



2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



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Stronger Together: Harnessing Sponsor and CRO Strengths for TMF Excellence

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Agenda

- 1. Why TMF Partnerships Strengthen Studies*
- 2. What Each Party Brings to the Table*
- 3. Common Pressure Points to Explore and Align*
- 4. Real-World Examples: Collaboration in Action*
- 5. Key Takeaways*

Speaker



Georgiana Brahy
Director, TMF
Parexel

- Georgiana Brahy is a TMF professional with over 14 years of hands-on and strategic experience across the Trial Master File lifecycle. As a Subject Matter Expert, she supports TMF management from document-level operations and inspection readiness to executive-level strategic planning.
- Georgiana is passionate about continuous improvement and the implementation of risk-based approaches in clinical research. She has led global TMF process-development initiatives and facilitates cross-functional leadership activities.
- Outside of advancing TMF practices, Georgiana enjoys the outdoors, reading, and exploring new recipes.

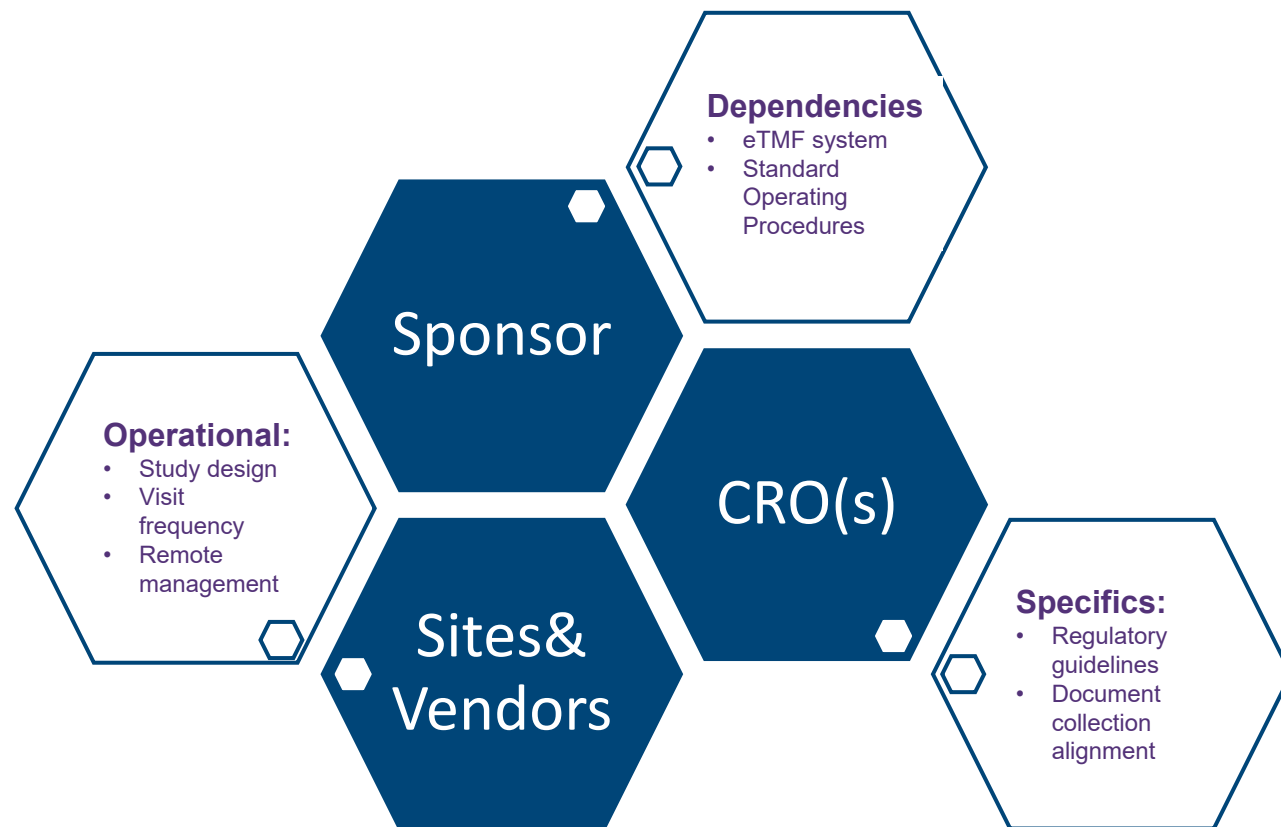
1. Why TMF Partnerships Strengthen Studies

“Cooperation is the thorough conviction that nobody can get there unless everybody gets there.”

- Virginia Burden, author



The TMF ecosystem



Strength in Collaboration



Complementary perspectives

- ✓ Sponsors and CROs bring different experiences, priorities, and ways of assessing risk, together creating a more complete view of the study.

Connecting the dots

- ✓ CROs contribute experience across multiple study phases, designs, and regions, applying cross-study best practices.
- ✓ Sponsors bring deep product knowledge, protocol intent, and clarity on expected deliverables.

Clearer expectations, earlier

- ✓ Sponsor experience with multiple CROs helps articulate what “good” looks like from the start, reducing rework later.

Learning flows both ways

- ✓ Open partnerships allow teams to learn from one another, strengthening processes and decision-making over time.
- ✓ When alignment is built early, TMF becomes a joint responsibility focused on study integrity and a shared vision for quality.

An opportunity for growth

- ✓ Strong TMF partnerships don’t just support individual studies, they raise capability and confidence on both sides.

2. What Each Party Brings to the Table

“Coming back to where you started is not the same as never leaving.”

- Sir Terry Pratchett, author

eTMF System –the TMF Landscape



CRO eTMF environment

- ✓ Strong operational KPI visibility enabling **direct CRO oversight** (line management, regional, and role-specific)
- ✓ Operates within a **complex, integrated eTMF landscape**, often connected to CTMS, start-up systems, EU CTR submissions, EDC, contracts, and other platforms
- ✓ Teams experienced across **multiple TMF models, study designs, and regions**; extensive system support and guidance
- ✓ Extensive inspection experience within integrated system environments

Sponsor eTMF environment

- ✓ Full access rights and ownership, including the **ability to configure TMF structure, workflows, KPIs, and reporting** aligned to Sponsor processes
- ✓ Reporting and review models designed to **support Sponsor oversight expectations** (e.g. review workflows, KPI logic, thresholds)
- ✓ Clear **alignment to internal governance and quality frameworks**; high inspection focus and continuous preparation.

Shared value

- ✓ CRO system experience can **accelerate Sponsor eTMF implementation and optimization**, drawing on what has worked most effectively
- ✓ CROs can also **learn from efficient Sponsor-designed processes**, improving future operating models on both sides

People - the TMF Cornerstone



Sponsor expertise

- ✓ **Deep understanding** of the product, protocol intent, and critical documentation
- ✓ Strong operational insight paired with **regulatory accountability** and oversight expectations
- ✓ Defined **TMF expectations**, KPIs, thresholds, and quality criteria
- ✓ Experienced Sponsor TMF teams capable of **targeted, risk-based oversight** and focused assessments
- ✓ Clear **roadmap** for what success looks like from a Sponsor perspective

CRO expertise

- ✓ **Global coverage**, or regional and language-specific expertise
- ✓ TMF professionals with **broad industry exposure** and repeated **inspection experience**
- ✓ Insight into **industry trends, innovation**, and evolving expectations
- ✓ Advanced **reporting and system knowledge** across commonly used eTMF platforms
- ✓ **Experience** managing multiple vendors and service models
- ✓ Deep **understanding of CRO processes** generating the documentation, enabling efficient reviews, cross-checks, and trend analysis
- ✓ Ability to provide TMF consultation to sponsors based on extensive and varied experience

Shared value

- ✓ Direct interaction enables **real time oversight, faster issue resolution, and stronger decision making**

Process – the TMF Building Plans



Defined frameworks

- ✓ Established TMF SOPs and functional SOPs on both sides. Critical to understand which SOPs apply, where, and why
- ✓ Clear TMF Plans defining scope, reviews, metrics, and communication pathways
- ✓ Agreed TMF Index / Expected Document Lists, including country specific expectations

Alignment is key

- ✓ Consistency and harmonization across:
 - ❑ Processes
 - ❑ TMF plans
 - ❑ System features
 - ❑ TMF index and EDLs
- ✓ Avoids duplication, gaps, and conflicting interpretations

Roles & responsibilities

- ✓ Sponsor and CRO roles are often defined differently in SOPs
- ✓ Explicit mapping is essential to ensure:
 - ❑ Accountability is clear
 - ❑ Oversight expectations are met
 - ❑ Teams understand who does what, when, and why

Shared value

- ✓ Well aligned processes turn TMF from a compliance activity into a predictable, inspection ready system

3. Common Pressure Points to Explore and Align

“In the middle of difficulty lies opportunity.”

- John Archibald Wheeler, physicist

From Pressure Points to Practical Alignment

Common Pressure Points	Constructive Alignment Approaches
KPI equivalence across CROs	Align on KPI intent and use-case Agree early on what KPIs are meant to demonstrate, while allowing flexibility in how CRO systems calculate and trend them. Use Sponsor feedback to refine KPI design over time rather than applying one-size-fits-all customization.
TMF system access and permissions	Define fit-for-purpose access models Jointly agree on access and reporting needs that support Sponsor oversight and CRO execution. Leverage CRO system expertise to propose practical solutions within system constraints.
Sponsor TMF oversight findings	Make expectations explicit early Document TMF review scope, applicability rules, and timing at start-up. Move TMF discussions beyond high-level study kick-off meetings into focused alignment sessions where needed.
Country-specific expectations	Embed country intelligence upfront Explicitly factor country-specific requirements into TMF plans, EDLs, and review interpretation from the outset.
System and process fit	Design a workable joint operating model Acknowledge constraints on both sides and agree on a model that balances standardization with necessary flexibility.
Communication gaps and assumptions	Ask the right questions at the right time Misalignment can arise when assumptions replace dialogue or when limited study history is documented, especially during role transitions. Replace assumptions with structured dialogue. Use TMF plans, decision logs, and storyboards to preserve context and continuity.
TMF delivery timelines	Align on phased delivery expectations Discuss preferences early and agree on pragmatic approaches such as initial TMF transfer followed by delta transfers.

4. Real-World Examples: Collaboration in Action

“If thou art not content with simples, canst thou not by the mixture of them make infinite compounds.”

Leonardo da Vinci, artist

Best Practices – A Quick Look



Shared TMF guardianship in practice: focused on TMF alignment, eliminating noise, streamlined collaboration.
How strong Sponsor–CRO partnerships support day to day TMF work.

Scenario A – Mature, long-standing collaboration

- Shared TMF metrics and dashboards** to create transparency and a common view of TMF health
- Joint TMF health and monthly metric reviews** to discuss trends, risks, and next steps together
- Collaborative interpretation of data**, improving traceability, accountability, and decision-making
- Co-authored TMF Plan and filing matrix**, clearly defining ownership from the start
- Shared training sessions and TMF partner meetings** to align expectations and system use
- Transparent working groups and trackers** to support open communication and follow-up
- Real-time collaboration in a shared eTMF environment**, supported by automation and system integrations to reduce manual handoffs

Scenario B – Partnership reset

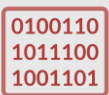
- Agnostic TMF Index used for TMF conduct, misalignment between CRO-specific documentation and Sponsor-specific expectations**
- Strategic alignment** between CRO generated documentation and Sponsor TMF expectations; alignment between studies from same account
- TMF related definitions, expectations, types of documents** covered in a joint Sponsor/CRO TMF Index, in alignment with EDL updates
- Decision acceleration** – involving higher level management to agree and implement decisions across multiple studies on the same time
- TMF System enhancements** - CRO joining Sponsor calls with TMF Vendor, targeting system updates for efficiency (dashboards and in system functionalities)
- TMF specific storyboard** for traceability of changes



Outcome



Earlier visibility of TMF risks



Smoother day-to-day TMF delivery



Clearer accountability across teams



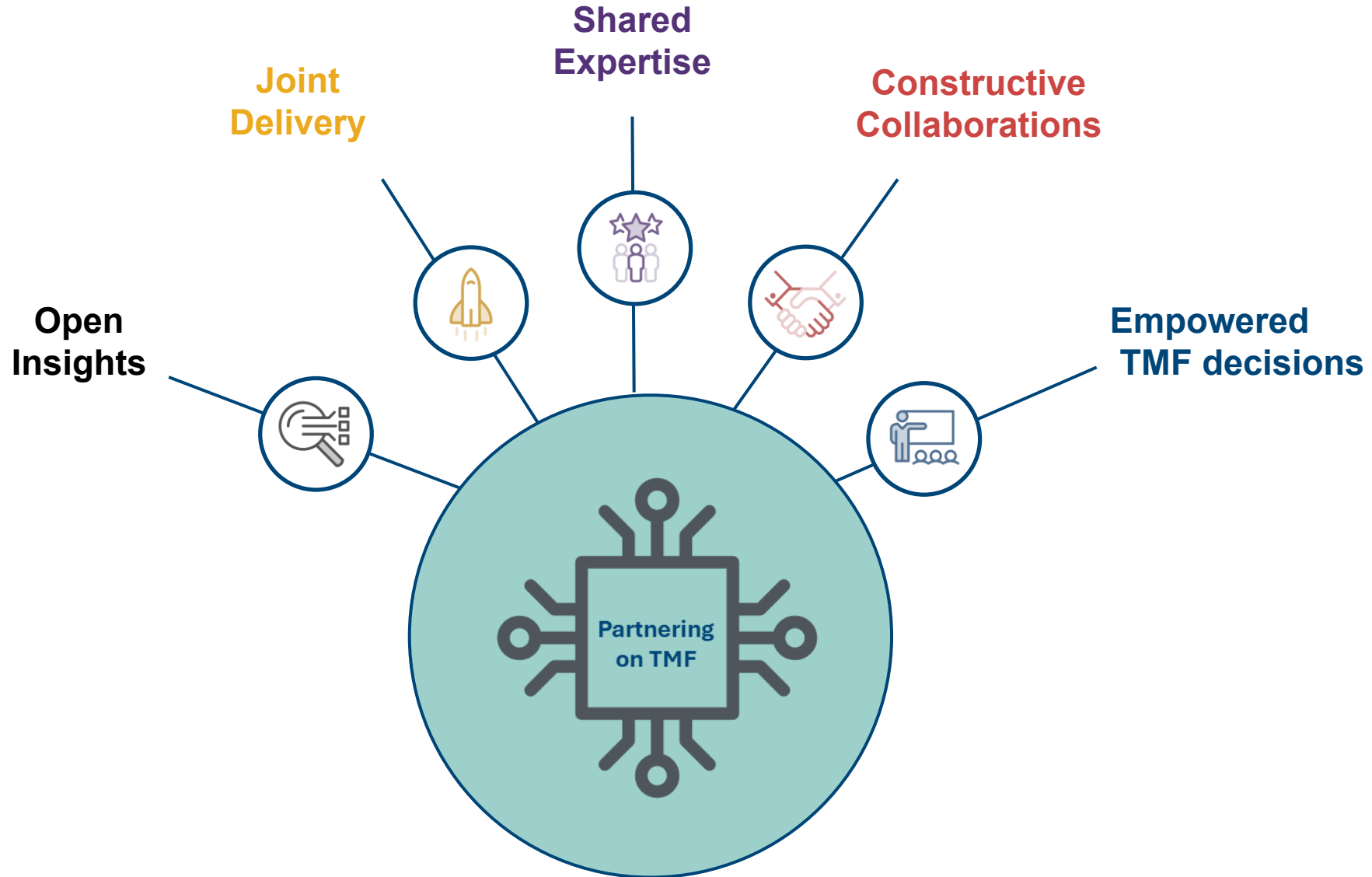
Greater confidence in Inspection Readiness

5. Key Takeaways

"I can't change the direction of the wind, but I can adjust my sails to always reach my destination."

- Jimmy Dean, singer/entrepreneur

At a Glance – Aligned TMF Ecosystem





Thank You!





Questions?

