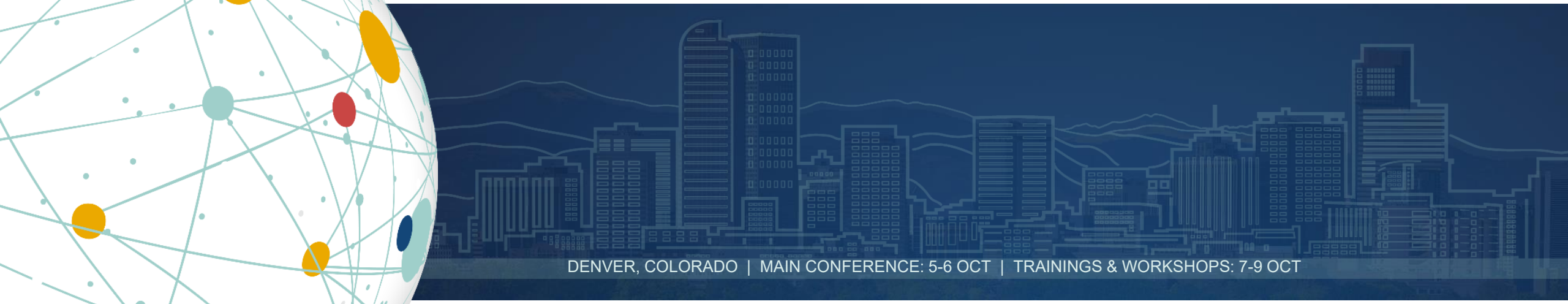


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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Case Study: The 12-Month TMF Turnaround
Oversight, Alignment, and Inspection Readiness

Suzanne Turner, Owner, ICE Consulting LLC

Agenda

1. Where we started
2. Two tracks, one deadline
3. Find the gaps: oversight & clean-up
4. Build the standard: process & CROs
5. Results & lessons learned

Speakers



Suzanne Turner
Owner
ICE Consulting LLC

Suzanne Turner is the founder of ICE Consulting, LLC, and a Trial Master File (TMF) expert with 14+ years of experience in clinical research.

She works with small sponsors to strengthen TMF oversight, improve quality, and prepare for inspections through practical, evidence-focused strategies.

Suzanne serves on the CDISC TMF Steering Committee and hosts *Heart of the Trial*, a podcast exploring the human side of healthcare.

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Where We Started

A sponsor with active studies, no TMF oversight, and a BLA on the horizon.

5
studies in progress

3
CROs managing the TMFs

3
different eTMF systems

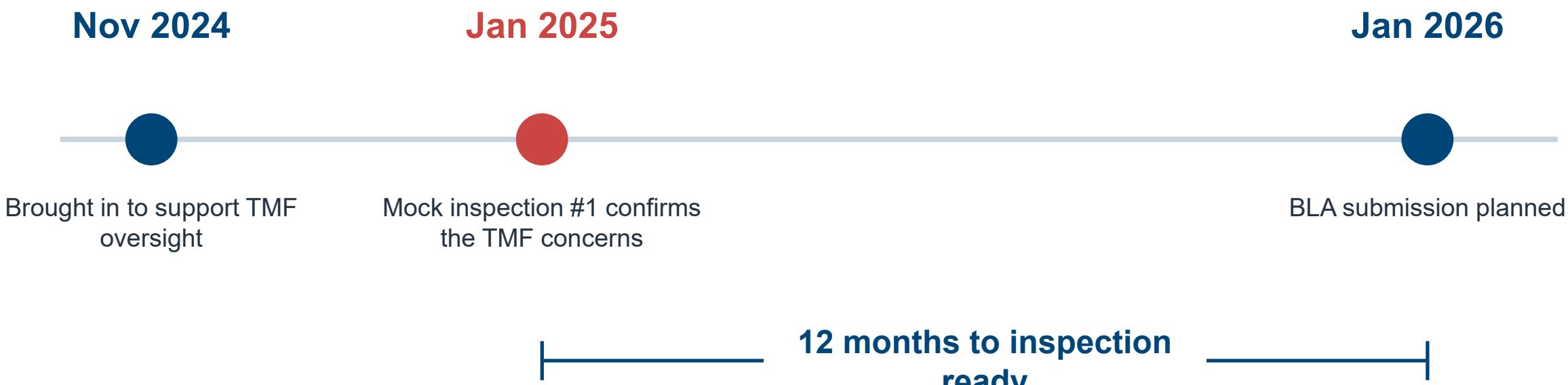
~2 yrs
running with no sponsor oversight

These are the sponsor's TMFs. Even with CROs running them, the sponsor holds the ultimate responsibility.

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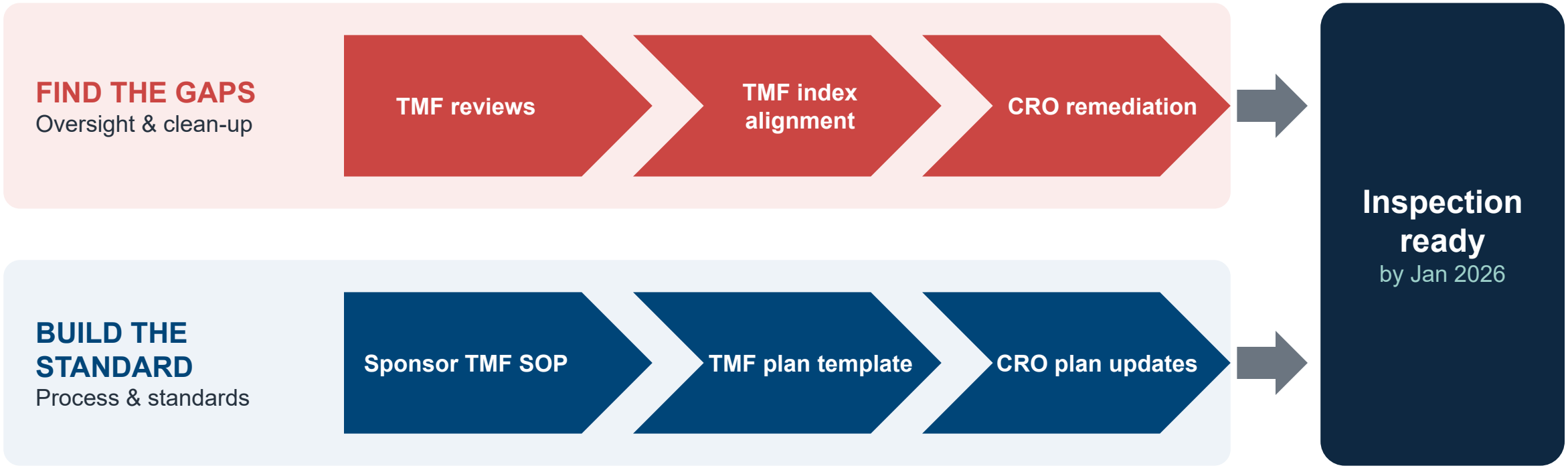
The Clock Was Already Running

The first mock inspection happened before the work began — and shaped many of our early decisions.



Two Tracks, One Deadline

Both work streams started at the same time and fed each other along the way.



Find the Gaps

Oversight reviews & TMF clean-up

Reviews With Two Jobs

1 Confirm quality & completeness

- Reviewed a selection of sites, not every site
- Trends at a few sites reflect the study as a whole
- Looked for missing, incomplete, duplicate, and incorrect records

2 Bring the TMF index up to date

- Met with each functional lead
- Walked through their sections of the TMF index
- Clarified what was — and wasn't — expected, on both sides
- Identified responsible parties

Scope and focus were influenced by the January 2025 mock inspection.

First Look: One Study's Quality Rate

91%

TMF quality rate after the first review

Not bad… right?

US-only study running for 2 years

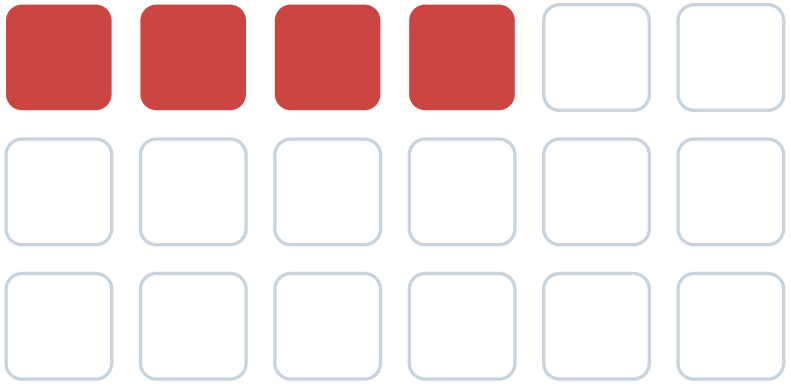
~9,100 records in the TMF

800+ quality issues logged

800 ÷ 9,100 = 8.8% issue rate

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But We Only Reviewed 4 of 18 Sites



Reviewed (4) Not yet reviewed (14)

800 issues found at 4 sites

+ 2,240 projected at the other 14 sites

= 3,040 potential issues ÷ 9,100 records

= 33.4% potential issue rate

Projected quality rate

67%

vs. **91%** at first glance

Assumes each issue affects a different record.

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Where the Gaps Concentrated



65%

of missing site records were training and staff qualification documents (341 of 521)

Study start-up was the weak point — and it showed up across CROs.

Build the Standard

Sponsor SOP, TMF plan & CRO alignment

One Standard Across Three CROs

The challenge: 5 studies, 3 eTMF systems, 3 CROs — each run differently. **The goal:** as much consistency as possible.

1

Define our own standard

How would we run the TMF internally? Veeva Vault was implemented for archival and for sponsor records kept out of the CRO TMFs.

2

Define sponsor oversight review

One oversight review process, applied to ongoing and future studies alike.

3

Define responsibilities

Clear responsibilities for every team member, sponsor and CRO.

A TMF Plan Built Around the Sponsor

Required in every CRO TMF plan by the sponsor SOP:

Sponsor oversight

How and when the sponsor reviews the TMF

KPIs

How TMF health is measured and reported

Service provider records

Where vendor records live and who files them

Access to the TMF

How the sponsor reaches the CRO's eTMF

CRO plans often leave out the sponsor's responsibilities.

But these are the sponsor's TMFs.

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A Big Shift for Our Service Providers

BEFORE

- CRO ran the TMF its own way
- No sponsor oversight
- No accountability to sponsor expectations

AFTER

- Sponsor expectations written into every TMF plan
- CROs held accountable to KPIs
- New ways to present TMF health

What it took: more meetings, more emails, a lot of exposed gaps — and a lot of collaboration and problem-solving together.

Where the Tracks Met: Results

Jan 2025

Mock inspection #1

TMF concerns confirmed

Oct 2025

Third-party audit

No high-risk items; only a couple of follow-ups. High praise from the auditor.

Jan 2026

Mock inspection #2

1 minor TMF finding. No major findings for the program.

From “concerns confirmed” to one minor finding — in 12 months.

Lessons Learned

1	**Own your standards**	A sponsor needs its own standards and expectations, even when a service provider manages the TMF.
2	**Communicate them early**	Service providers can’t reach a goal if they don’t know where it is.
3	**Tie quality to payment**	Building TMF quality into milestone payments is a useful tool.
4	**Watch study start-up**	Site qualification and training records are a consistent gap across CROs — this process needs more oversight.
5	**Bring the study team along**	Success only happens with support from the clinical trial team.

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Questions?

