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The Challenges of Investigator Site Files and why the Investigator Site File Reference Model Initiative is Needed!

Dr. Konrad Janik, Accelerated Enrollment Solutions
Dawn Niccum, inSection Group
Matt Lowery, The Pathways Group
Jamie Toth, Beigene



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Meet the Speakers



Dr. Konrad Janik
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Reference Model
Liaison to the ISF
Initiative



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ISF Initiative Co-
Lead



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CDISC TMF Reference
Model Liaison to the
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ISF Initiative Co-Leads



Matt Lowery, ACRP-CP, CCRC

**CEO / Principal Consultant
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**Associate Vice President
Clinical Innovation and Research Institute
Memorial Hermann Health System
Society of Clinical Research Associates (SoCRA), Houston
Chapter Chair, National Board Member**

What is the ISF Initiative?

An ISF reference model for sites to use that mirrors the TMF Reference Model.

The initiative just kicked off on 16-Apr-2024 with over 35 volunteers on the call!

Subteams have been formed for:

1. Evaluation: Review of Existing ISF Structures
2. Standards: Setting Standards
3. Proofing: Review of deliverables
4. Outreach: Presentations/Publications/White Papers
5. Training: Training the industry on ISF RM

Charter will be created at next meeting.

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





Discussion with Dr. Konrad Janik

- General feedback from German sites
- Paper ISF
- Electronic ISF



Thank You!

