



cdisc[®] 2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

How AI-powered Standardization and Automation Can Improve Collaboration Between Clinical Sites and Sponsors?

Guillaume GERARD, 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

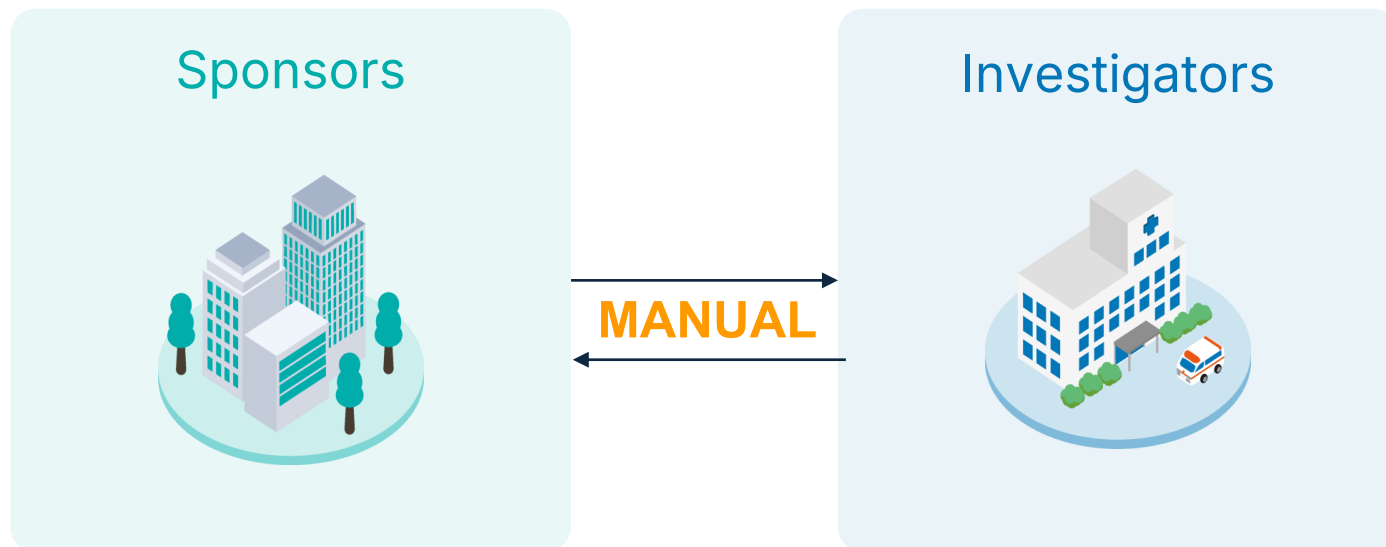


Guillaume GERARD
Chief Operating Office
Co-Founder
Agatha Inc.

- 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





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!





Root cause:

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**





Root cause:

Lack of Standardization at Sites

Sponsors



eTMF

Investigators



usually: own eISF
structure



Lack of Data Integration



Manual Overhead

**Lack of compliance
quality issues**





Summary



Diverse Structures



Interoperability

X



Efficiency

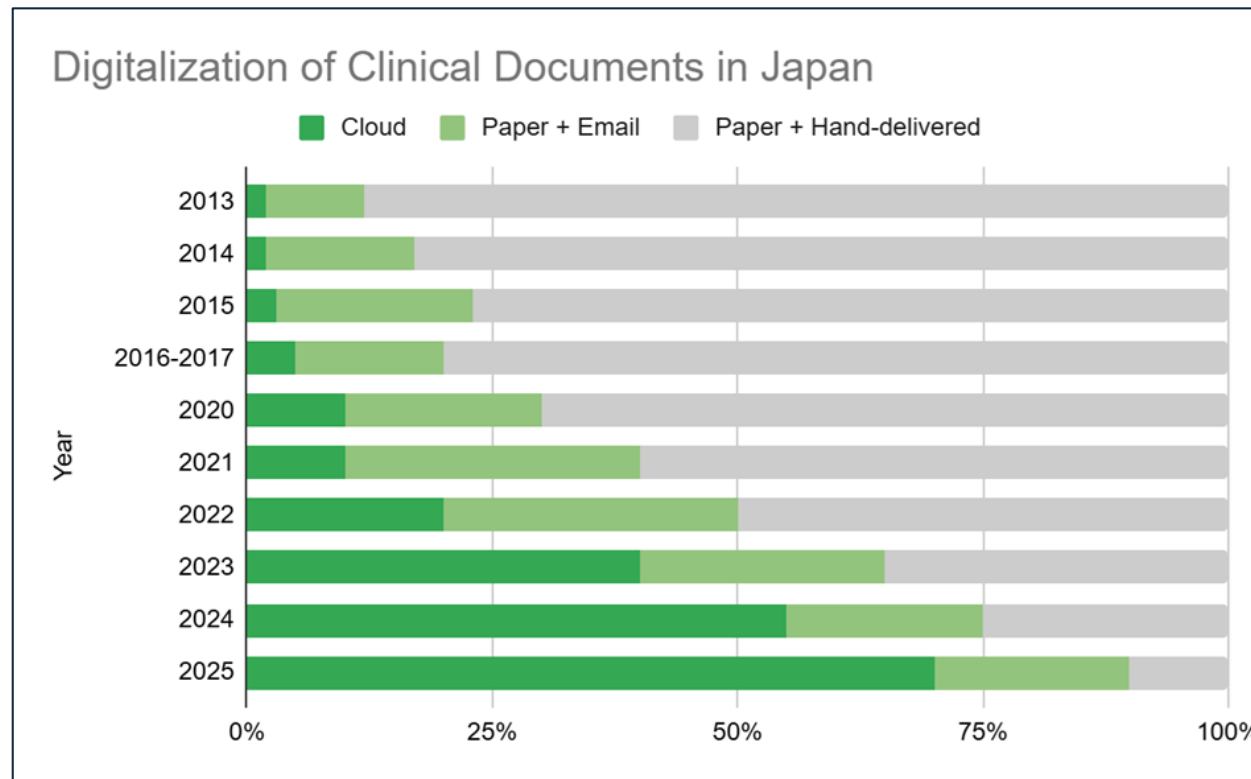


Quality



Site standardization progressing slowly

- Moved from Paper or Folders to Electronic (eISF) in past 5 years in some regions
- But Adoption of CDISC eISF is slow





AI for eTMF x eISF collaboration

AI supports interoperability across heterogeneous systems.



**Reclassify
Documents**



**Remap
Metadata**



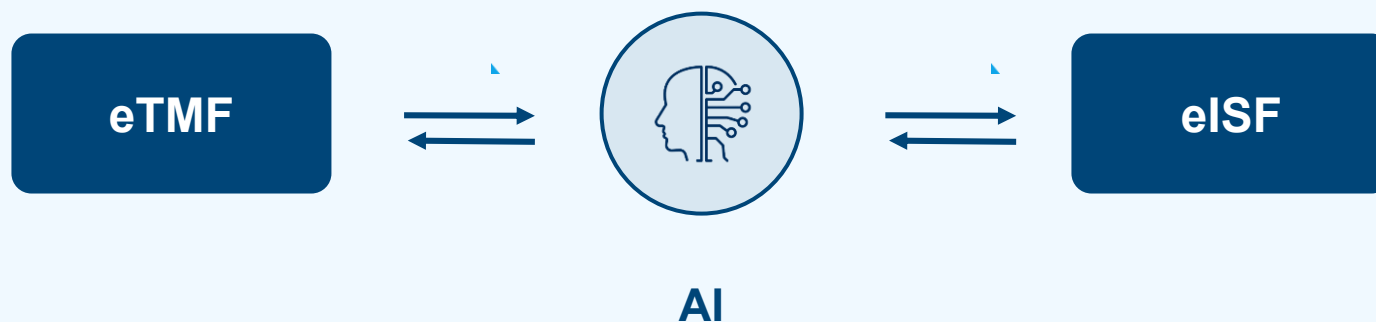
**Connect eTMF
& eISF**



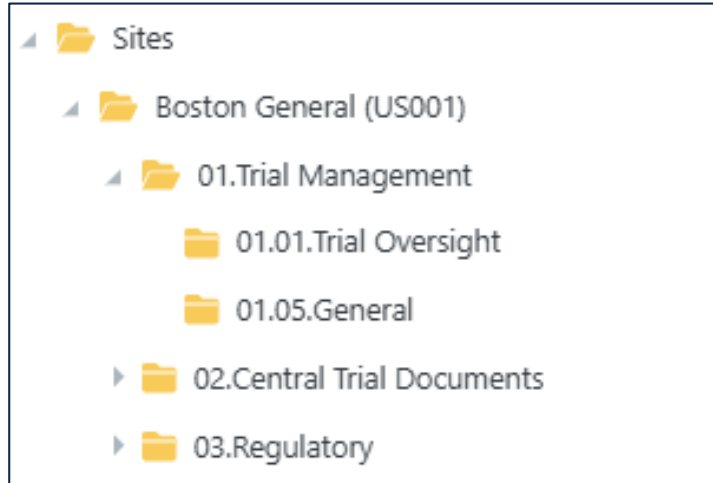


How Does AI-powered Remapping Work?

Bidirectional AI Remapping Flow

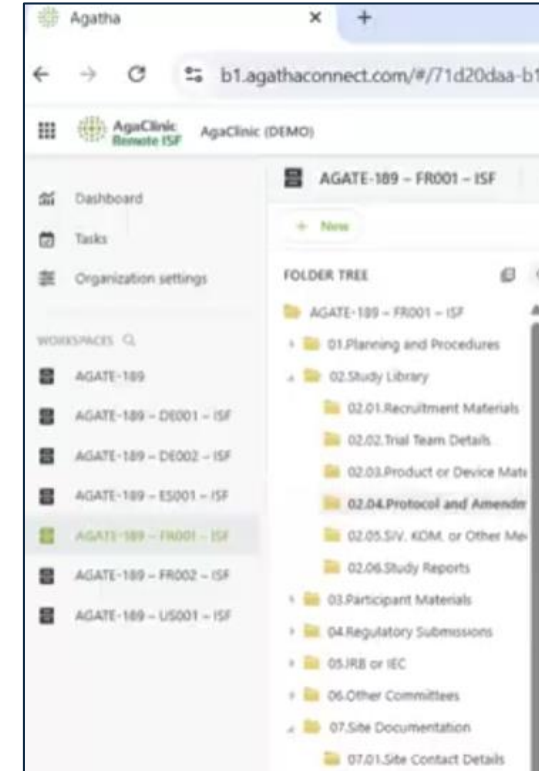


AI for eTMF x eISF collaboration



TMF Ref Model

→
←
AI MAPPING

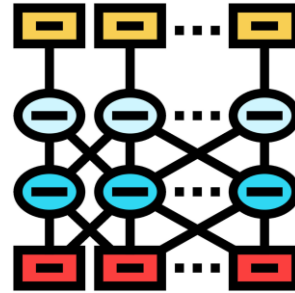


ISF custom model
or CDISC

Practical Example in Japan



CRA uploads documents
(e.g. safety information)



Machine Learning Model

- Trained on clinical documents
- Compliant with data privacy

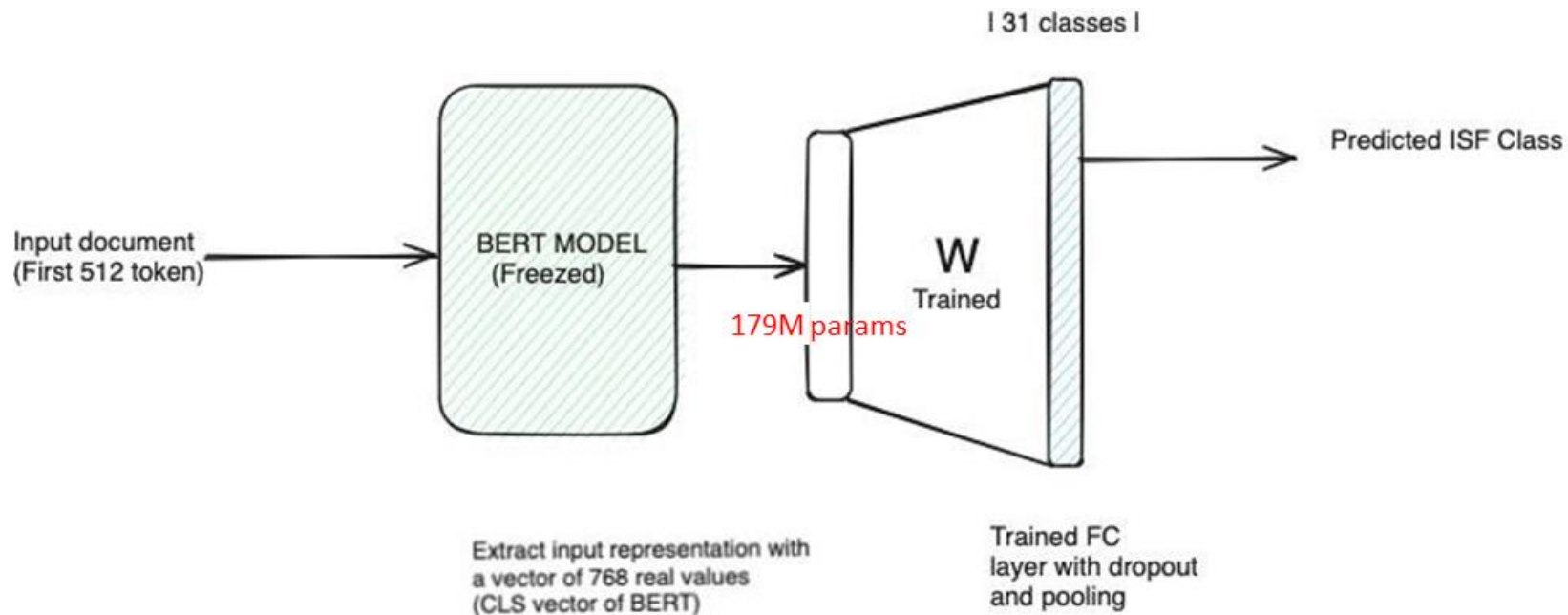


Categorized

- Extraction of document data

Practical Example in Japan

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**



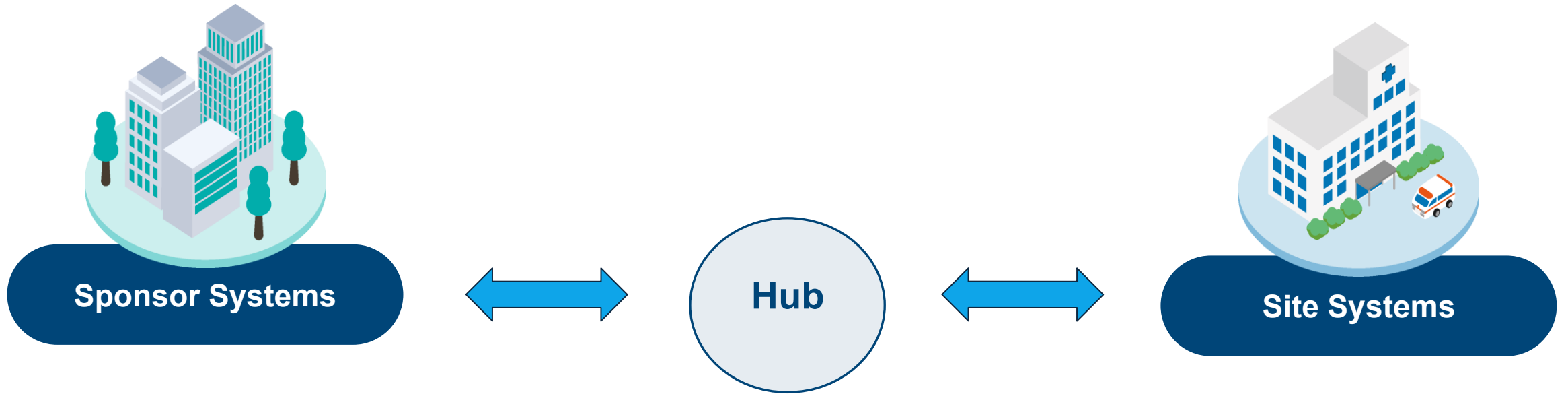


Practical Outcome

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



Clinical hub vs. point-2-point integration



Strategic Architecture



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?

Guillaume GERARD
Chief Operating Office & Co-Founder
Agatha Inc.

guillaume.gerard@agathalife.com

