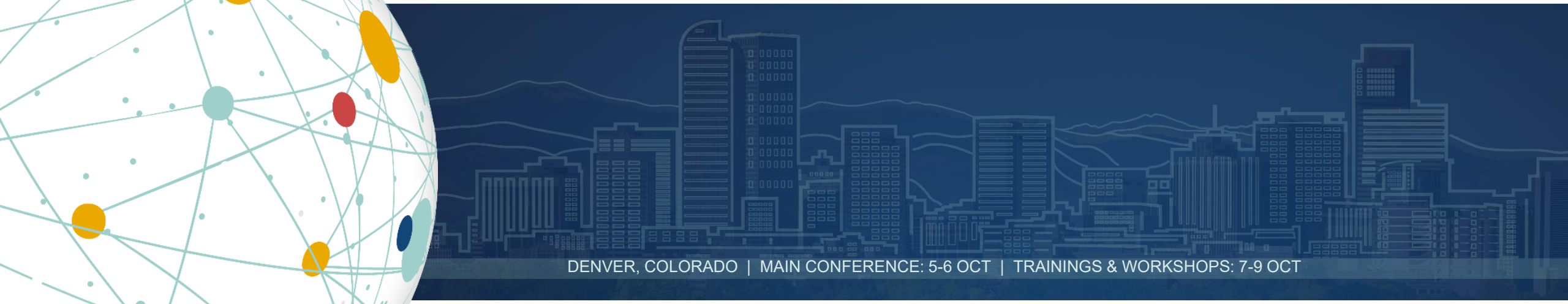


# 2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION




## Proactive Oversight Means Compliance Confidence

Jenn Stamper Director, Client Partnerships
Carol Radwanski  Director, TMF Services
Just in Time, GCP

# Speakers



Jenn Stamper
Director, Client Partnerships
Just in Time, GCP



Carol Radwanski
Director, TMF Services
Just in Time, GCP

# TMF Health Assessments:

## More Like a Doctor Visit Than You Think

Annual physicals = Routine TMF Health Assessments

Regular lab work = QC checks and metrics monitoring

Lifestyle adjustments = SOP/policy updates and retraining

Loss of credibility→ like skipping your medication and still hoping for good results

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# TMF Oversight Challenges Go Beyond Completeness

The challenges are about whether the TMF supports quality, risk, and consistent oversight, not simply whether expected records are present.

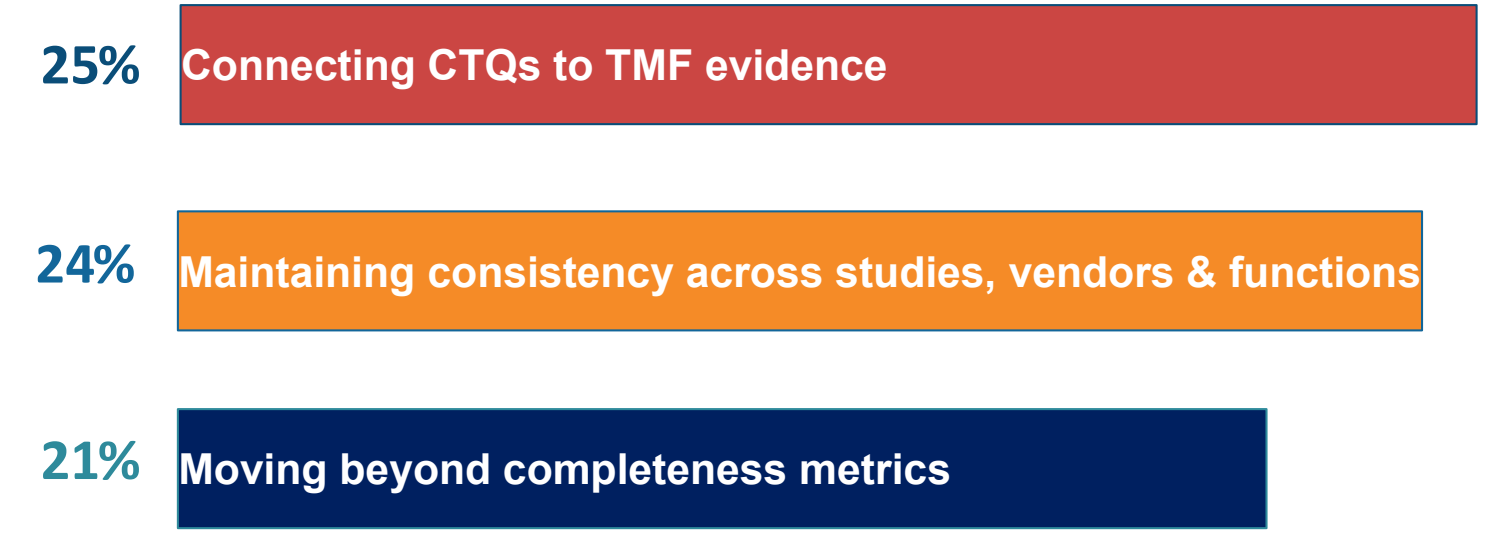
**70%**

**of responses**

point to challenges that require looking beyond traditional completeness metrics

**Evidence • Risk • Oversight**

**What respondents are struggling with**




## Why assess TMF health?

To evaluate whether the TMF provides the right evidence, connects to what matters in the study, and supports consistent oversight.

# Record Quality Signals can Reveal Deeper Trial Quality Issues

*A record can be present and on time but still fail to show reliable evidence of control.*



# Why it matters

A neglected TMF is like skipping the doctor until symptoms worsen

Regulatory fines, inspection findings, and trial delays are the “emergency room” equivalents

Proactive assessments allow early detection and course correction

Proactive assessments in TMF health allow sponsors and CRO’s to:

- Identify root causes early
- Course-correct with minimal disruption

Builds inspection readiness

Like staying in shape through small, consistent habits – not crash training before a marathon



# TMF Health Assessment

Your TMF needs regular check-ups, just like your body to  catch issues early and stay healthy.

- Completeness = Essential records are in place (wellness health checks)
- Timeliness = Filed on time (regular lab work)
- Quality = Legible, accurate, and final (test results)
- Process Adherence = Filing follows SOPs (following your treatment plan)
- Consistency = Metadata and filing align with expectations  (entering test results in the correct patient chart)



# Routine Maintenance is the Cure

Just like regular wellness checks, the health checks of your eTMF should be:



**Scheduled at intervals (e.g., quarterly, mid-study, pre-lock)**



**Consistent in scope and methodology**



**Collaborative, involving CROs and internal teams**



**Actionable – issues are graded, and follow-up plans are clear**

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# Staying Ahead of TMF Risk:



Spot risks early with targeted TMF reviews



Drive quality with oversight on completeness and timeliness



Use risk-based sampling to focus efforts



Act on health data – don’t just collect it



Prevent audit surprises through early intervention

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# Our eTMF Health Assessment Approach

**Risk-Based Sampling** tailored to trial phase and complexity

**Findings Rated by Impact** (1–5 scale) – so teams know what truly matters

**Action-Oriented Reporting** – includes issue summary, recommended fix, and classification

**Workshops & Follow-Up** – support for root cause analysis and continuous improvement

# Compliance Confidence in Action

Health Assessments have achieved the following:



Flagged 200+ records missing from the expected filing locations



Early intervention led to reconciliation before interim database lock



Prevention of potential major finding during sponsor audit



Increased team awareness and SOP revisions were implemented



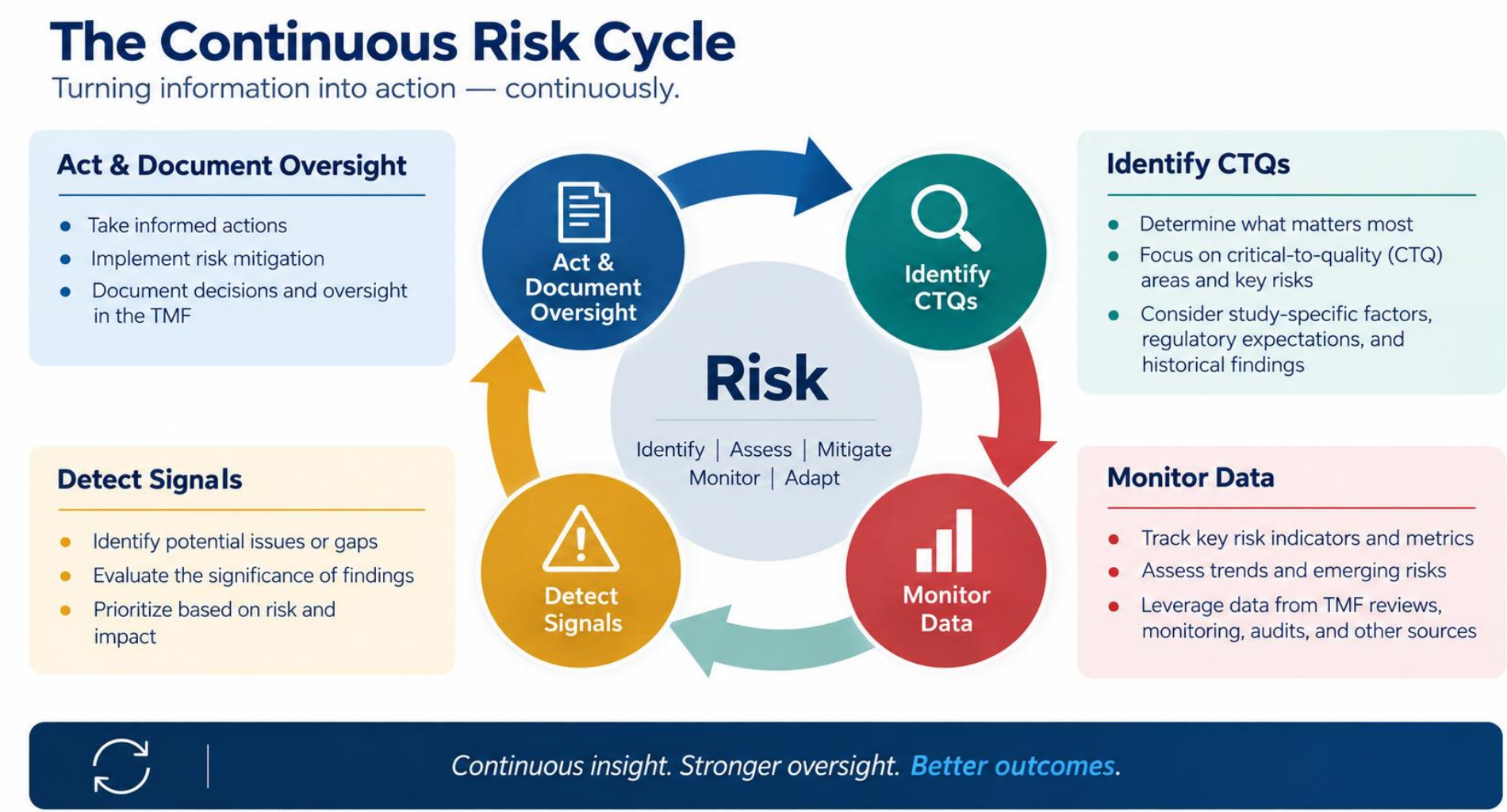
Demonstrated how strategic oversight drives real compliance outcomes

# Making TMF Wellness a habit

| | |
|---|---|
| **Build** | Build TMF Health reviews into trial rhythm |
| **Train** | Train teams in TMF health literacy |
| **Normalize** | Normalize raising and tracking TMF health issues |
| **Don’t wait** | **Don’t wait for audit day to start caring** |



# The Cycle continues…



# Key Takeaways

- The TMF is evidence of oversight control, not just record storage.
- Timeliness and quality provide early signals of process health.
- Completeness, reviewed across sites, reveals study-level risk.
- Repeated gaps are risk signals, not filing issues.
- Risk-proportionate oversight requires documented follow-through.
- Sponsors must be able to clearly articulate how TMF oversight protects study integrity.

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# Conclusion

**“AN OUNCE OF PREVENTION IS WORTH A POUND OF CURE.”**

**- BENJAMIN FRANKLIN**

**TMF Health is not a project—it’s a practice.**

**Stop treating symptoms and start building resilience.**



# Questions?

