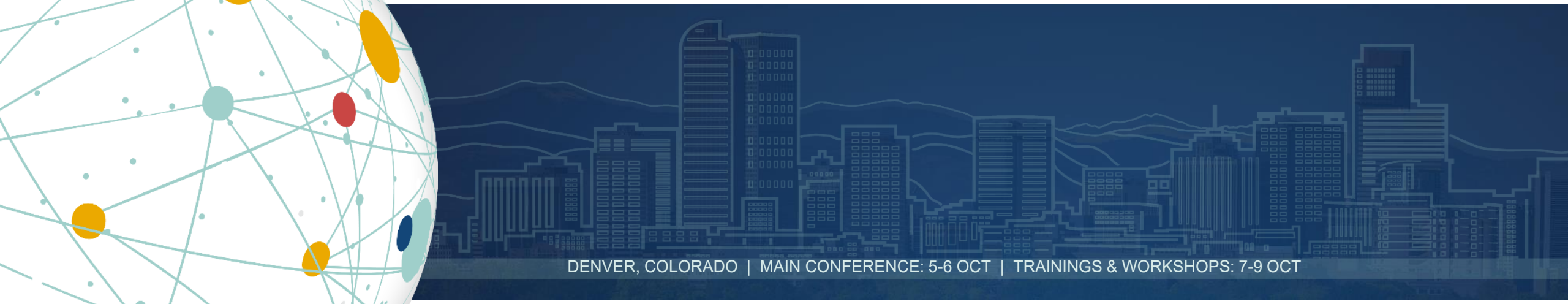


2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Leverage AI To Accomplish the Impossible: An Inspection Ready TMF

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// CLASSIFIED — TMF OPERATIONS BRIEFING

MISSION: INSPECTION READY

Using AI to bring the Trial Master File to an inspection-ready state in 90 days.

Your mission, should you choose to accept it, begins now.

90

DAYS TO INSPECTION READY

TMF QUALITY & COMPLIANCE // JERION CONSULTING

Why This Mission, Why Now

MISSION OBJECTIVE

Bring the TMF to a state we can defend on day one of an inspection:

- Complete against the Expected Document Listing
- Contemporaneous — filed as the trial happens
- Retrievable in minutes, not hours
- AI screens everything; people judge what matters

THE STANDARD HAS MOVED

ICH E6(R3) expects the TMF to be complete and contemporaneous throughout the trial — “always inspection ready,” not a pre-inspection scramble.

INSPECTORS MOVE FAST

Inspections can arrive with little notice. Completeness and retrieval speed are tested in the first hours — there is no remediation window once the request lands.

SCALE IS THE ENEMY

A Phase II/III TMF holds tens of thousands of records across 11 zones. Manual review alone cannot see all of it — which is exactly the gap AI closes.

// MISSION FILE 02 — THE OBSTACLE

Mission Impossible? Only the Manual Way

MANUAL REVIEW ALONE

- Sampling sees a fraction of the inventory — issues hide in the rest
- QC lags filing by weeks; findings surface after the window to fix them
- Duplicates and misfiles found one document at a time
- Storyboards assembled by hand under inspection pressure

AI-ASSISTED REVIEW

- Screens 100% of records — nothing is invisible
- Flags issues at the point of filing, not months later
- Risk-ranks zones so human effort goes where it matters
- Retrieves and assembles evidence in minutes

DO THE MATH: **40,000 records × 2 minutes each ≈ 1,300 hours of eyes-on review. Remember: you only have 90 days.**

// MISSION FILE 03 — YOUR GADGETS

What AI Actually Does for the TMF



DUPLICATE & MISFILE DETECTION

Screens the full inventory for near-duplicates and records filed against the wrong artifact.



EDL GAP ANALYSIS

Compares actual inventory to the Expected Document Listing to predict what should exist but doesn't.



COMPLIANCE AND RISK ASSESSMENT

Evaluates your plans to ensure compliance and determines any deficiencies.



SEARCH & STORYBOARDING

Natural-language retrieval to pull the evidence trail for any inspection question in minutes.

// MISSION FILE 04 — RULES OF ENGAGEMENT

AI in a GxP World: Non-Negotiables



HUMANS STAY IN THE LOOP

AI flags are leads, not verdicts. A qualified reviewer makes every quality decision — and the record shows they did.



PROTECT THE DATA

Confirm vendor terms before use: no trial data or personal data leaves the validated environment or trains external models.



DOCUMENT YOUR AI USE

Inspectors will ask how AI is used. Keep scope, procedures, and human oversight in writing — before findings start flowing. AI features in your eTMF go through change control and vendor assessment like any other release

Break these rules and the mission fails — an unvalidated, undocumented AI tool is an inspection finding, not a shortcut.

Assemble Your Team

Recon



Evaluating Risk based on Type of Inspection

Team Member: GPT “Chat”

Scour the internet for prior findings
Changes to Regulations
Understanding or Regulatory Body / potentially the Inspector is information has been provided

Action



Risk Review Analysis and Evaluation

Team Member: Claude

Analytical and in-depth review of content for areas of risk based on Storyboard details, study team discussions, and study plans.

Mission Ready



Study Team Inspection Prep

Team Member: Agent CoPilot

Study team can practice responding to study questions based on review findings, storyboard events, and general inspection questions.

T-0 // INSPECTION DAY: **the TMF answers every request in minutes — because you rehearsed it.**

// MISSION FILE 06 — THE TIMELINE

The 90-Day Mission Map

T-90



PHASE 01 — High Value Targets

Days 1–30

Risk Based approach to High Value records the EDLs for the study, study team feedback, type of inspection and prior inspections.

T-60



PHASE 02 — Zone Risk

Days 31–60

High value zones based on study team input, storyboard, metadata, protocol and other plans for the study (study end point).

T-30



PHASE 03 — Resolution

Days 61–90

Close the gap, keep consistency for new files being uploaded. Inspection knowledge and understanding for study team. AI-assisted storyboards, final sweep, readiness confidence.

T-0 // INSPECTION DAY: **the TMF answers every request in minutes — because you rehearsed it.**

Phase 01: RECON · Days 1–30



RECON

T-90

OBJECTIVE WINDOW
DAYS 1–30

01 **Baseline the battlefield.** Run an AI completeness sweep against the EDL; capture starting metrics for completeness, quality, gap analysis, risk assessments.

02 **Risk-rank the 11 zones.** Combine study risk with zone risk scores to decide where sampling depth and remediation effort go first.

03 **Sweep for duplicates & misfiles.** Let AI screen the full inventory; queue confirmed issues for correction.

04 **QC at the point of filing.** Monitor new records on arrival, so the backlog stops growing while you fix the past.

05 **Stand up study team touch points.** Explain the approach, review workflow, and how documentation of gaps will be shared, as well as expectations — before findings start flowing.

Phase 02: STRIKE · Days 31–60



STRIKE

T-60

OBJECTIVE WINDOW
DAYS 31–60

01 **Remediate by risk, not by zone order.** Highest-risk zone gaps first; accept documented rationale where perfection isn't achievable.

02 **Chase the missing.** AI-predicted EDL gaps become targeted document requests to the study team, CRO and sites — each with an owner and a due date.

03 **Fix the metadata.** Correct classification, dates, and naming/titles — retrieval speed on inspection day depends on clean indexing.

04 **Align the CRO.** Sponsor oversight doesn't transfer. Agree metrics, cadence, and remediation ownership in week one.

05 **Track the countdown.** Weekly metrics review. Anything not trending to target by day T-45 gets escalated, not hoped about.

Phase 03: REHEARSE · Days 61–90



REHEARSE

T-30

OBJECTIVE WINDOW
DAYS 61–90

01 **Run a mock inspection.** An independent reviewer plays inspector: unscripted document requests against the live TMF, findings logged formally. Or use an AI agent to support.

02 **Dry-run retrieval.** Explain to the study team how to look for content in the system. Explain that Time is essential for request — the target is minutes, not hours. AI-powered search is your advantage only if the team has practiced it.

03 **Finalize the storyboards.** Assemble the study narrative — key decisions, deviations, safety flow — with AI-assisted retrieval, reviewed by humans. Using a system inventory in Excel, have links easily available for TMF Team to support study team retrieval.

04 **Final sweep & sign-off.** One last AI completeness pass; close residual gaps or document the rationale; readiness sign-off healthy TMF is available.

05 **Prep the war room.** Roles, request logging, escalation paths, who speaks to what — everyone knows their part before day one.

AI in Real Life - Prompting Examples

Example 1

- Evaluate these eTMF documents for inspection readiness activities in preparation for an upcoming PMDA inspection using ALCOA++ standards, ICH-GCP E6 R(3), and PMDA regulations and guidelines for completeness and consistency.

Example 2

- Compare these two reports – one is a current eTMF inventory report, and one is a current placeholder report. Your job, using ALCOA++ standards and the CDISC TMF Ref Model v3.3.1, is to determine if documents in the inventory report are also present in the placeholder report.

Example 3

- Analyze this study plan to determine what records should be generated/filed from this plan. Create a table of record type, when it is required, and who is responsible for the record. You may also indicate if another plan or SOP is referenced.

Common thread: Action word, standards used, evaluation criteria, purpose, expected output.

Example 1 – Japan PMDA Inspection Review

MANUAL REVIEW ALONE

- ~200 documents sampled
- Time: 8 hours
- Output: Manual excel tracker on completeness alone
- 99% accuracy
- Found some high-risk essential records missing

AI-ASSISTED REVIEW

- 2000 Japan country and site documents
- Time: 2 hours
- Output: Full TMF Health assessment from a PMDA inspector and GCP perspective
- ~80% accuracy
- Provided starting point for further review and evaluation

DO THE MATH: 10 times the output in 1/4 of the time! Even with 80% accuracy factor. Alternative bite-size approach is to look at specific record types or classifications.

Example 2 – Placeholder vs. Inventory Report

MANUAL REVIEW ALONE

- ~100 placeholders sampled
- Time: 5 hours
- Output: Manual 1:1 excel comparison
- ~80% accuracy
- Metadata and document date limitations

AI-ASSISTED REVIEW

- ~2000 placeholders with 50,000+ documents
- Time: 1 hours
- Output: Tracker comparison with Medium, Low, No confidence analysis of placeholders and documents
- ~60% accuracy
- Metadata and document date limitations

DO THE MATH: 20 times the output in 1/5 of the time! Even with 60% accuracy factor. BOTH methods required confirmation and follow-up with CRO.

Example 3 – Study Plan Compliance

MANUAL REVIEW ALONE

- ~1 plan evaluated
- Time: 2 hours
- Output: Manual listing of expected content listed in excel and rational for requirement
- ~80% accuracy
- Human review can miss nuances in plans

AI-ASSISTED REVIEW

- ~1 plan evaluated
- Time: 3 minutes
- Output: Table output of required content identified in the plan with expected filing timing and accountable entity
- ~90% accuracy
- Study team agreements not documented in plan (but in other records)

DO THE MATH: Non bias output, less hours of organizing more time eyes-on confirmation. Minutes instead of hours. Scales with more plans. Remember: you only have 90 days.

// CLASSIFIED ANNEX — MISSION: INSPECTION READY

AI & the TMF: Limitations and Future Considerations

KNOWN VULNERABILITIES

Limitations to manage now

It only sees what it's given.
Gap analysis is only as good as the EDL and records available at the time. With records spread across multiple CROs and systems, AI coverage can be limited.

It can't judge significance.
AI can confirm a document exists and looks right — not whether the trial conduct it records was adequate. GCP judgment stays human.

Errors cut both ways.
False positives and false negatives can exist. Watch for automation bias, hallucinations, drift, etc.

Messy inputs degrade accuracy.
Poor scans, handwriting, wet-ink signatures, non-English site documents, metadata errors, and migrated legacy content all reduce reliability.

AI Models Matter and Change.
Vendor releases can shift behavior without notice, limitations based on company policies. Validation is a lifecycle, not a one-time event.

THE NEXT MISSION

Considerations for what comes after

Regulatory expectations are forming around AI.
FDA and EMA have published risk-based thinking on AI. Expect sharper GCP expectations — and inspectors asking how AI use was controlled.

TMF Standard Model transition.
Classification models and EDL mappings built on the TMF Reference Model will need remapping and revalidation for CDISC's TMF Standard Model.

Generative and agentic AI is evolving.
Storyboard drafting, summaries, autonomous document chasing. Outputs must link to source records and be checked for fabrication.

Interoperability across partners is possible.
Multi-CRO studies need AI that works across systems — and can verify completeness when a TMF transfers between organizations.

Beyond day 90.
Turn the readiness project into continuous monitoring. Budget for ongoing validation, reviewer training, and the human capacity to act on flags.

BOTTOM LINE: **AI accelerates the mission. Accountability for the TMF never transfers to the machine.**

// END OF BRIEFING — FILE 17 OF 17

This TMF Will (Thankfully) Not Self-Destruct.

It will be inspected. The only question is whether you rehearsed.



AI CAN SEE EVERYTHING

Full-inventory screening replaces TMF sampling — completeness, quality, and timeliness measured continuously.



PEOPLE JUDGE WHAT MATTERS

Every AI flag meets a qualified reviewer. Governance is documented, validated, and ready to show an inspector.



90 DAYS CAN BE ENOUGH ONLY WITH AI

Recon, strike, rehearse — thirty days each. But only if the mission starts today.

YOUR MISSION, SHOULD YOU CHOOSE TO ACCEPT IT: DAY 1 STARTS NOW. // END OF TRANSMISSION

Resources

Prompting Guide

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Questions?



Thank You!

