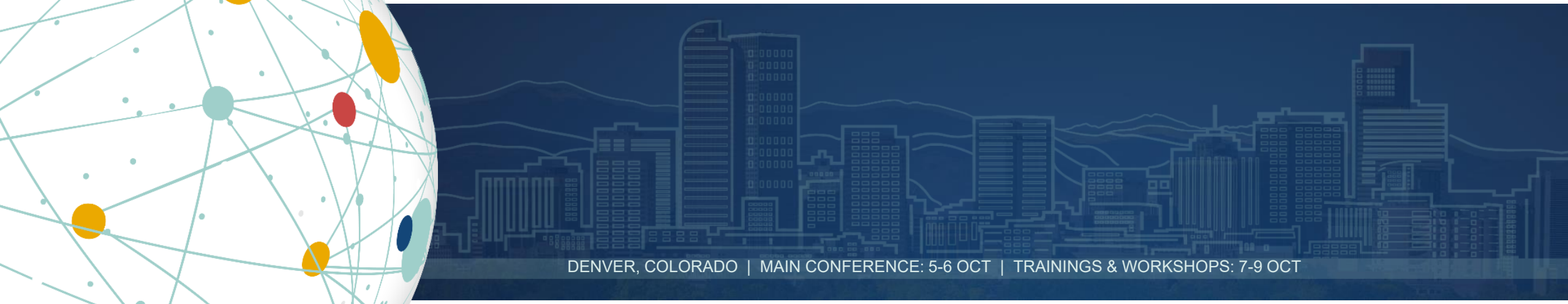


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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Elevating the Investigator Site File: Driving Standardization and Data Integrity in Global Clinical Trials

Guillaume Gérard, Chief Operating Officer and Co-Founder, Agatha Inc.

Agenda

- Digital gap between sponsors and sites
- AI-powered Standardization & Automation
- Practical Example & Outcomes
- Q&A Session

Speaker



Guillaume GERARD
Chief Operating Office
Co-Founder
Agatha Inc.

- Co-founder & COO, Agatha Inc.
- Leads product strategy, global operations
- 18+ years in regulated Life Sciences software in Europe, US and Japan
- Expert in compliant clinical & quality content management
- Passionate about technology, innovation & product development

The challenge

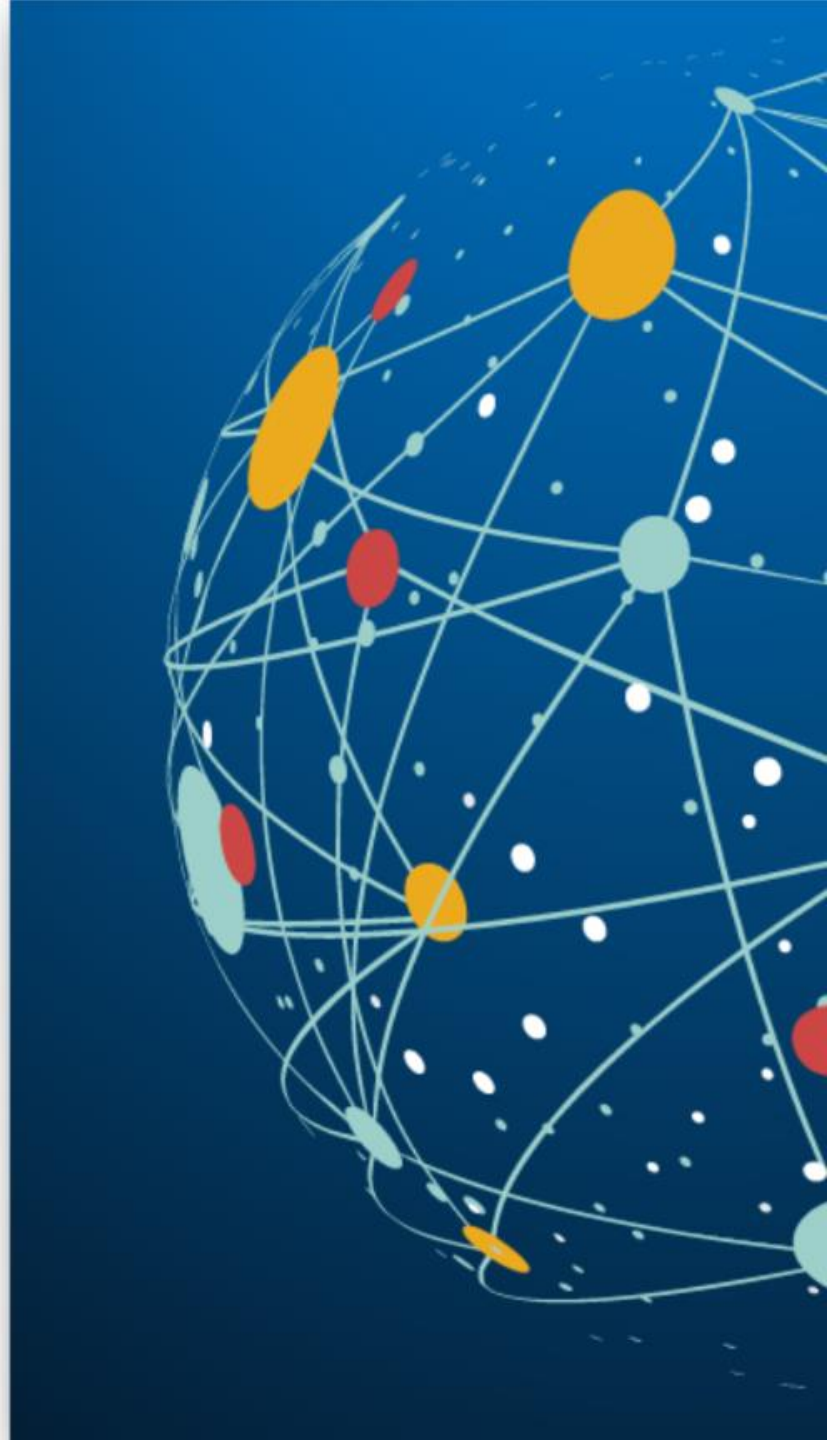
Sponsors



MANUAL

Investigators





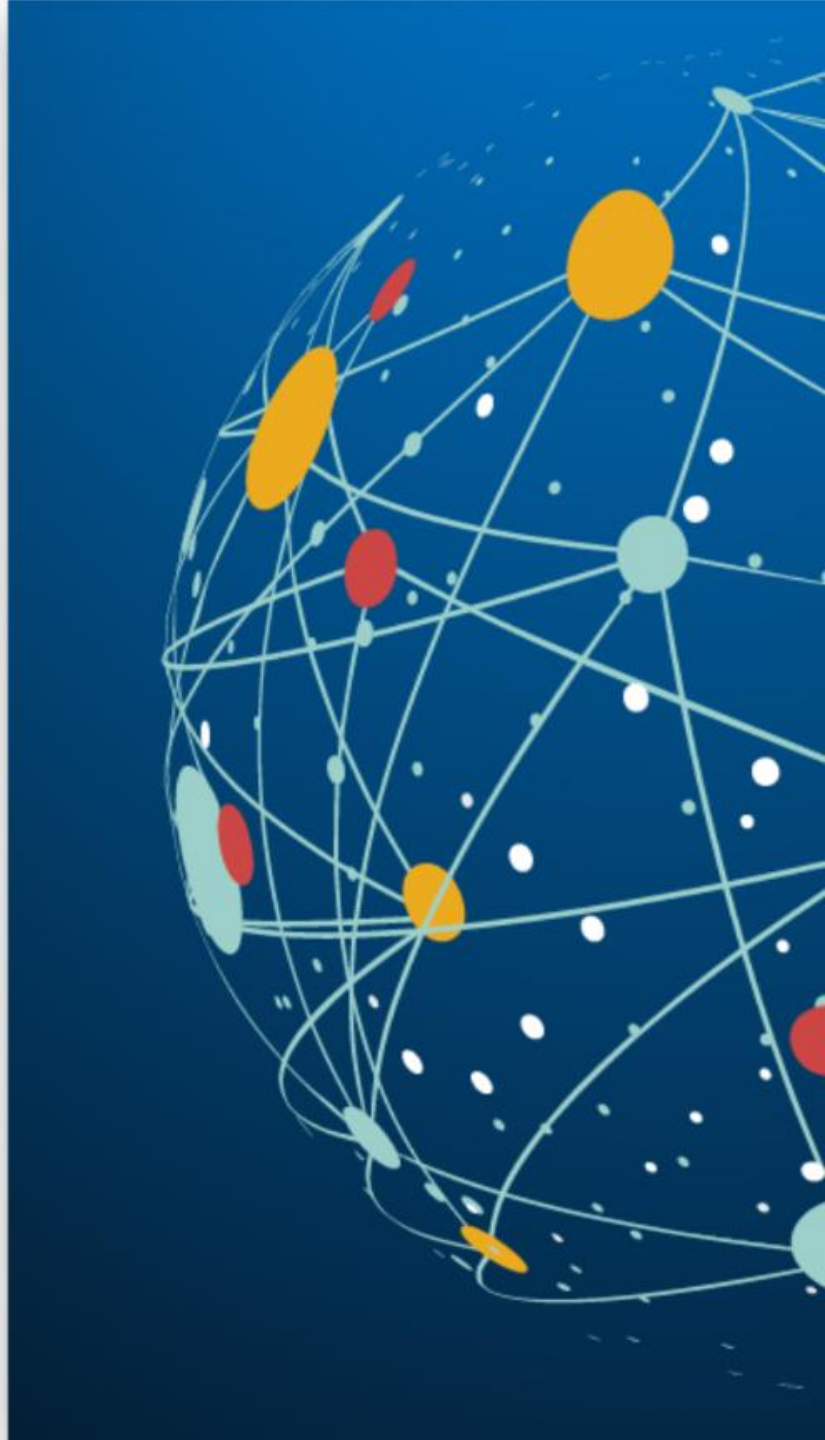
The scale of the issue

>1,000,000 document version

per site-level, per year, per study (tier-1 sponsor)

Time Impact

Up to 1 hour per document!



Lack of Proper Solutions at Site Level



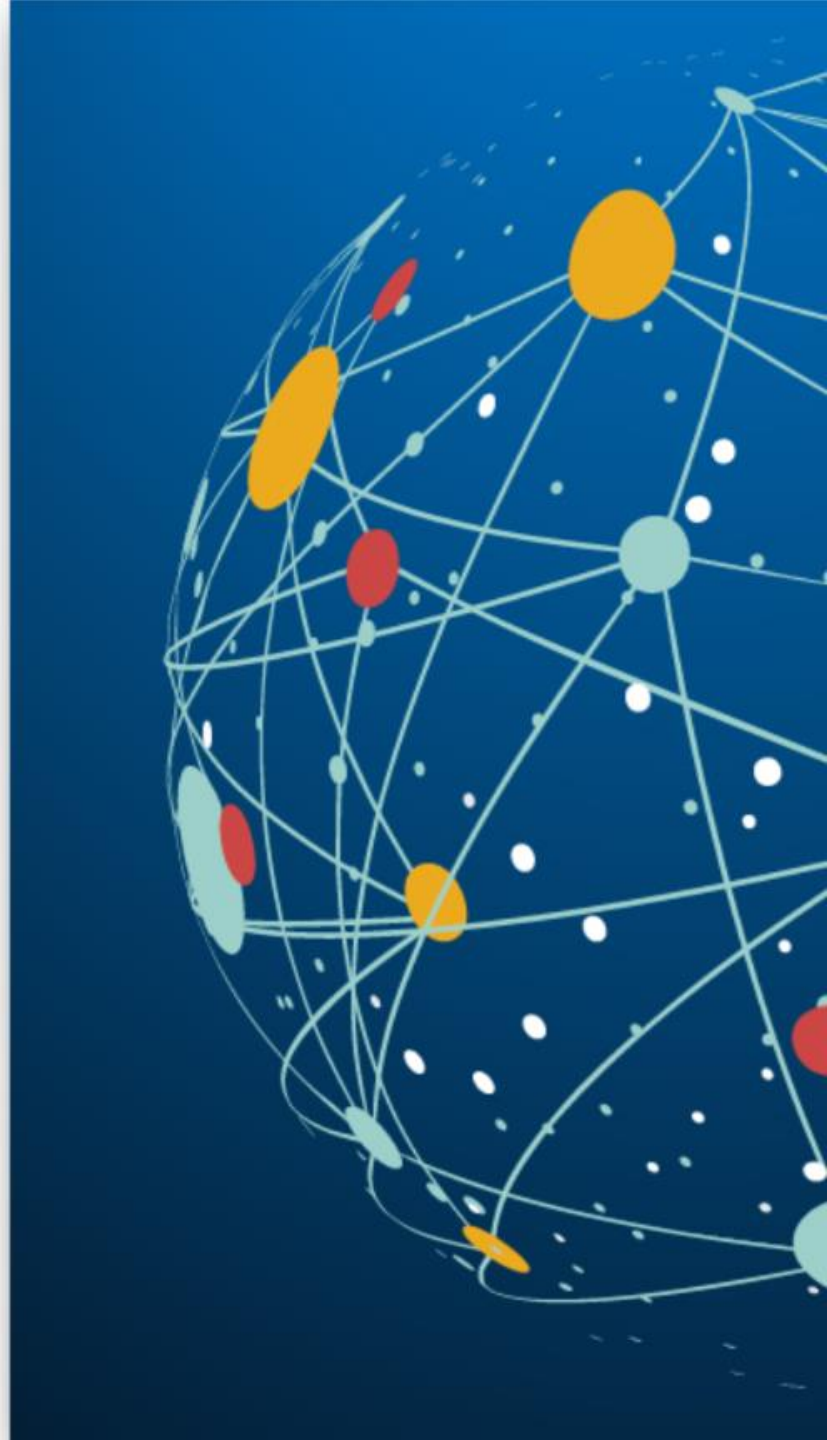
Sponsors

- Well-equipped digital ecosystems
- eTMF, CTMS and integrated platforms



Sites

- File systems & Shared folders
- Excel tracking
- Paper or hybrid workflows
- **Limited eISF adoption in many regions**



Lack of standardization: Where Fragmentation Appears in Practice

SPONSOR SIDE



- Established TMF structures
- Standardized taxonomy and metadata
- Central oversight



SPONSOR A

Folder structure A
Naming convention A
Portal A

SPONSOR B

Structure B
Metadata B
Portal B

SPONSOR C

Structure C
Upload process C

One clinical trial. Two perspectives on the same essential records.

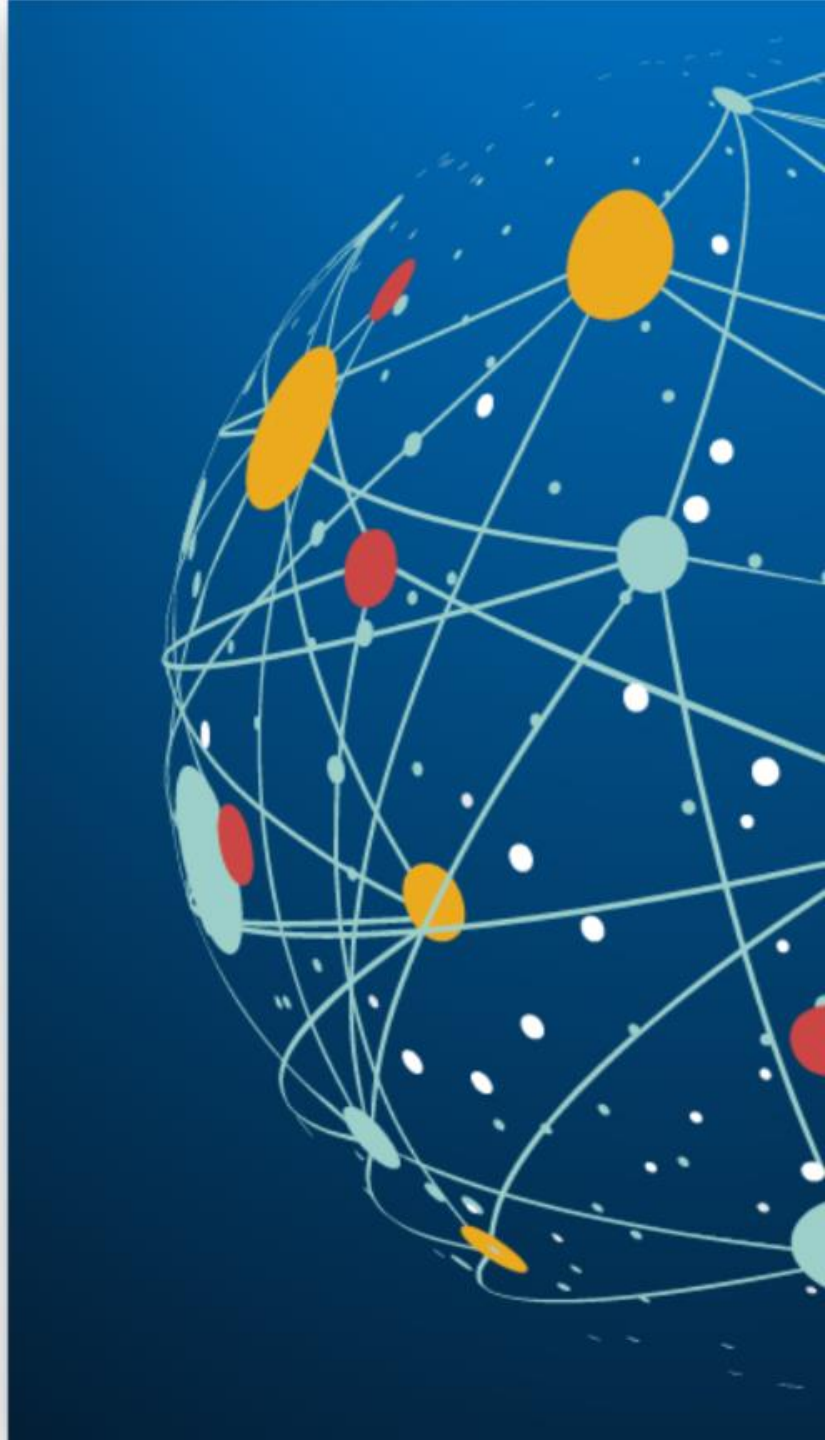
Source: CDISC, Investigator Site File presentation (2024) - sites inconsistent document organization, repeated submission, misfiling and labeling errors among the problems its ISF model addresses.

Outcome

Lack of Data Integration

Manual Overhead

Lack of compliance quality issues



Summary

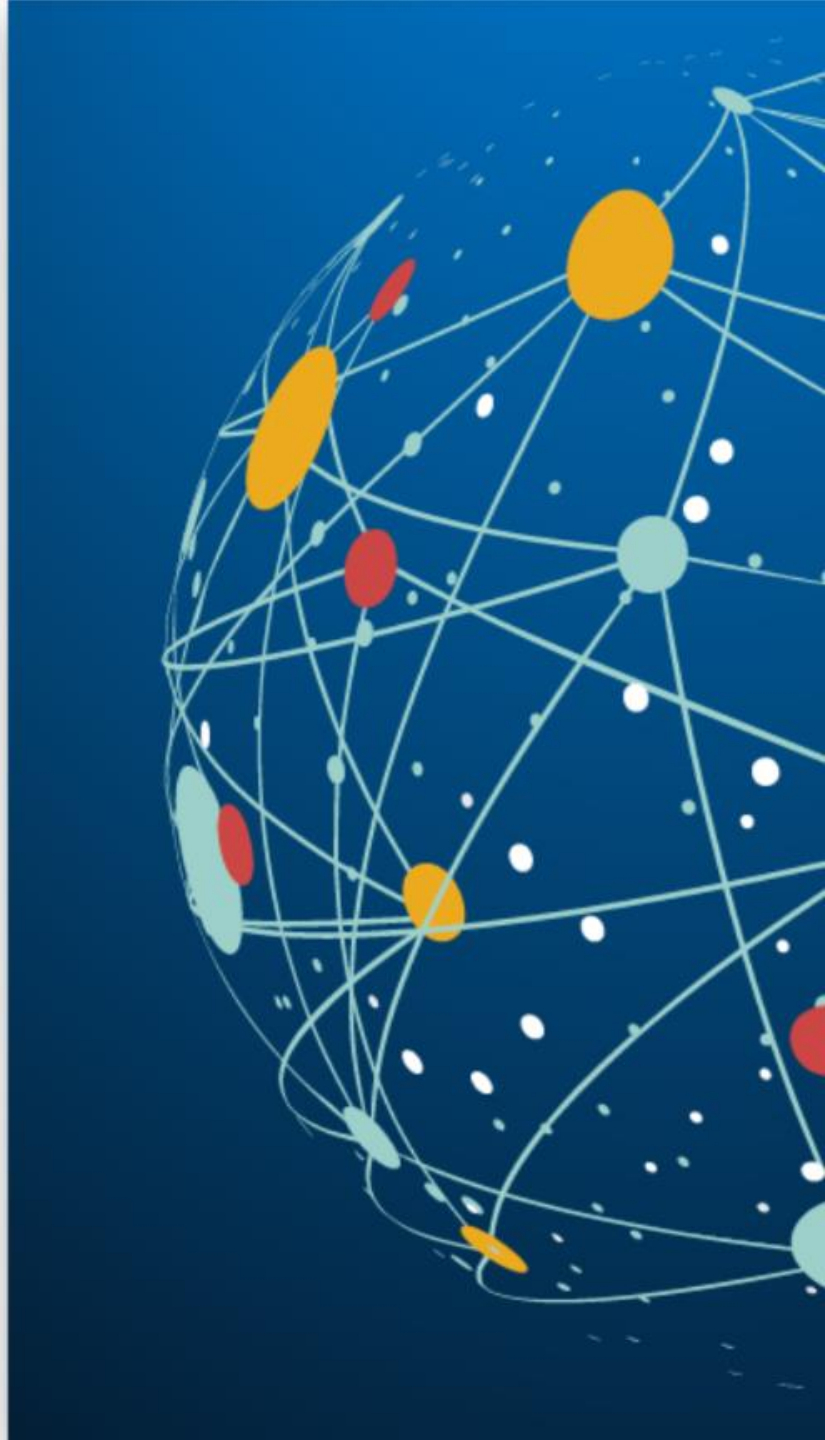
Diverse Structures

Interoperability

X

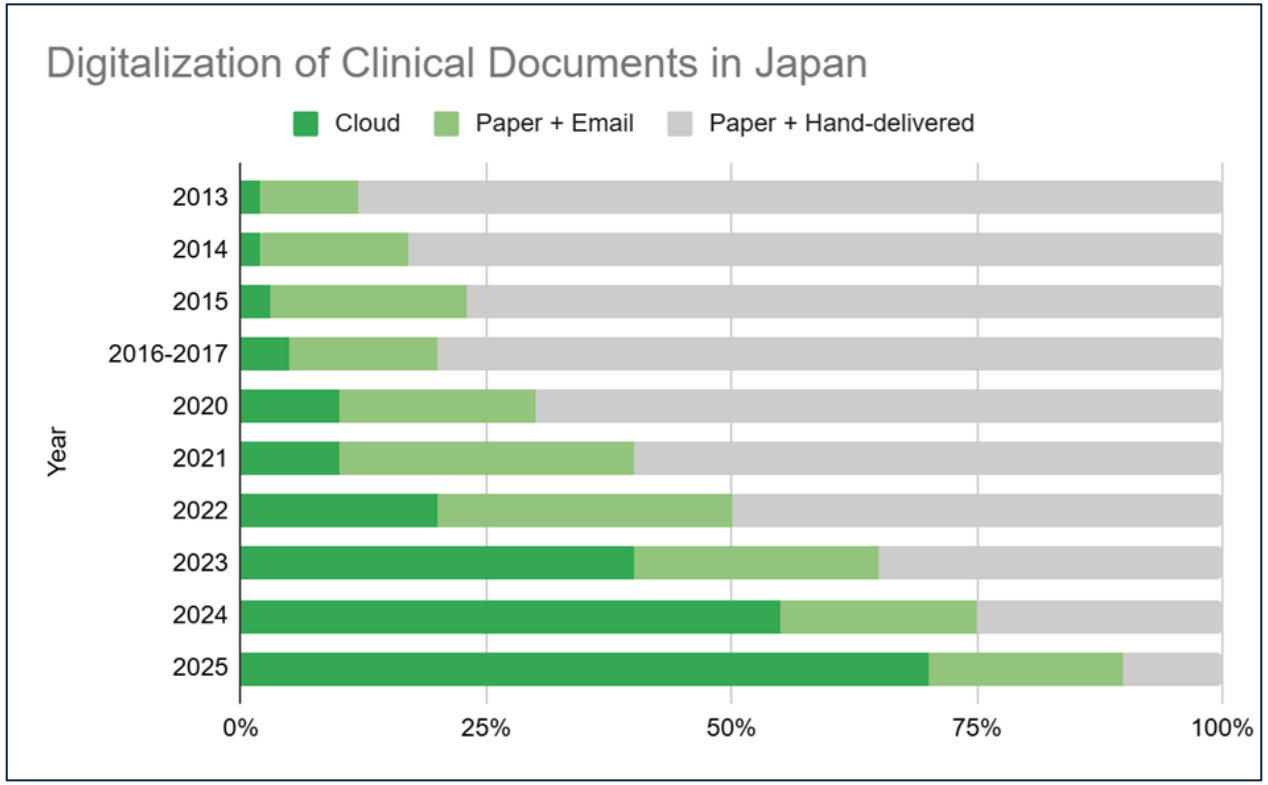
Efficiency

Quality



Site standardization progressing slowly

Moved from Paper or Folders to Electronic (eISF) in past 5 years in some regions



But the Industry Now Has a Framework for ISF Harmonization

- Common artifact names
- Consistent structure

CDISC ISF Reference Model v1.0 (Provisional)

- Standard naming conventions
- Alignment with sponsor TMF
- Shared terminology

Source: CDISC, "Introducing the Investigator Site File (ISF) v1 (Provisional)," Feb 2026; CDISC TMF Reference Model General Meeting materials, Mar 2025. Next step: integration into the upcoming TMF Standard Model, targeted 2026–2027.

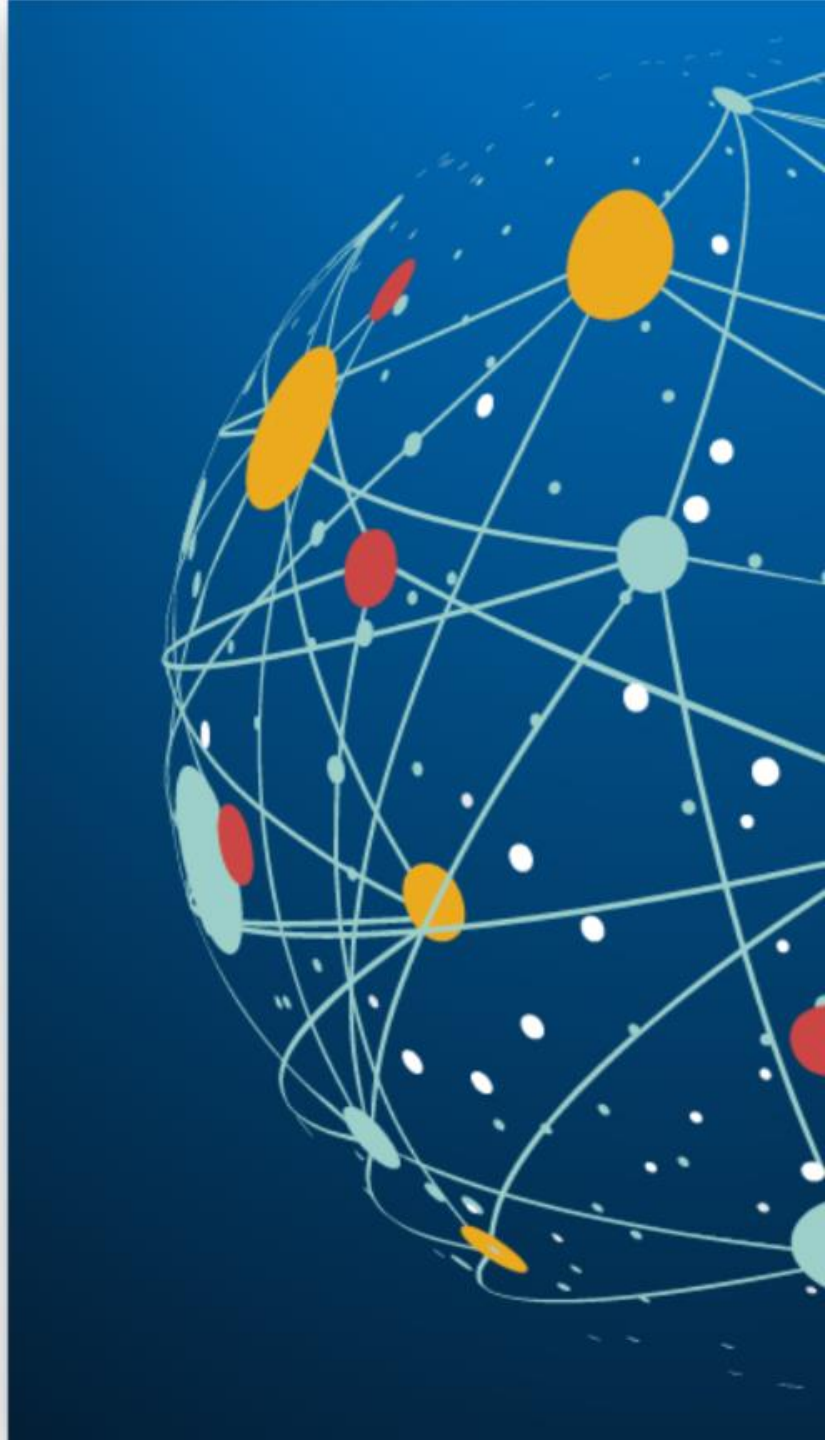
Where AI Can Remove Manual Work and strengthen Collaboration

AI supports interoperability across heterogeneous systems.

Reclassify Documents

Remap Metadata

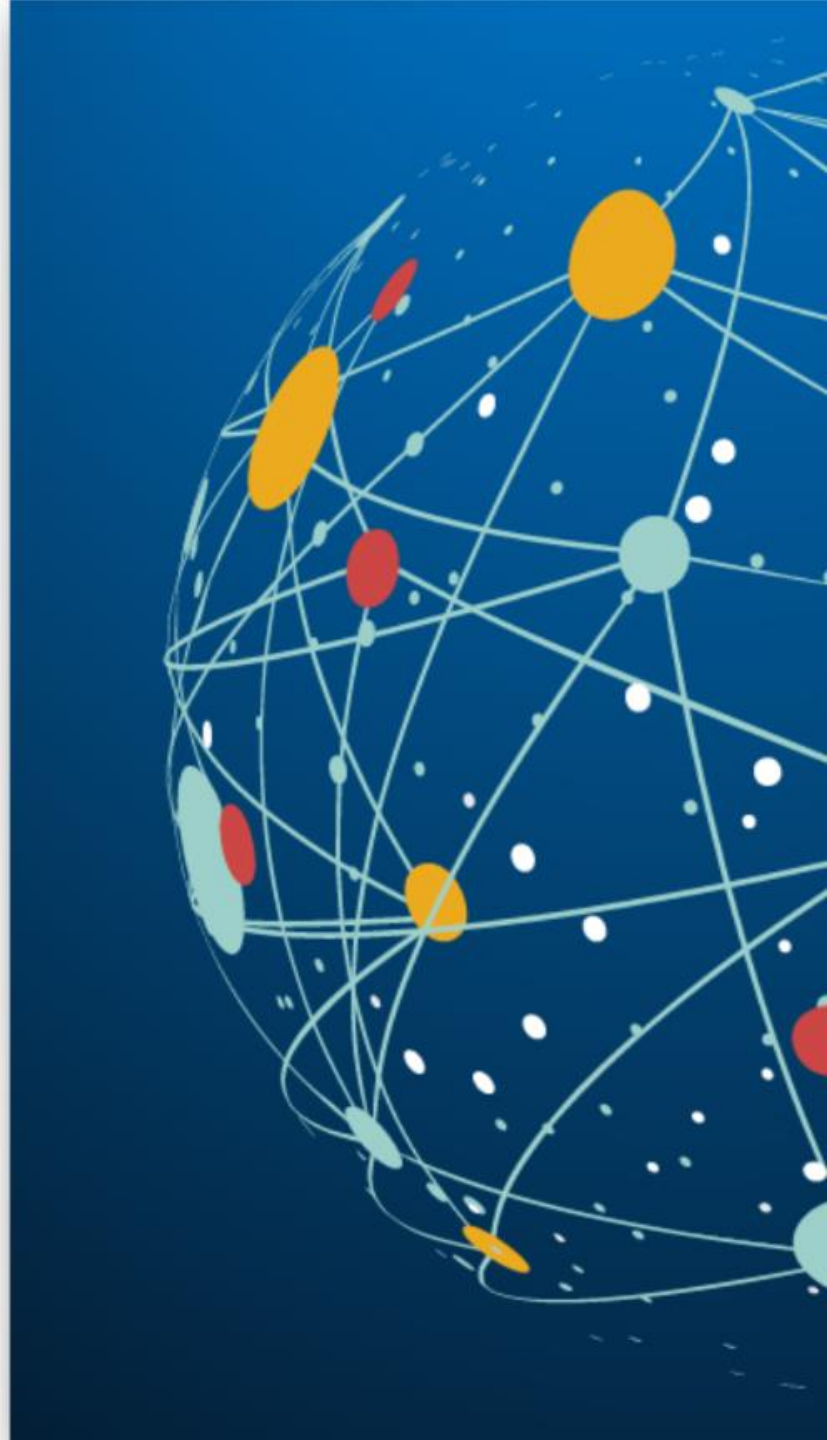
Connect eTMF & eISF



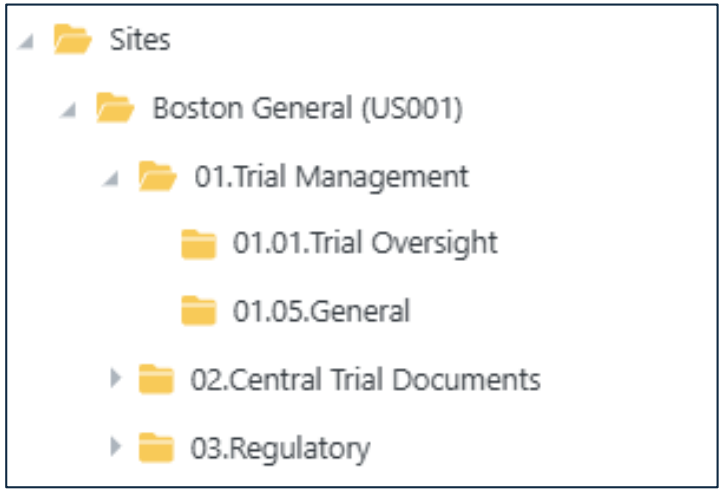
How Does AI-powered Remapping Work?

Bidirectional AI Remapping Flow



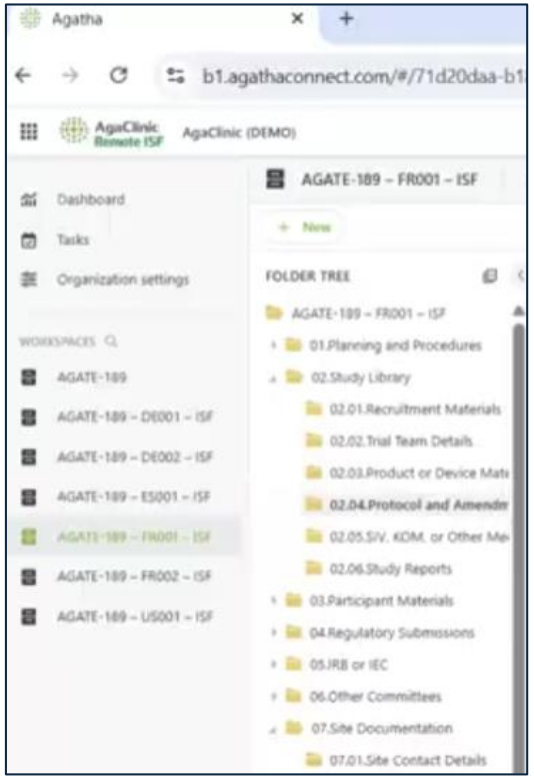


AI for eTMF x eISF collaboration



TMF Ref Model

AI MAPPING



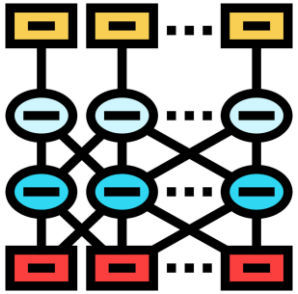
ISF custom model or CDISC

Practical Example



CRA uploads documents
(e.g. safety information)





Machine Learning Model

- Trained on clinical documents
- Compliant with data privacy



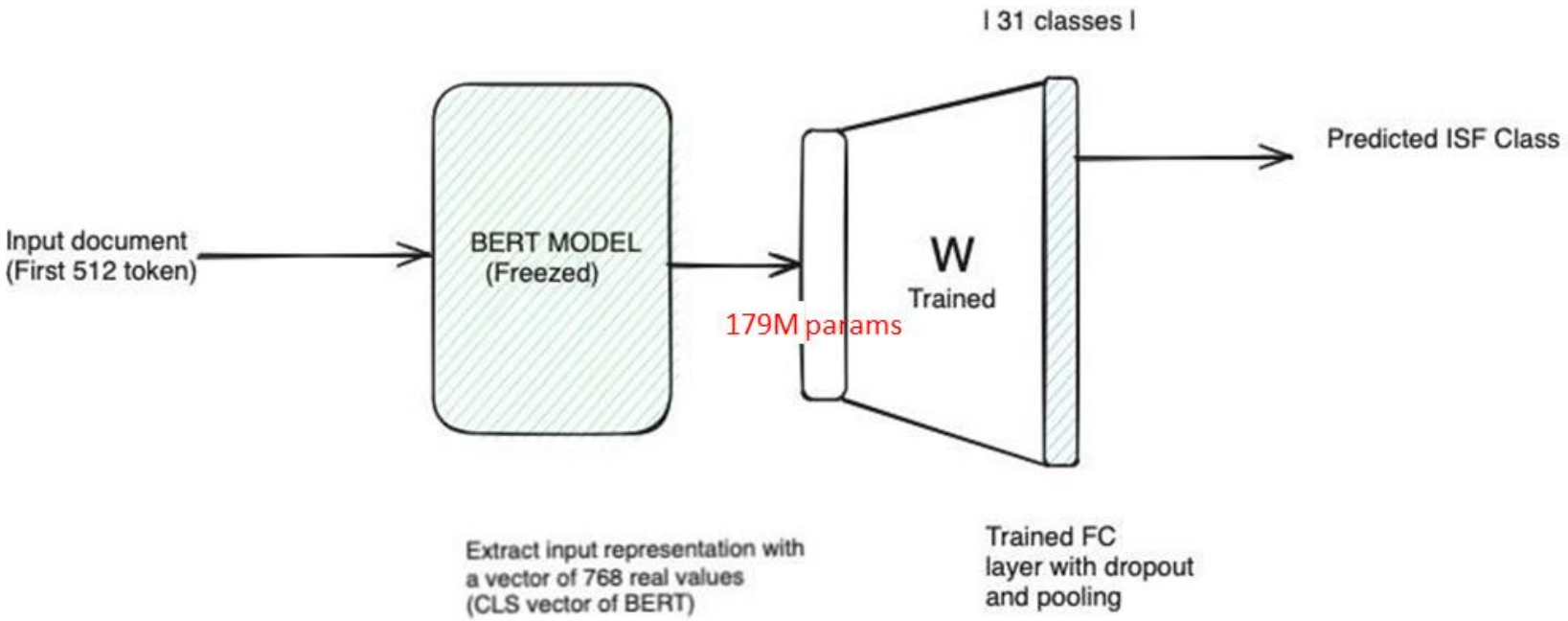


Categorized

- Extraction of document data

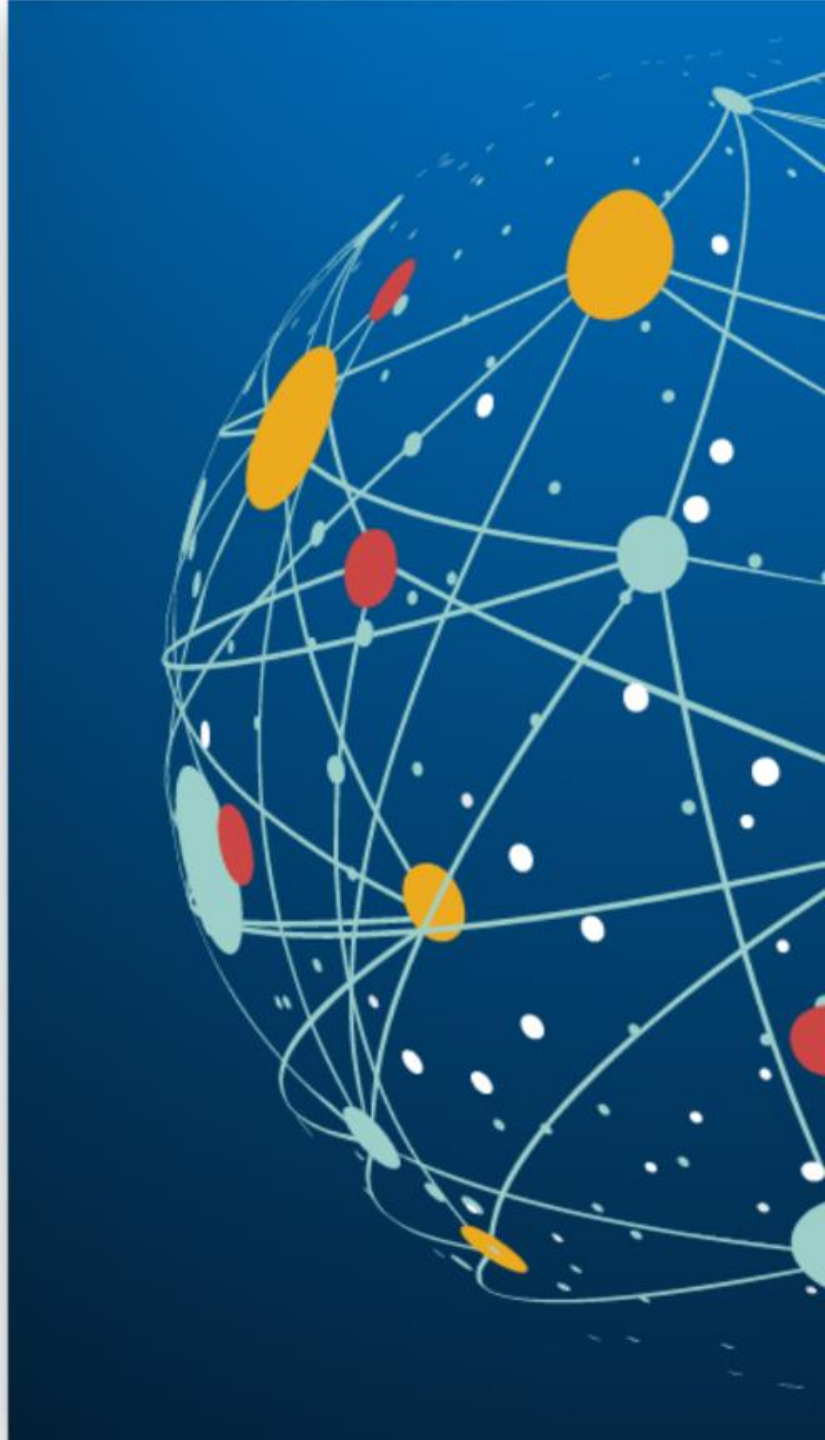
Practical Example

End-to-End Approach: This approach integrates feature extraction and classification into a single model. It allows for simultaneous learning, streamlining the process and potentially discovering patterns that may be overlooked in the classical method.



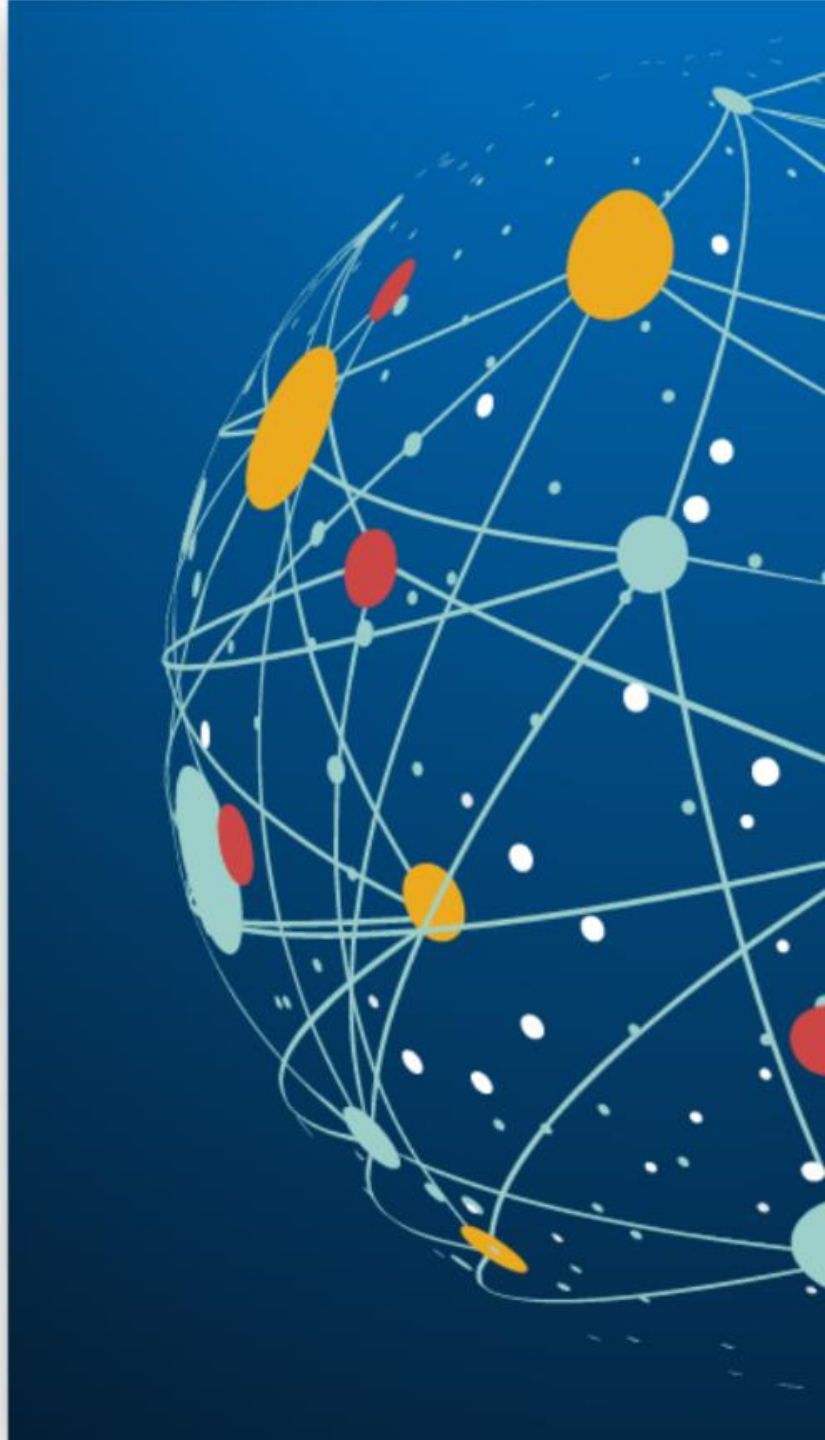
AI Privacy & Compliance

- Hosted AI models
- Data segregation
- Privacy protection
- Regulatory compliance



Practical Outcome

Form type	Average Accuracy
ISF Standard forms	**100%**
Non-standard forms	**96%**



From Two Document Repositories to One Connected Record Lifecycle



Standardize the structure

Preserve the context

Connect sponsor and site processes

The ISF is becoming a structured component of the clinical trial information landscape rather than an isolated site binder.

Practical Outcomes

Impact on Sponsors

Efficiency
Major workload reduction

Reporting
Real-time KPIs

Quality
Full auditability

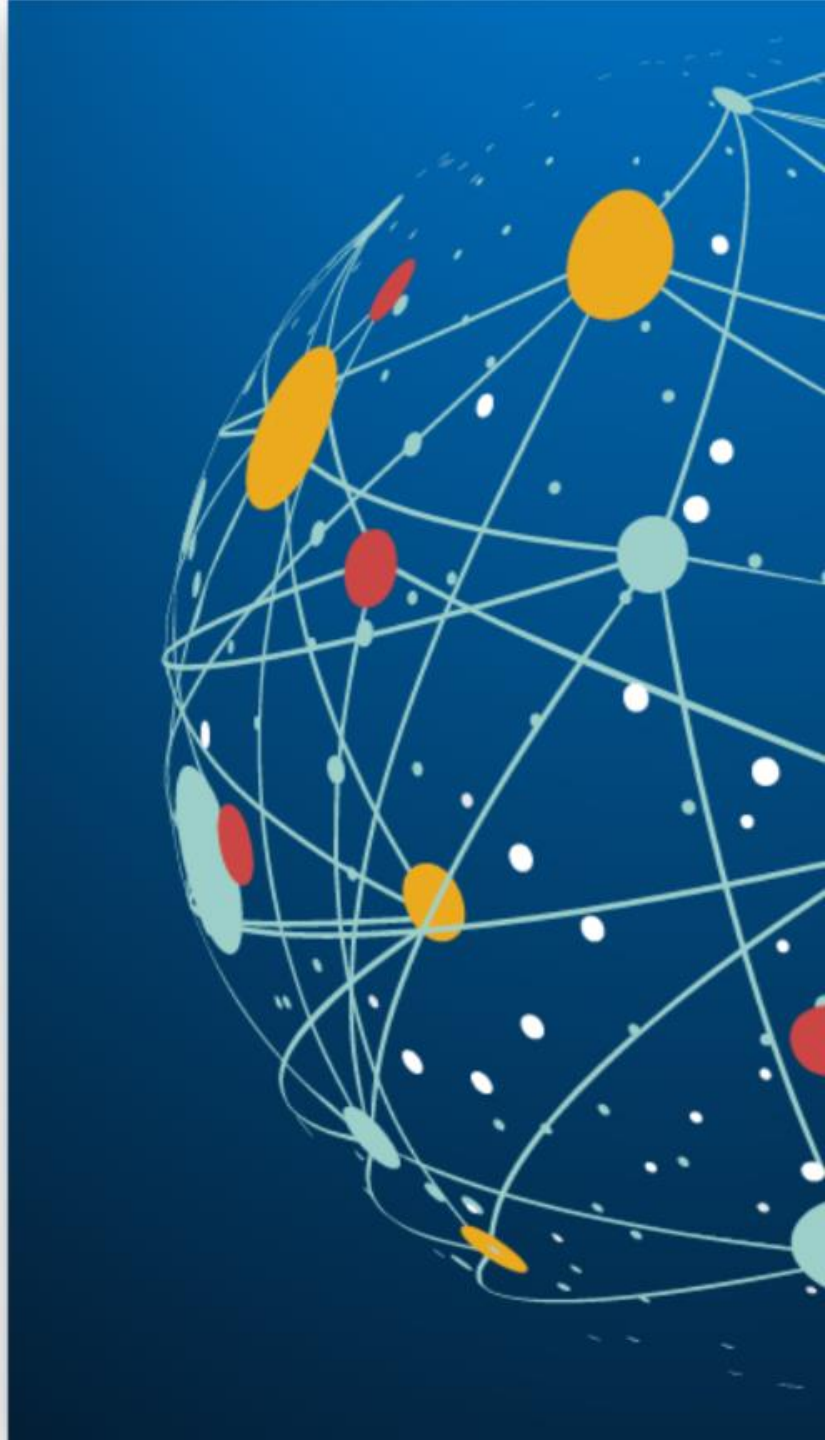
Impact on Sites

Less administrative burden

No need to explain local rules

Reduced risk of errors

Improved security



Practical Outcomes

Processing Time Reduction

41%
for eISF → eTMF flows

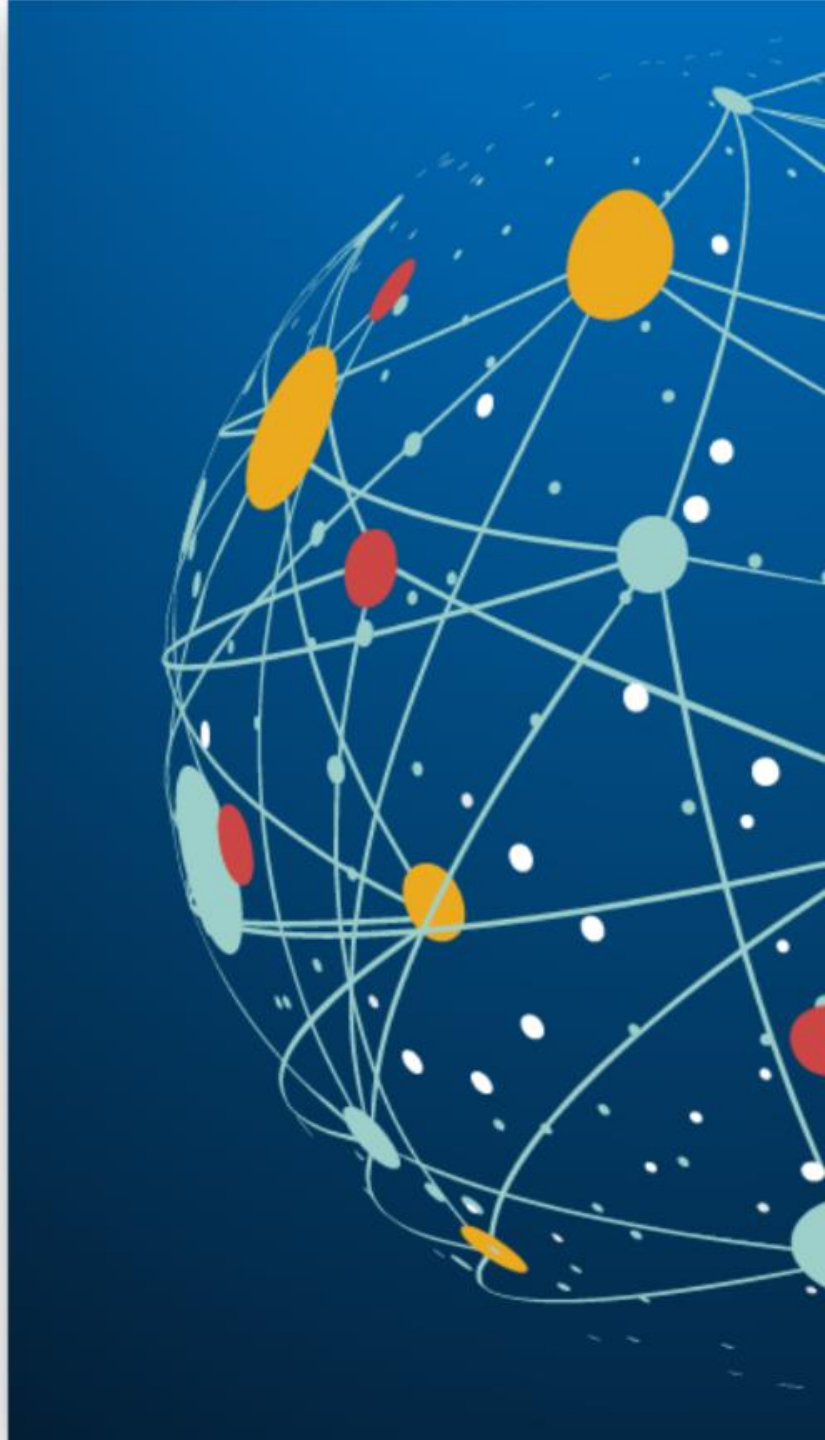
29%
for eTMF → eISF flows

Efficiency Gains

Per document processing time:

49 min → 29 min
In primary workflows

72 min → 51 min
In alternative workflows



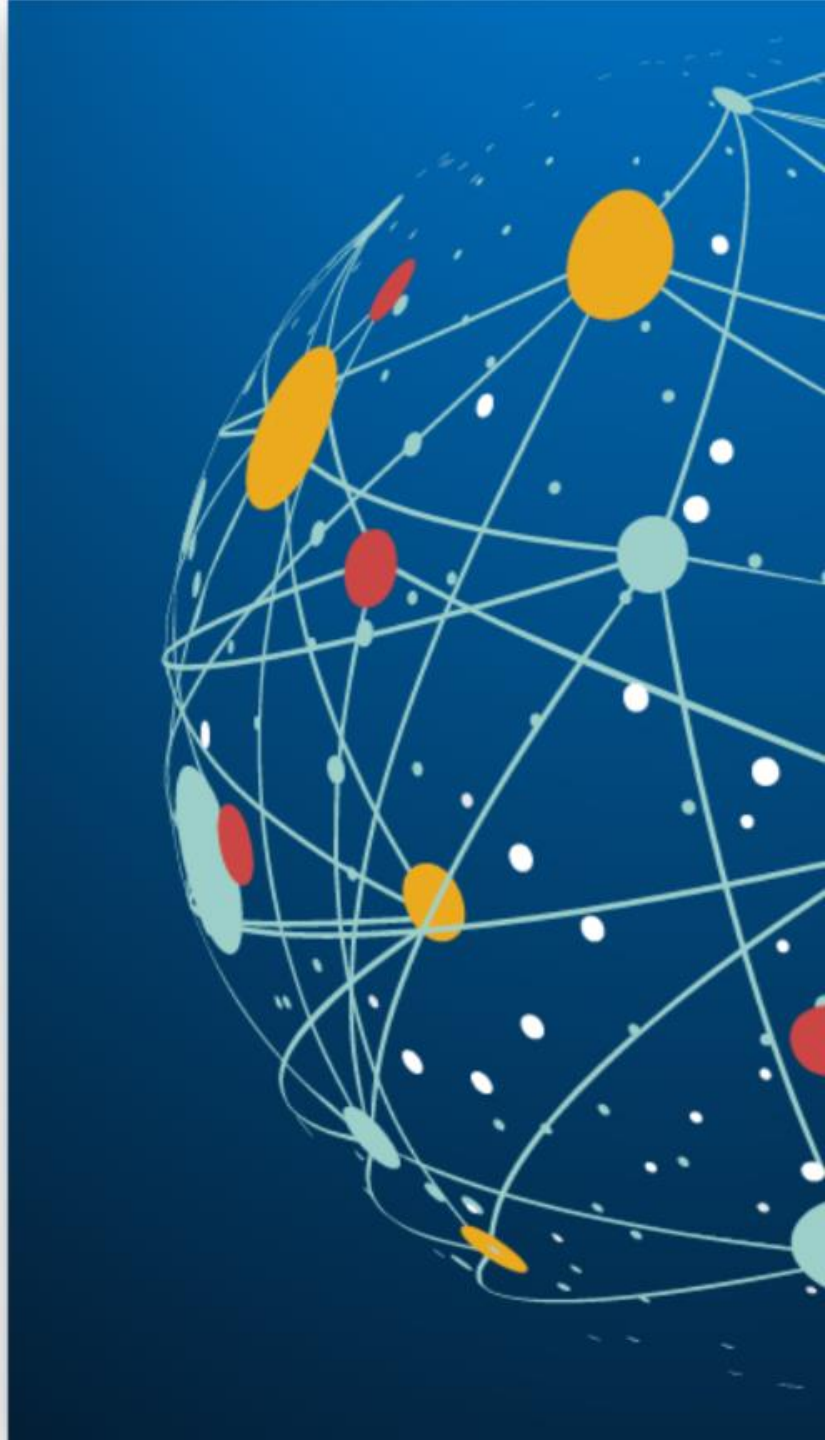
Conclusion

Challenges between sponsors and sites remain significant

Standardization alone is not sufficient

Interoperability across systems is critical

AI-powered automation can improve collaboration across ecosystems



Thank You for your attention!
Any questions?



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