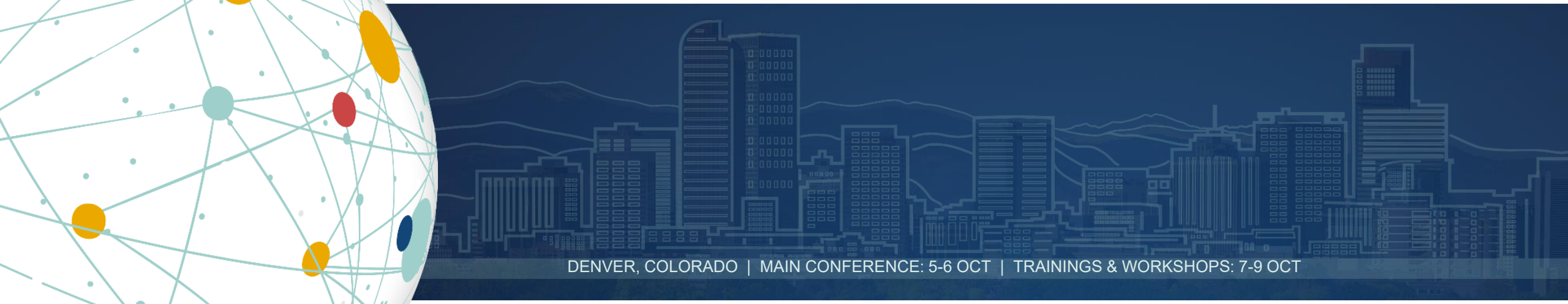


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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

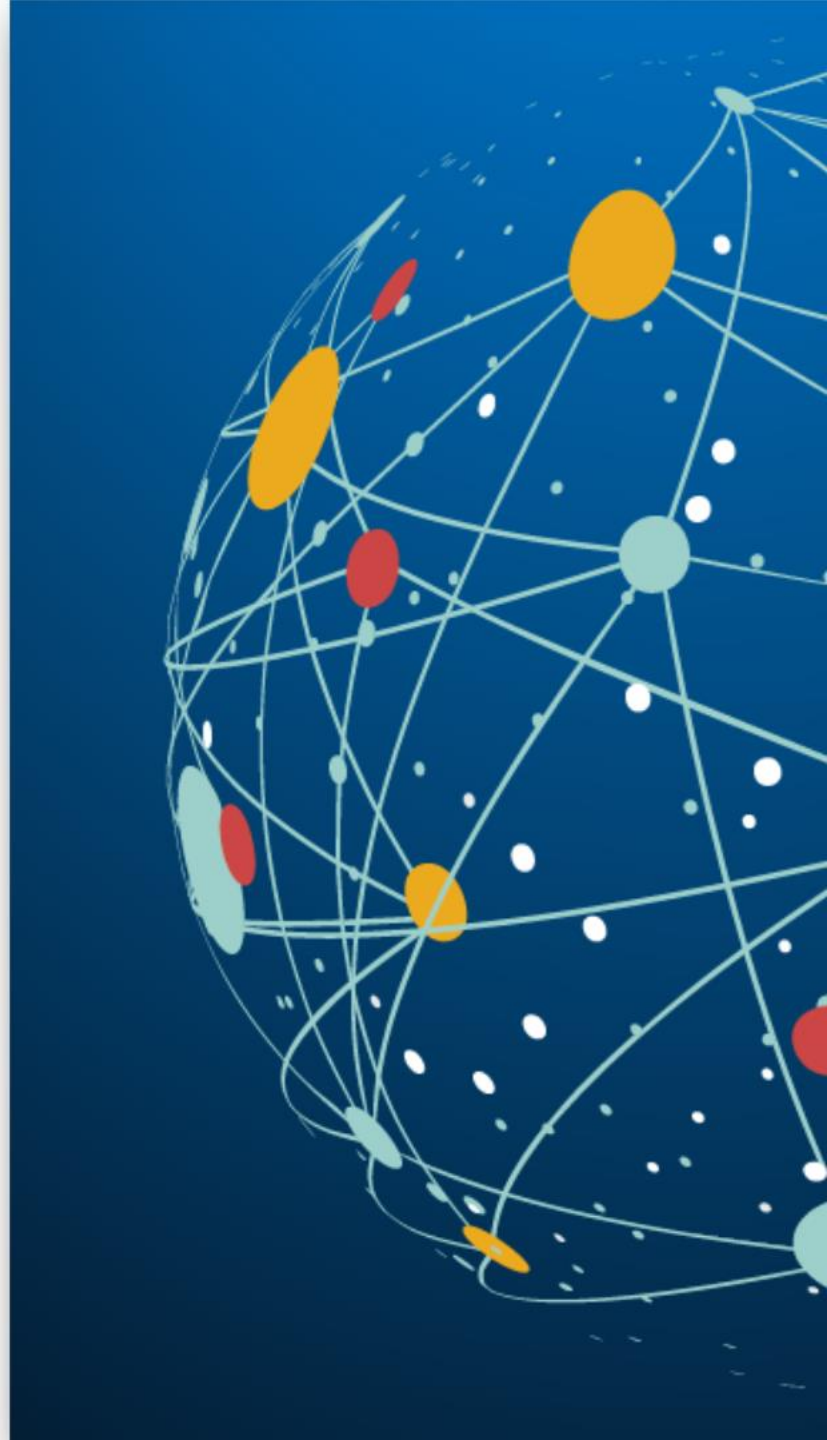


Transforming TMF Oversight: Applying AI to Address Persistent Site Personnel Record Gaps

Niamh Smith, Director Clinical Compliance, CSL Behring
Aaron Grant, Head of Innovation, Just in Time GCP

Agenda

- Transforming TMF Oversight
- Transformation & Business Need
- TMF Oversight Challenge
- Site Automation Tool Case Study
- Issue Identification- how did this help
- Project Benefits; Targeted Action



Meet the Speaker



Niamh Smith

Director, Clinical Compliance

CSL Behring

Niamh is the Director of Clinical Compliance at CSL Behring, leading compliance processes across clinical development programs, while fostering a culture of continuous improvement. Throughout her 20+ year career, she has developed expertise in clinical operations, TMF management, quality systems, and compliance, helping organizations strengthen inspection readiness and operational excellence. Driven by a commitment to excellence & quality, Niamh's leadership is shaped by a strong appreciation for the impact that well-executed clinical research can have on the advancement of science, healthcare and ultimately patients.

Meet the Speaker



Aaron Grant

Head of Innovation

Just in Time® GCP

Aaron is the Head of Innovation at Just in Time GCP, leading the integration of advanced technologies to enhance clinical operations and ensure GCP compliance. With over 20 years of experience in regulatory and clinical research technology, he is focused on delivering practical, usable solutions that delight users and improve business practices. Aaron is a regular contributor to the CDISC TMF Reference Model helping shape the technical direction of the TMF industry including EMS, DDF and V1.

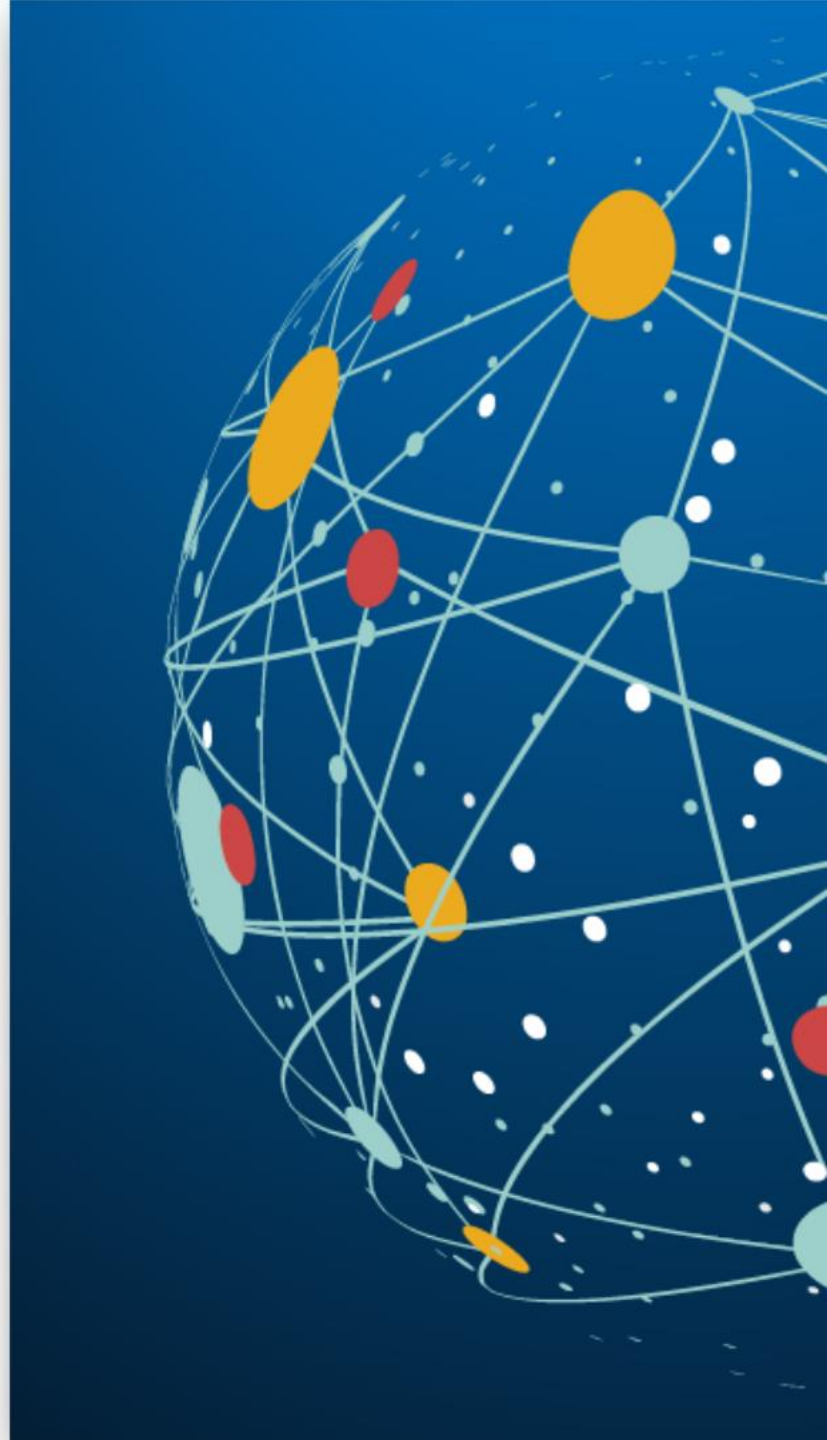
Transforming TMF Oversight

Applying AI to Address Persistent Site Personnel Record Gaps

Transforming TMF Oversight

- Regulatory bodies no longer view the Trial Master File (TMF) as a document repository, only checked at end of trial, but rather the primary evidence that quality and compliance are actively maintained through the lifecycle of the trial

- ICH E6 (R3) defines Sponsor oversight expectations with emphasis on continuous, proactive risk-based control rather than a standard passive approach. Requires Sponsors to actively monitor TMF health, inspection readiness and implement effective controls to ensure TMF completeness, quality and compliance through the lifecycle of the trial



Company Transformation

Optimizing clinical operating model to improve study execution while maintaining an unwavering focus on patient outcomes

- **Outsourced Management:** Enhancing fully outsourced study models utilizing preferred External Service Providers. While responsibilities may be delegated, accountability remains with the sponsor requiring continuous, real-time evidence of oversight activities, ensuring delegated tasks are performed effectively and in compliance

- **Beyond Basic Metrics:** Assessing expansion of Traditional metrics e.g. document counts and basic completeness percentages. Focusing on expansion of metrics to demonstrate proactive management, including issue identification and scalation; the TMF must clearly tell the story of effective study oversight

- **Optimizing Automation in an Outsourced Model:** Focusing on identifying practical and cost-effective automation opportunities that enhance trial execution and strengthen TMF delivery and oversight in outsourced study model

Business Need

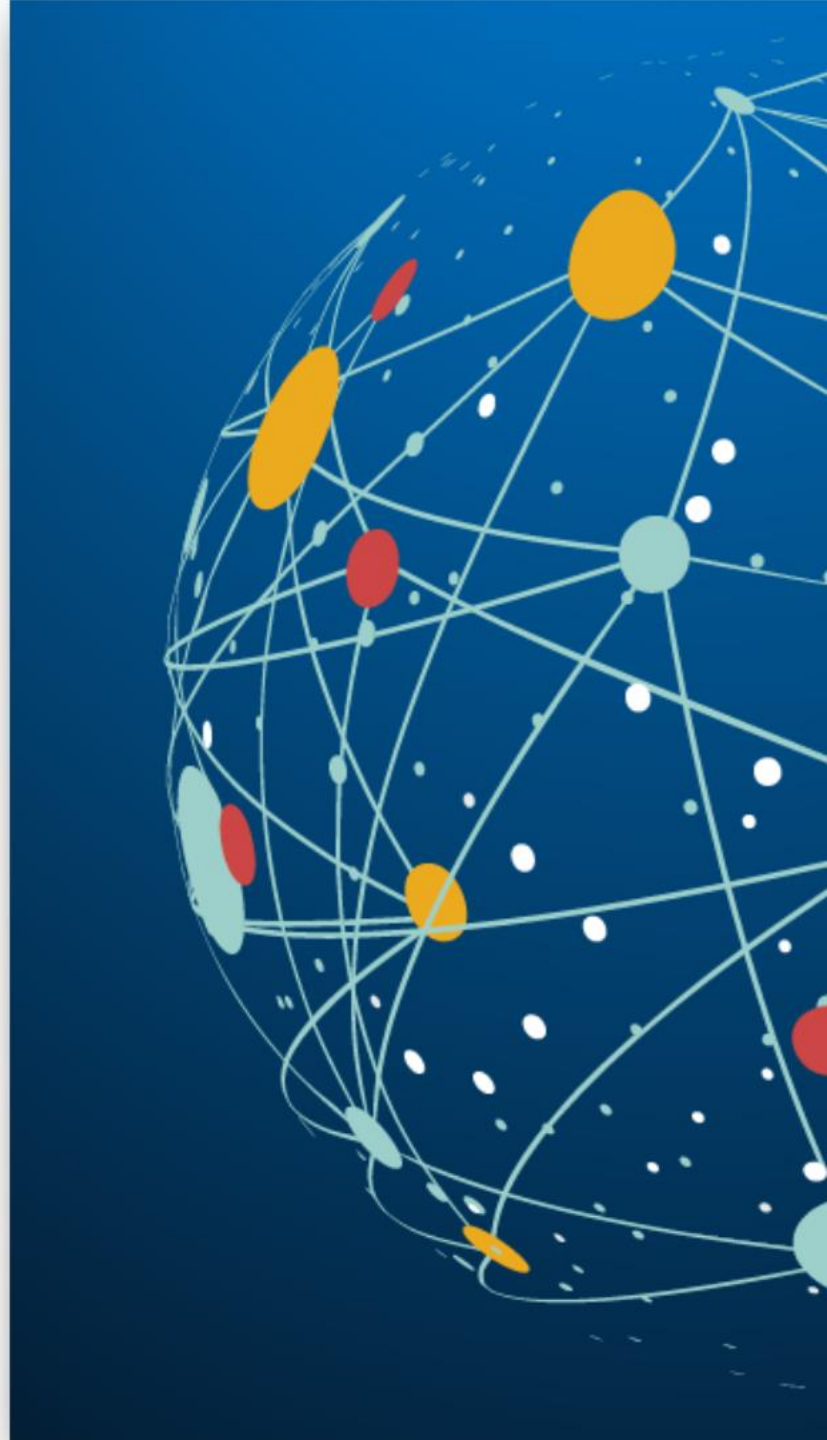
- With increased TMF complexity, reliance on manual review processes delay issue detection, limit oversight visibility, and increase compliance risk, highlighting the need for more scalable and proactive quality oversight solutions

- Across company & Industry the increased need for scalable technology enabled approaches that can proactively identify documentation deficiencies & enhance TMF quality oversight was a driving force to investigate & assess vendors to assist with achieving these goals

- CSL TMF Operations began a project with Just in Time GCP to target a specific TMF oversight challenge

TMF Oversight Challenge: Site Personnel Records

- Site personnel records are critical TMF documents that demonstrate appropriately qualified, trained, and adequately staffed individuals are performing trial-related activities throughout the study
- Industry continues to face challenges in efficiently managing and identifying missing site personnel documentation post site Greenlight
- Sponsors often rely on external service providers to conduct periodic reviews; however, existing oversight tools do not consistently identify documentation gaps
- Ongoing reconciliation required to ensure TMF completeness, yet gaps are identified too late, exposing TMF to increased risk
  - ***Often indicate broader TMF risks & concerns***
- Manual review processes are labor-intensive and time-consuming, requiring approximately **2 hours per site** and significantly more time for large studies with numerous sites and personnel
- Long-running studies further increase complexity; Reference study with some sites maintaining records for **100+ personnel**



Case Study

- Read & Processed 3000+ documents for 29 sites
- Study running for 7+ years
- Some sites large academic institutions with 100+ personnel
- Evolution of study operating models & filing requirements from study initiation to present, leading to potential inconsistencies

Site Personnel Automation Tool



AI Broadens Review; Experts Interpret Risk

Just in Time offers a service with trained artificial intelligence to perform review of site personnel records across CSL's 29 sites

- AI flags missing and inconsistent records
- Risk weighting helps focus deeper review
- Experts validate context and decide next steps

So we can:

- Cover more scope
- In less time
- With clear oversight risk identification
- And analytical insights

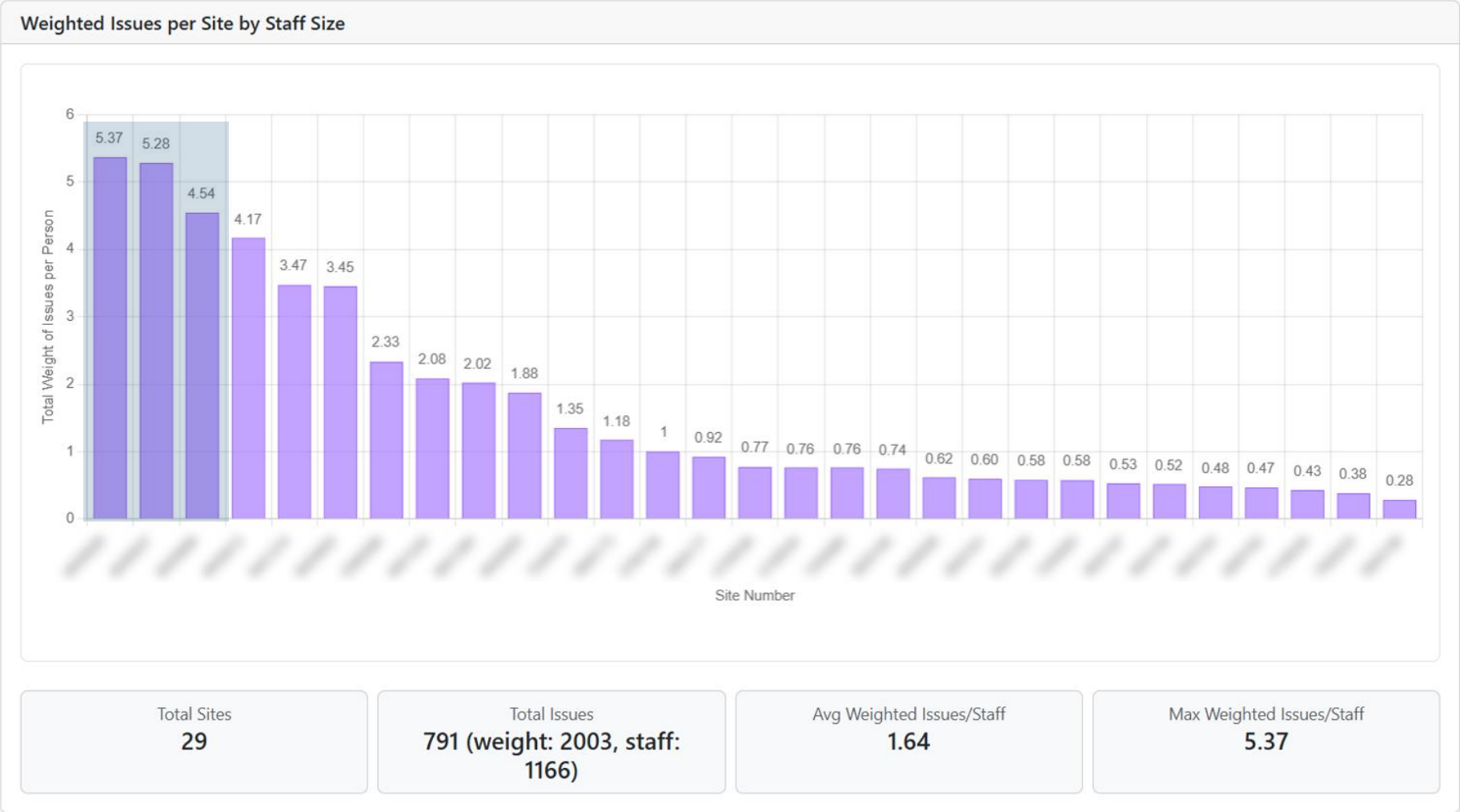
Three Record-Gap Patterns

RECORD COMPLETENESS
Missing CVs, licenses, disclosures and reference records

PERSONNEL ACCOUNTABILITY
Delegation-log and Form 1572 omissions

FILING & DATA QUALITY
Misfiles, duplicates and eTMF metadata/date errors

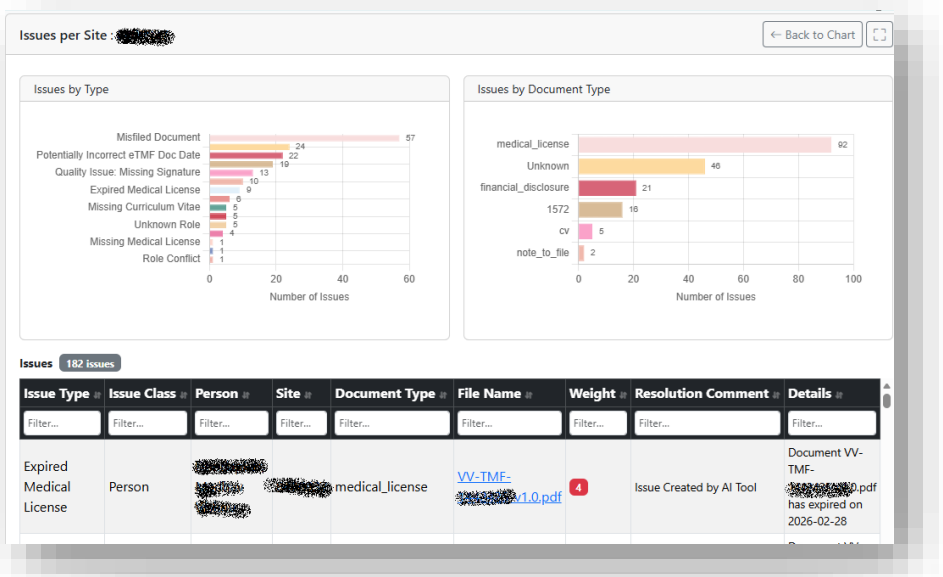
Risk Weighting Narrows the Sites to Investigate

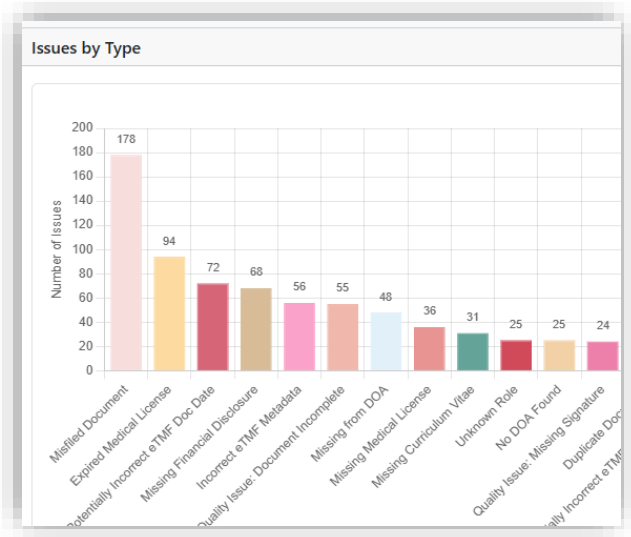


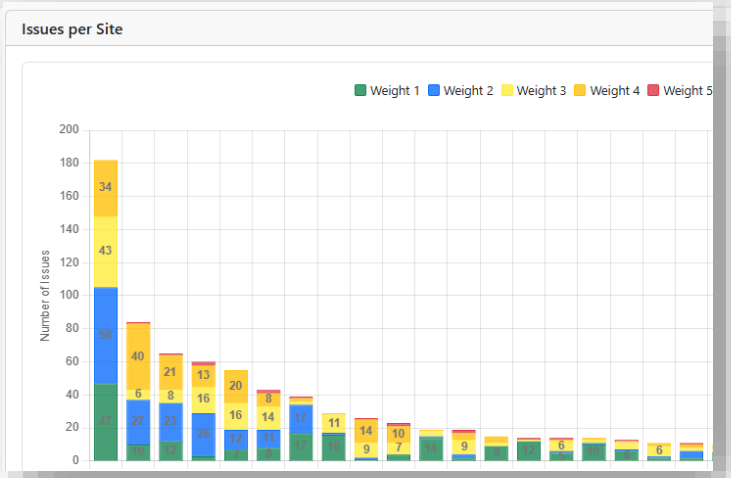
3 Sites flagged for further investigation

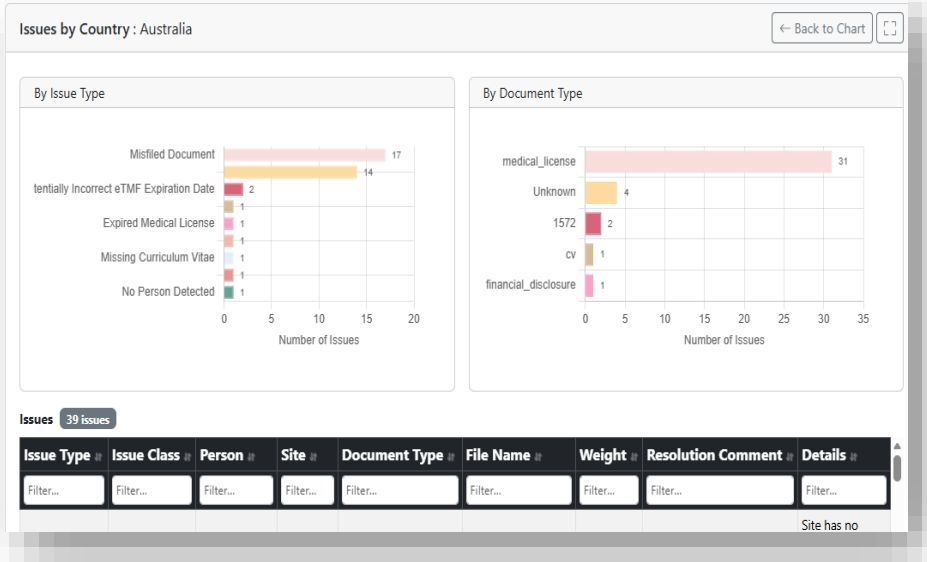
Weighted issues per staff member help focus where human review starts.

AI Makes Issue Patterns Visible at a Glance









Visualizations provide clarity and insight

While Analytics are not new, AI tools allows rapid buildout of visuals that move us away from spreadsheets

AI Finds the Signal; Experts Explain the Why

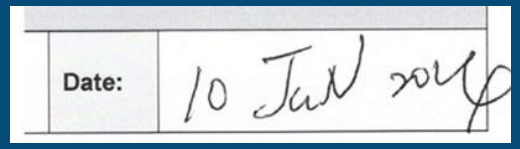
What the review surfaced

- 791 issues identified across 29 sites
- 293 serious issues (weight ≥ 3)
- 3 sites flagged for further investigation

What experts add

- Check apparent gaps against site context
- Explain why records differ
- Decide where follow-up is warranted

Where AI shouldn't decide



3 investigators had documents filed at 3 different sites

2 investigators listed on first 1572 and then never again

Flags prompt investigation, not automatic conclusions.

Issue Identification – How did this help?

How did this evaluation help in our (CSL) TMF Objectives moving forward

"It has allowed us to identify gaps through automated cross-checking that we've never had the tools for before; the tool helps provide a complete picture of where are problem areas are and what risks to work to mitigate"- AD TMF Operations, CSL

- Provided issue report for sites ahead of site close out visits; for high volume sites allowed identification of older issues
- TMF Index; Lack of updated TMF index on file; proved challenging for automation tool and review team as did not demonstrate changes in filing requirements
- Requirements for filing interim logs i.e. DOA, changed from study initiation to present at CSL; resulted in missing DOAs which made reconciling site files challenging due to lack of DOA
- Finding: **AI increases the need for updated periodic logs in order to do evaluations …**

"We wish we had this sooner…."
–CSL Study Team

Project Findings Became Targeted Actions, Supporting Lasting Change

Result:

Simpler views of the data, faster leadership decisions, and evidence-backed change

AI performed the cross-checking; People remain accountable for the decision making

EVIDENCE IN ACTION

01

Cross-site patterns

Highlighted potential same investigator documents filed across multiple sites; *Directs the team to action*

02

Missing continuity

Identified people listed on the initial 1572 with no other documents on file. *Allows targeted focus in review*

03

Focused clean-up

Misclassified documents enabled a more targeted TMF remediation approach

PROCESS CHANGE

Interim-log filing reinforced

CAPABILITY BUILDING

TMF index training targeted

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Questions?

