2026 CDISC China Interchange

Modernizing TMF Management: Applying AI to Drive Quality, Completeness, and Efficiency

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Speakers

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- 13+ years of experience supporting clinical trials in the life sciences industry (including sponsors, CROs, sites, and non-profit organizations), with a focus on language services and electronic clinical solutions.
- Support sponsors and CROs in identifying risks and gaps in TMF management to strengthen inspection readiness and compliance.
- Help clients resolve operational challenges efficiently while reducing GxP-related risks.

5 Most Time-Consuming TMF Tasks?

- Metadata entry
- Document indexing
- Quality checks
- Chasing of missing documents
- Duplication cleanup

5 Most Valuable TMF Tasks?

- Establishment and maintenance of a fit-for-purpose TMF plan
- Risk-based TMF planning and review
- Ensuring inspection readiness and traceability
- Risk identification and trend analysis
- Cross-functional governance and collaboration

5 Most Boring TMF Tasks?

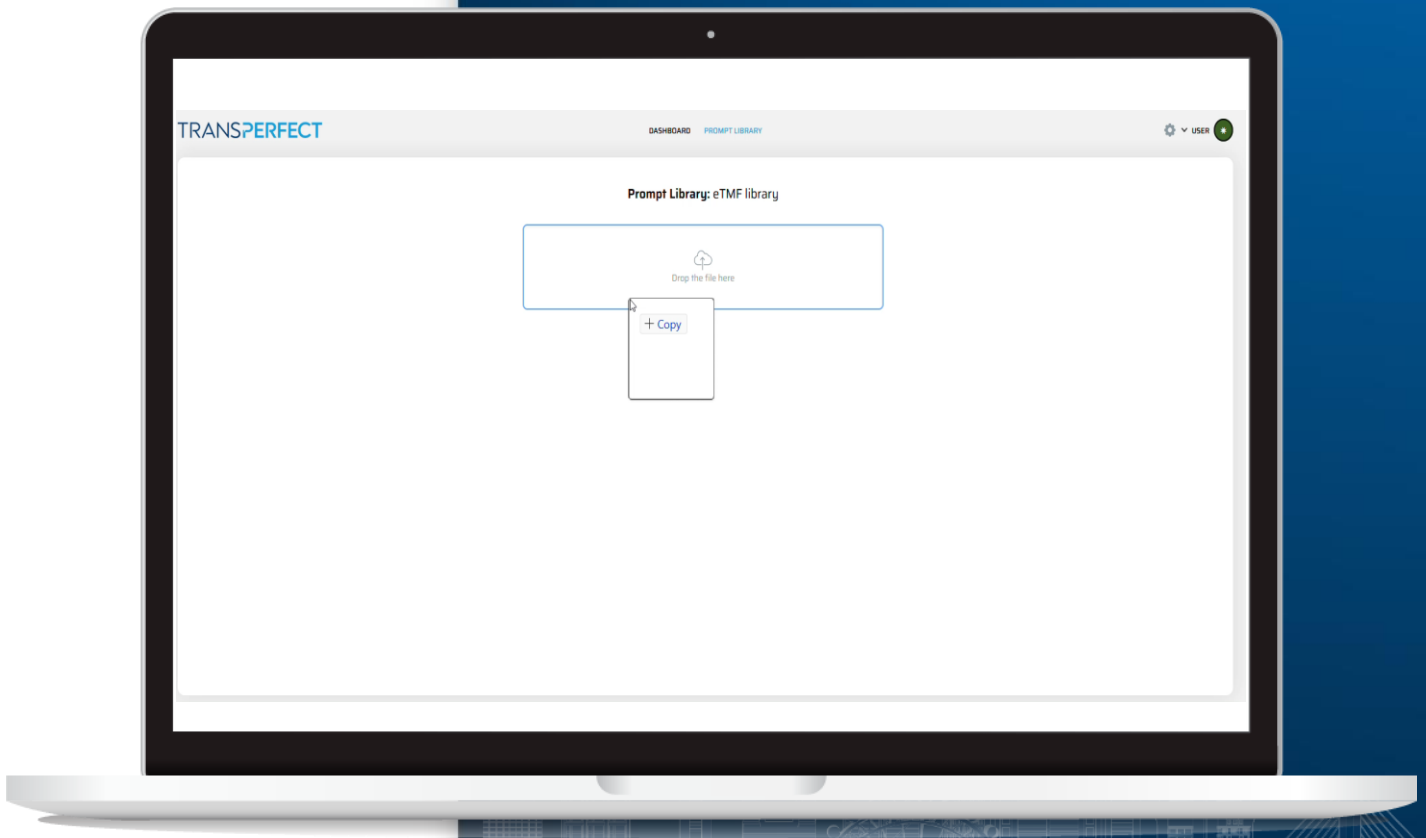
- Metadata entry and maintenance
- Document processing and indexing
- Manual QC of document
- Following up on missing / late document
- Double data entry across systems and reconciliation activities

My Chats with 豆包, DeepSeek, 千问, ChatGPT …

TMF Automation

- Metadata Extraction & Classification
- ALCOA++ Document Quality Checks
- Mock Inspection and Cross-Doc Edit Checks
- Live TMF and Compliance Copilot
- eClinical and eTMF Chatbot

Automation for Metadata Extraction & Classification



- Automates classification & metadata extraction for clinical trial documents
- Pretrained on CDISC model: no heavy training required
- Extracts 25+ metadata fields & flags document issues
- Works in 40+ languages: translation + metadata in one workflow
- Confidence score enables risk-based QC

AUTOMATE — MEASURED RESULTS

Automate cut manual TMF coding by up to 70%

Across sponsors and studies, Automate auto-coded 2,032 of 3,439 TMF documents, the work a team would otherwise do by hand.

Sponsor

70%
decrease in manual effort

3.4×
productivity increase

960 of 1,366 documents auto-coded

30 document types fully automated (100%)

CRO

52%
decrease in manual effort

2.1×
productivity increase

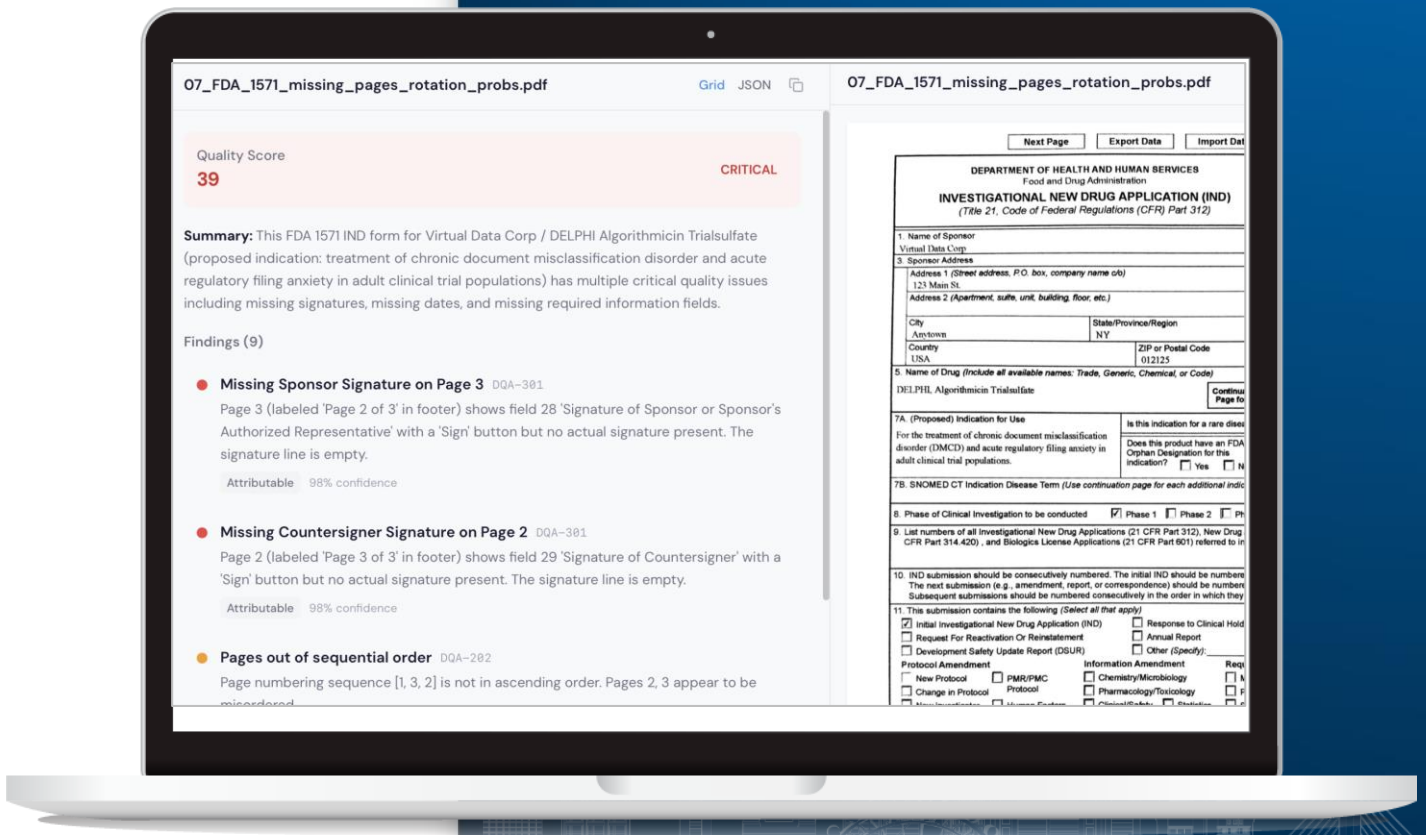
1,072 of 2,073 documents auto-coded

58 document types fully automated (100%)

Combined: 59% less manual coding effort across 3,439 documents — 2.4× the throughput of hand-coding.

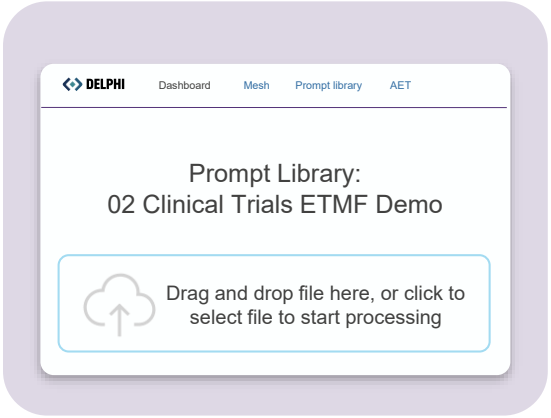
Automate score = documents automatically coded ÷ total documents, across every document type in each sponsor's TMF. Source: per-room Automate metrics export.

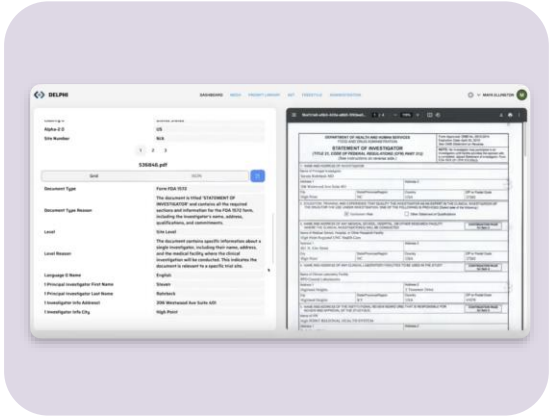
Automation for Document Quality Checks

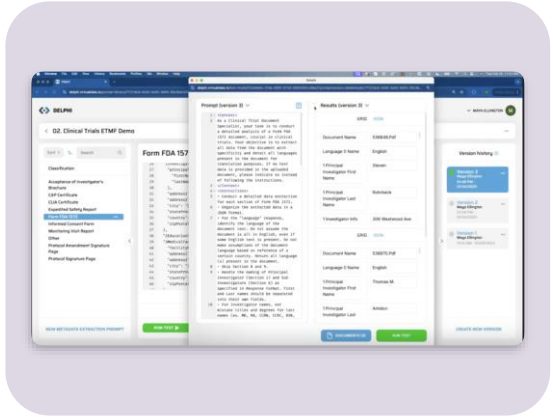


- ALCOA++ aligned inspection-grade controls
- Detects missing signatures, draft watermarks, page gaps, scan defects
- Flags PII/PHI exposure & improper redactions
- Generates document quality scorecard + full audit trail
- Supports eCTD submission-readiness checks

Enhancing Clinical Document Workflow with Automation







INGEST

AI-powered automation ingests and classifies unstructured documents simultaneously, in seconds

PROCESS

LLM-driven workflows structure the raw data into metadata, perform document quality checks, analyze completeness and surface key data with high accuracy

REVIEW

Human-in-the-loop validates and refines results for accuracy, while the AI learns from feedback to improve future extractions

LOG

Real-time audit trails for FDA, HIPAA, and GDPR compliance

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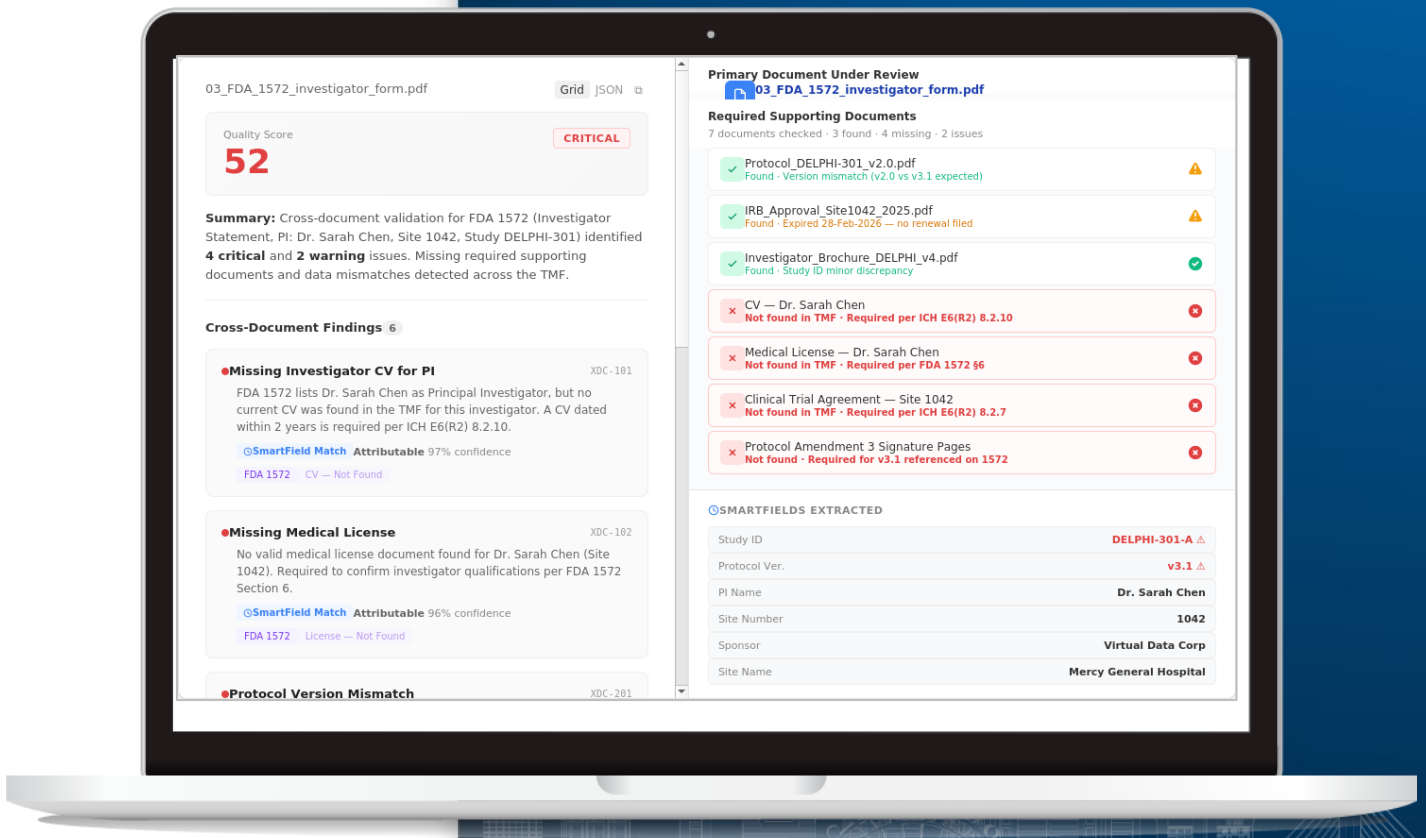
Automation for Cross-Document Checks



- Agentic AI that verifies relationships across TMF documents and study data using Smart Fields
- Detects cross-document compliance risks that manual filing often misses
- Examples:
  - ❑ Detect unblinded data in blinded study files
  - ❑ Flag documents filed in the wrong study TMF
  - ❑ Validate required CVs, licenses & contracts against FDA 1572
  - ❑ Confirm all protocol signature pages collected for amendments

Regulations for Automation in eTMF

Must be explainable and transparent

Cannot replace human accountability for regulatory compliance

Should have appropriate risk management strategies

Must comply with GDPR and data protection requirements

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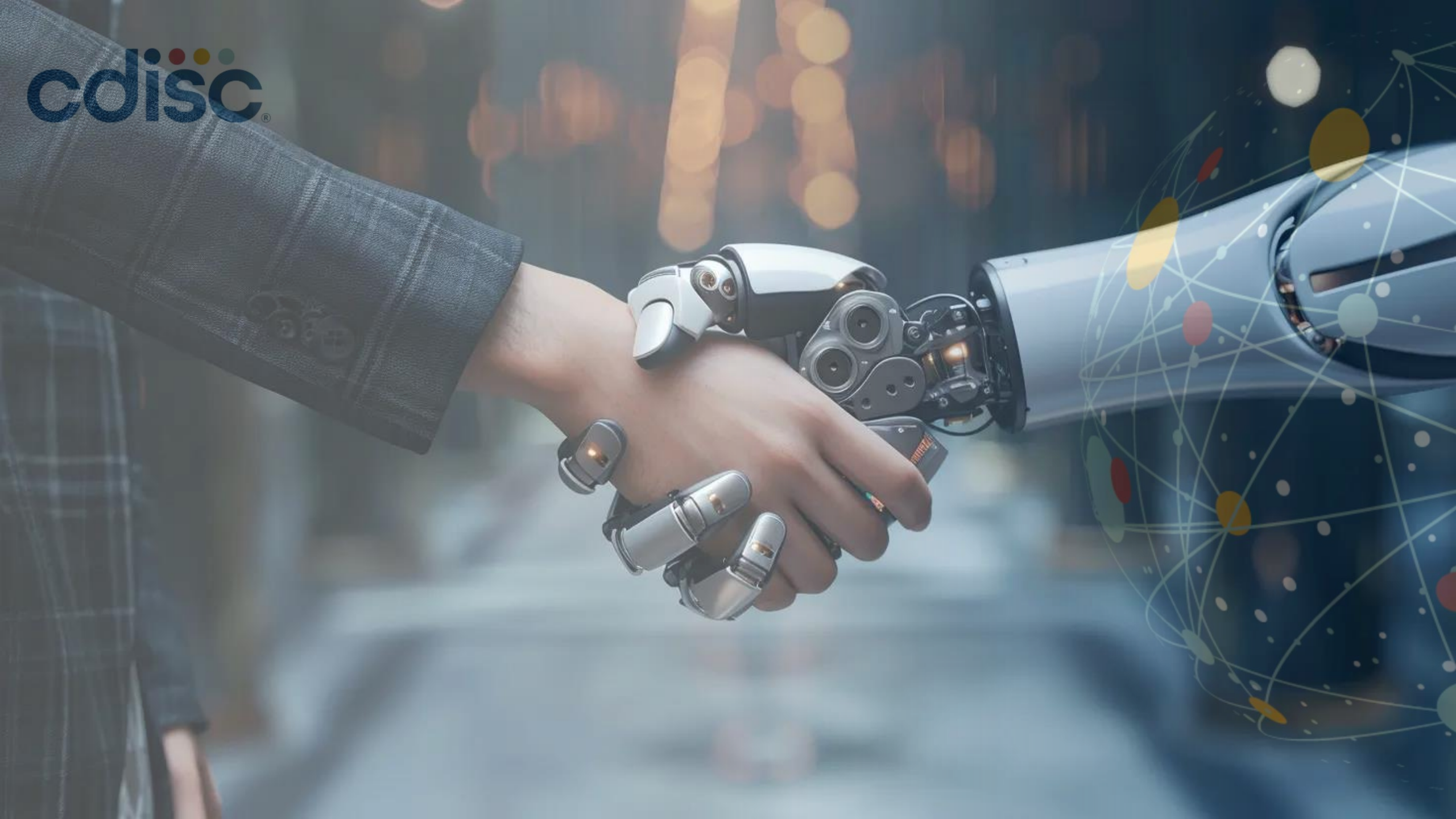

China TMF Community – Official Establishment Today!!

- Shared space for TMF-related discussions
  - Specifically designed for China!
- Regular online / offline meetings
  - TMF management standards
  - Common challenges and best practices
  - Inspection readiness preparation tips
  - Industry trends and hot topics
- Open to anyone involved or interested in TMF management ☺

Thank You!

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