co-Lead for the ISF Initiative

Progress to Date

Progress to Date



Feedback from Sites

Discussion with Anna Fehr & Nikki Jundt

Anna Fehr
CEO
One of a Kind Clinical Research Center

Nikki Jundt
Assistant Regulatory Specialist
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Thank You!