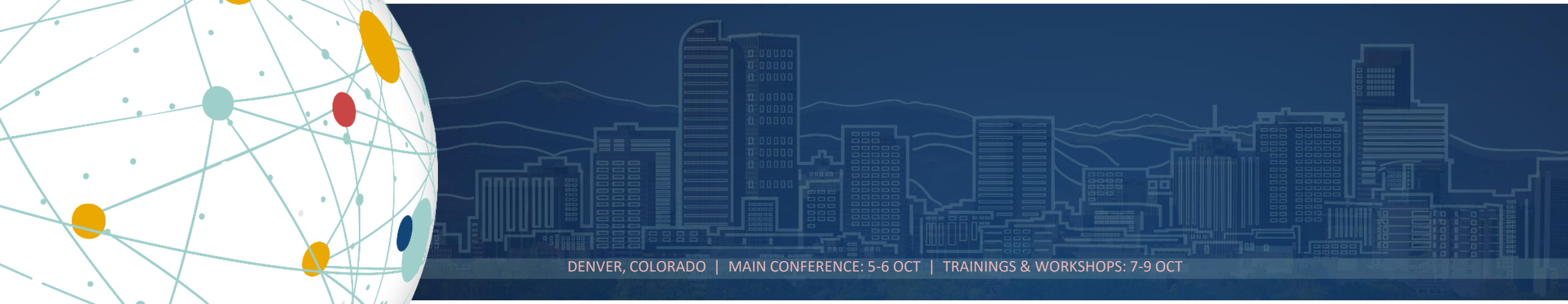


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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Integrating the Risk Based Principles of ICH E6 R3 to Drive TMF Inspection Steadiness

Dawn Niccum, Executive Vice President, Quality; inSeption Group

Agenda

1. Shift in Regulatory Focus
2. Opportunities of TMF SM V1
3. Game changing metadata

Speaker



- Dawn heads Quality Assurance at inSeption Group. She is an expert in the development, management, and implementation of clinical trial systems including the TMF. Dawn is active in the CDISC TMF Community as a Steering Committee member and ISF Reference Model liaison. Dawn is on the Board of Directors for Society of Quality Assurance and past chair for the Council for Professional Registration. Dawn is a Registered Nurse and holds Masters' degrees in Regulatory Affairs and Quality Control and Nursing Education as well as certifications Quality Assurance and Clinical Research.

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Executive Vice President, Quality Assurance
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Shift in Regulatory Focus

What E6(R3) Says About Trial Records

- E6(R3) reframes the long-familiar "essential documents" as essential records: those needed to reconstruct and evaluate how the trial was conducted and to trust the data it produced.



Fit for purpose

Records should be sufficient to show the trial was conducted properly and the data are reliable, not exhaustive for its own sake.



Determined by risk

Identify which records matter most, guided by risk to participants and to the reliability of results.



Held by the right party

Sponsor and investigator each keep the records they generate or need. Format and system are flexible; accessibility and integrity are not.

The Shift from Uniform Effort to Proportionate Effort

Traditional TMF practice

- ✗ Every filing-plan artifact treated as equally important
- ✗ Same QC intensity for every record
- ✗ Filing batched toward milestones
- ✗ Completeness measured by counting placeholders
- ✗ Inspection-readiness sprint at study end

Risk-based TMF practice

- ✓ Records prioritised by impact on participants and data
- ✓ QC concentrated where errors would matter most
- ✓ Contemporaneous filing, tracked continuously
- ✓ Completeness measured against what is actually expected
- ✓ Ongoing oversight that keeps the TMF inspection-steady

The Regulatory Shift

From compliance with everything toward quality focused on what matters

E6(R2) MINDSET

Essential documents
↓
Completeness
↓
Filing
↓
Periodic inspection readiness

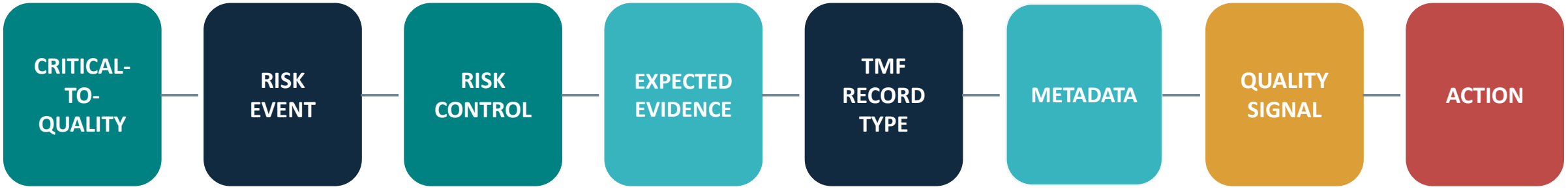
E6(R3) MINDSET

Critical-to-Quality
↓
Risk identification
↓
Risk evaluation
↓
Proportionate controls
↓
Continuous oversight (inspection steady)

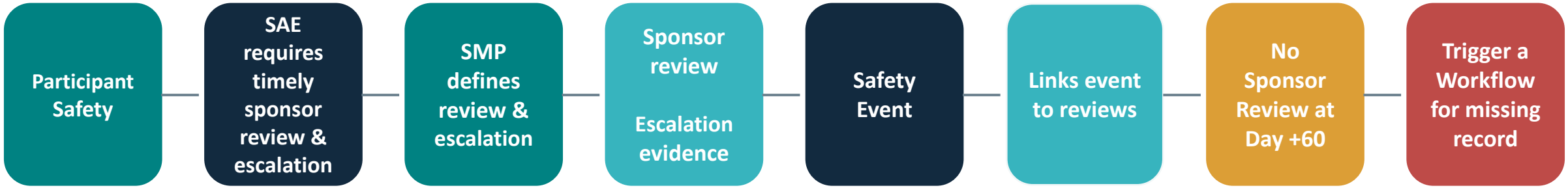
E6(R3) does not mean "less documentation."
It means smarter decisions about what matters and how much control is appropriate.

The TMF as a Risk Evidence Map

Connect the risk to the record and the record to the quality signal



Example



Opportunities of TMF SM V1

FROM RECORDS TO RISK INTELLIGENCE



Opportunity to turn the TMF from a record repository into a risk-informed quality intelligence system

Two Developments. One Opportunity.



ICH E6(R3) supplies the quality philosophy

↓

TMF standardization supplies the structure

The Missing Link

Where does the TMF fit into Quality Risk Management?



Can we trace a critical risk → control → evidence → quality signal?

The answer should be "yes"

It should not require an inspection scavenger hunt.

Reframing the TMF

TRADITIONAL QUESTION	RISK-INFORMED QUESTION
Is the document filed?	Is the required evidence present?
Is the TMF complete?	Is evidence sufficient for the risk?
How many are missing?	Which gaps matter most?
What is the filing backlog?	Where are risk signals emerging?
Are we inspection ready?	Can we demonstrate effective oversight?

Record completeness ≠ risk-informed inspection steadiness

Game Changing Metadata & Metrics

Why Metadata Changes the Game

RECORD

Monitoring Visit Report

MVR_12345.pdf

A record becomes analytically useful when its context is structured

Study: ABC-001
Country: US
Site: 1045
Record Type: Monitoring Visit Report
Visit Type: Interim
Visit Date: 15-Aug-2026
Status: Final
Expected: Yes
Filed: 18-Aug-2026
Criticality: High
Related Risk: Site oversight

Now the TMF contains structured information, not just a file

Metrics That Matter

TRADITIONAL METRICS

% completeness
Documents filed
Documents overdue
Filing turnaround time
QC error rate

RISK-INFORMED SIGNALS

Critical record availability
High-risk record lateness
Repeat metadata errors
Unresolved critical gaps
Risk-weighted completeness
Recurring deficiencies
Oversight evidence availability

Risk-Weighted TMF Health = Σ(Expected Evidence × Criticality × Quality Status)

From Dashboard → Early Warning System

Structured TMF data can help us see patterns before an inspection does.

STUDY TMF HEALTH
Overall: WATCH

CTQ Evidence STRONG

Regulatory Records WATCH

Site Oversight Evidence RISING RISK

SIGNAL → PATTERN → HYPOTHESIS → ACTION

Late monitoring records
↓
Concentrated in 12 sites
↓
Same CRO team
↓
After monitoring model change
↓
Investigate process / training / capacity
↓
Targeted corrective action

The TMF should help us ask: “Where might quality risk be developing?”

The Future TMF Is a Quality Intelligence System

ICH E6(R3)

WHY IT MATTERS

Risk
CTQ
Proportionality
Quality

TMF SM V1

HOW WE DESCRIBE IT

Taxonomy
Record Types
Metadata
Terminology

DATA & ANALYTICS

WHAT WE CAN DO

Visibility
Signals
Traceability
Action

STANDARDIZATION gives us structure.

RISK MANAGEMENT gives us meaning.

DATA gives us visibility.

Together: the opportunity to make the TMF continuously inspection steady.

Summary

What Organizations Can Do Now

01	**Identify CTQ factors**	Start with what must go right—not with records
02	**Map risks to evidence**	Ask: what record demonstrates this risk is controlled?
03	**Assess metadata**	Can you consistently identify study, site, record type, status, date and owner?
04	**Rebuild metrics**	Move from record volume toward risk-weighted signals
05	**Design for analytics**	Ask vendors for TMF data—not only records

You do not have to wait for TMF SM V1 to start

Traceability: The Regulatory Superpower

Can you tell the story behind the evidence?

“Show me how you knew this was a risk, what you did about it, and how you know the control worked.”



The mature TMF reconstructs the decision story, it’s not merely the document list.

Thank You!



Questions?

