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2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

The Placeholder Paradox: Standardization, Automation, and the Future of Expectedness

Suzanne Turner, Owner, ICE Consulting LLC

Speakers

Suzanne Turner
Owner | TMF Consultant
ICE Consulting LLC

Suzanne Turner is the founder of ICE Consulting and a TMF Subject Matter Expert with 13+ years of experience in TMF Management, sponsor oversight, inspection readiness, and TMF process improvement. She is also the host of the Heart of the Trial podcast.

Who works in a system that utilizes placeholders?

What Is a Placeholder?

- A marker for anticipated trial evidence
  - Represents an expected record in the TMF
  - Indicates **what** document is expected and **where** it should be filed
- How they are created
  - Sources include TMF Index, study events, expected deliverables
  - Some systems create them
  - Team members create them manually

Why Placeholders Matter

- Placeholders are widely used across TMF systems
- Often treated as a standard part of TMF management
- Supports traceability, completeness, and inspection readiness
- But… inspection and oversight are starting to expose gaps

Are placeholders helping us… or creating hidden risk?

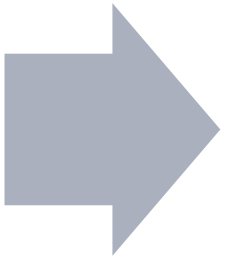
Where It Breaks Down

- Human dependency
  - Relies heavily on human input and interpretation
  - Larger studies drive higher volumes, increasing the overall burden
- Impact on quality
  - Misalignment between expectation and study conduct
  - Placeholder exists and document is present but not attached
  - May tell you a CV is missing, but not whose
  - **Inaccuracy creates a false sense of completeness**

Rethinking Expectedness

Static Expectedness

Manual definition
Fixed lists (EDL)
Human-driven

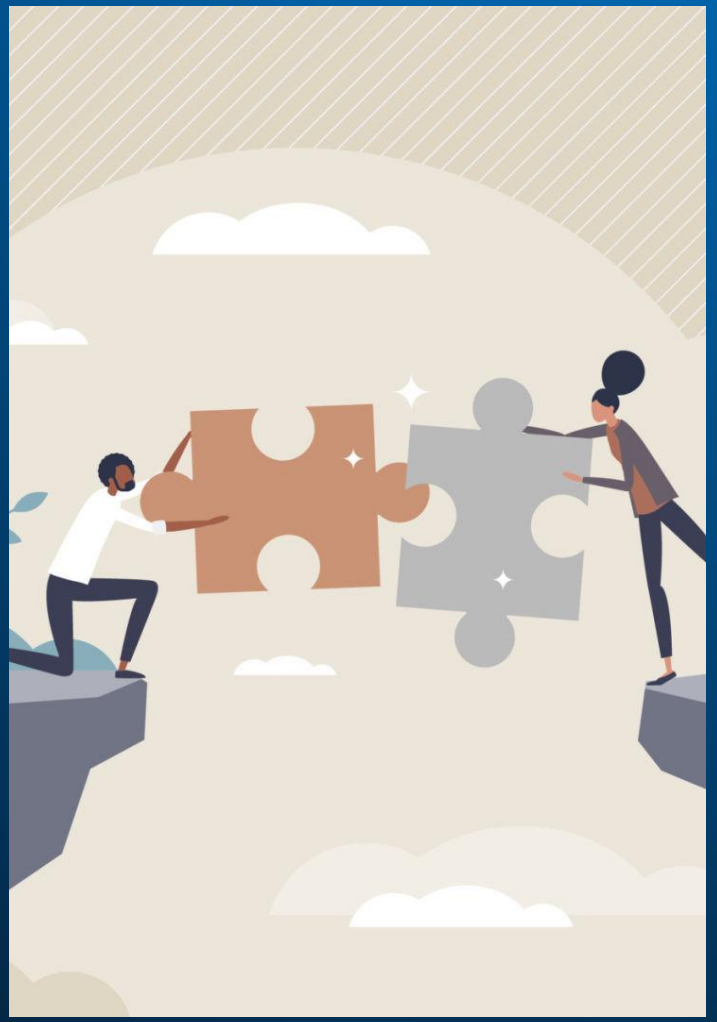


Dynamic Expectedness

- Metadata-driven
- System-generated
- Adaptive

Role of TMF RM v4

- Clear, standardized definitions of expected records
- Reduced reliance on interpretation
- Consistent expectations across studies and systems
- Foundation for automation and scalability



Intelligent Expectedness (AI)

- Automation
  - Reduces manual creation
  - Uses system data to trigger expectations
  - Improves efficiency and consistency
- AI
  - Generates placeholders based on study data
  - Interpret protocols and plans
  - Identifies and matches documents to expected records
  - Creates *and fills* placeholders intelligently

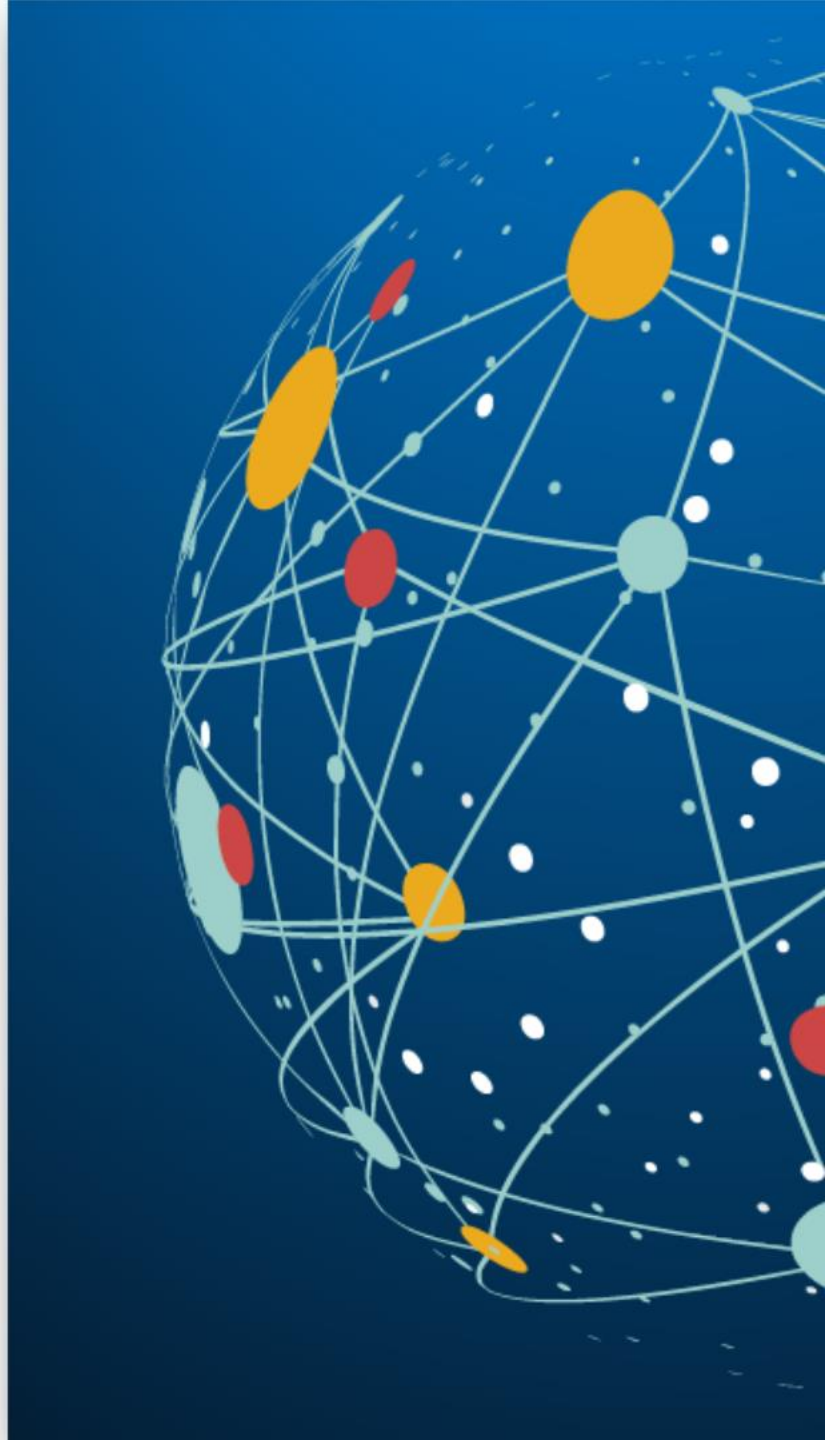
Not just creating placeholders…but knowing what belongs in them

Examples

- Based on the TMF Index, the system understands what records are expected and where they belong
- Provide it information on study type and it knows what is/isn't applicable
- When a study plan is finalized (e.g., Data Management Plan), expected outputs and related events are created
- When a site and DOA are entered, placeholders are automatically created based on roles and active study dates (e.g., CV, ML, training)
- As documents approach expiration, the system generates new placeholders in advance
- When a document is uploaded, it is not only filed correctly and all metadata applied, but can trigger identification of additional required records

Key to Making This Work

- Data Quality at the Source
  - Reliance on sites for accurate, readable records
  - May require a shift to fully electronic capture
- Clear and Defined Expectations
  - More robust SOPs and study plans
  - Explicit definition of evidentiary support



Transparency & Oversight

- Transparency and Explainability
  - Systems must show why placeholders are created (i.e., source)
  - Supports trust, auditability, validation
  - Prevents blind reliance on automation
- Oversight
  - Oversight remains critical
  - Focus shifts from creation to validation
  - Risks include over-reliance and errors at scale

Intelligent expectedness still requires human accountability.

Documenting Expectedness

- Defined in SOPs, TMF Plan, and supporting documentation
  - not just what is done, but **how expectedness is determined**
- Clearly outlines automation and system logic
  - What drives expectations and how outputs are reviewed
- Establishes evidentiary requirements
  - What constitutes a complete and acceptable record
- Supports inspection readiness and consistency

Automation relies on clearly defined expectations and processes.

Summary

- Static expectedness creates risk, including false completeness
- Expectedness is shifting to dynamic, data-driven models
- Automation improves efficiency…but requires transparency and oversight
- Data quality and clearly defined expectations are critical
- These elements together enable consistent, reliable expectedness

Questions?

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Shifting the Lens: Capturing TMF Clarity Through a Portfolio View

Jacqueline Petty, Associate Director – Study Resourcing & Consulting, Phlexglobal
Kasia Lipska, Regional Lead – TMF Readiness, Phlexglobal

Speakers

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Associate Director, Study Resourcing & Consulting
Phlexglobal

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Regional Lead, TMF Readiness
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Agenda

1. Introduction
2. TMF in Auto Mode
3. In the Spotlight
4. Staying Focused


ISO AUTO
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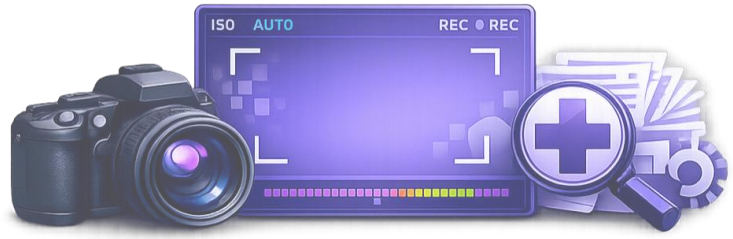
TMF in
Auto-Mode

Most organizations feel reasonably comfortable with their TMF Metrics.

The problems we see don't come from missing metrics.

They come from looking at the right metrics, through the wrong lens.



TMF in Auto Mode

When we talk about TMF Metrics, what do you think of?

Staying Zoomed In

Patterns aren't visible when studies are viewed individually

Strain on resources may not be seen until it's too late

Recurring issues can look like a one-off

Inspection Readiness is assessed late, and often defensively

To solve this, we need to take the time to zoom out.

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Shifting the Lens: Why Portfolio View Matters

Looking across studies with intention

Enables true trend analysis and not just status reporting

Supports proactive governance and sponsor oversight

Aligns the day-to-day reality with leadership decision-making

It is:

- *aggregated insights*
- *comparable metrics with consistent definition*
- *focused on patterns, performance and flags for risk*

It isn't:

- *more metrics for the sake of it*
- *a replacement for study level metrics*
- *a one size fits all!*

Portfolio view doesn't mean more metrics.
It's asking better questions of what you already measure.

Patterns Hiding in Plain Sight

Recurring issues masked as “one-off” events

Consistent pressure points by region, function, or CRO

The same document types repeatedly failing for the same reasons

Early signals of risk long before escalation thresholds are reached

Study metrics tell you if something is happening. Portfolio metrics tell you whether it keeps happening.

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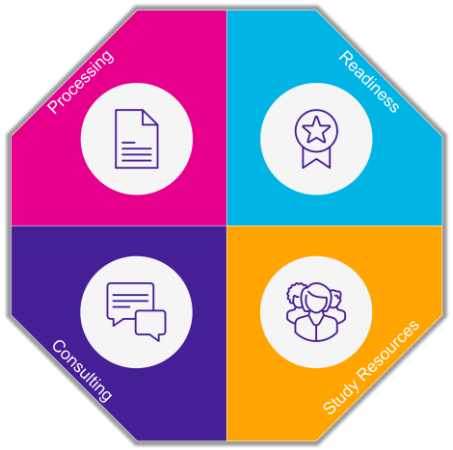
In the Spotlight

Real-world Application



Document QC

- In-line quality checks to ensure TMF documents meet ALCOA++ standards and any defined business rules.

Heatmaps

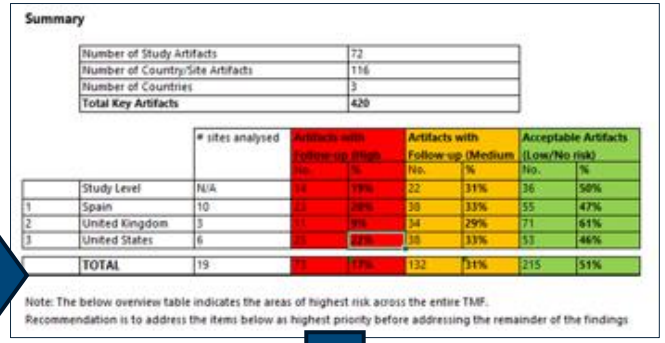
- First-line TMF analysis to identify areas of risk.
- Provides an actionable analysis that can help define target areas for review and refined scope for QR.

Quality Review

- In-depth document level analysis including logical and cross-checks to identify TMF deficiencies.

TMF Health

- Ongoing oversight of TMF Health Metrics, as monitored across Studies

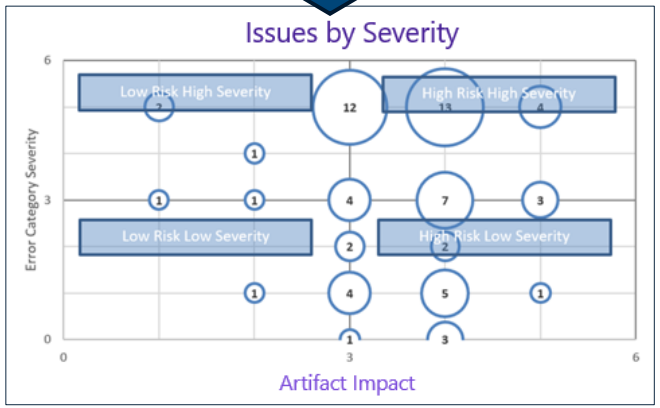


Summary

Number of Study Artifacts	72
Number of Country/Site Artifacts	116
Number of Countries	3
Total Key Artifacts	420

		# sites analysed	Artifacts with Follow-up (High)		Artifacts with Follow-up (Medium		Acceptable Artifacts (Low/No risk)	
			No.	%	No.	%	No.	%
	Study Level	N/A	24	19%	22	31%	36	50%
1	Spain	10	23	28%	30	33%	55	47%
2	United Kingdom	3	11	9%	34	29%	71	61%
3	United States	6	25	22%	38	33%	53	46%
	TOTAL	19	73	17%	132	31%	215	51%

Note: The below overview table indicates the areas of highest risk across the entire TMF.
Recommendation is to address the items below as highest priority before addressing the remainder of the findings



Spotlight on: Processing (1)

Centralized processing metrics demonstrate consistent timeliness, predictable throughput, and well-understood rejection drivers, across the portfolio.

Issues that are repeatable and content-based can be actively managed, evidencing control rather than reactive remediation.

A portfolio view consolidates processing performance across studies, allowing leadership to see patterns that are invisible at individual study level.

High document volumes can be processed consistently and on time when workflows and controls are standardized.

Quality issues repeated across studies and sponsors, indicates systemic, content-driven challenges rather than isolated failures.

Centralized models enable predictable throughput, even during peak periods.

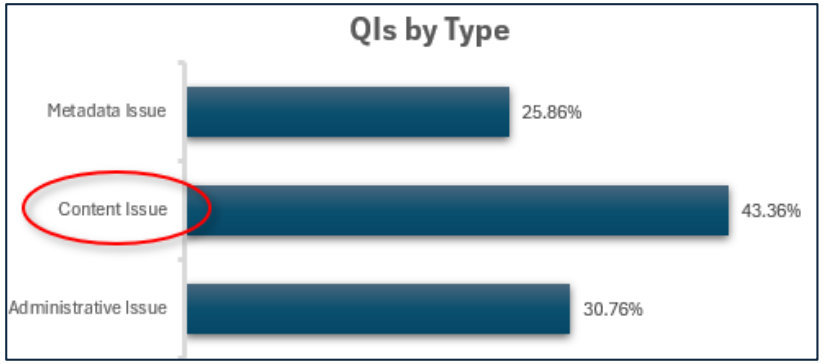
Spotlight on: Processing (2)

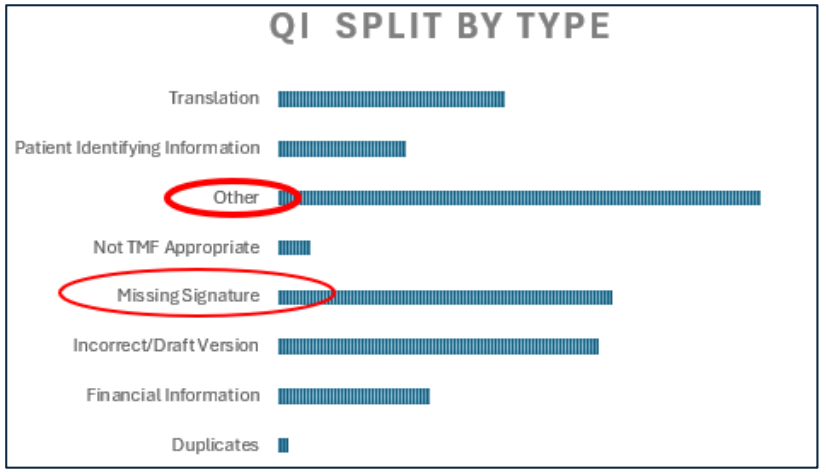
A review of multiple studies demonstrates operational control at scale, extending beyond individual trials.

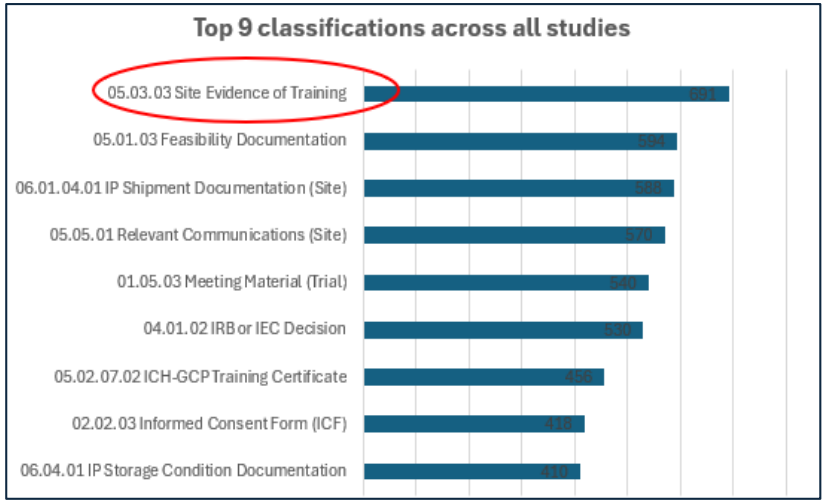
Distinguishes volume-driven pressures from genuine quality risks.

Pinpoints areas where quality control efforts should be concentrated to minimize rework.

Offers objective proof of advanced TMF operations, consistent with inspection requirements.







Spotlight on: Heatmaps (1)

Flags TMF risk and non-compliance early

Visualises trends by zone, level, department, and CRO

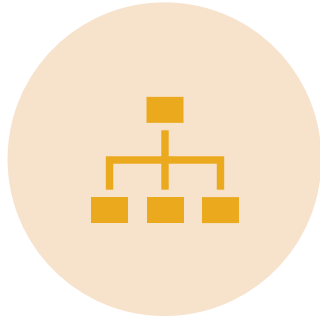
Focuses review effort where it matters most

Supports ongoing completeness and filing control

ENABLES EXAMINATION OF ISSUES AND TRENDS ACROSS MULTIPLE STUDIES, WITH BREAKDOWNS BY PHASE, IP, CRO, ETC., WHEN DATA GRANULARITY PERMITS.

ALLOWS TARGETED REVIEW OF SPECIFIC AREAS FLAGGED AS POTENTIAL CONCERNS TO DETERMINE WHETHER THE ISSUE IS ISOLATED OR PERVASIVE ACROSS STUDIES.

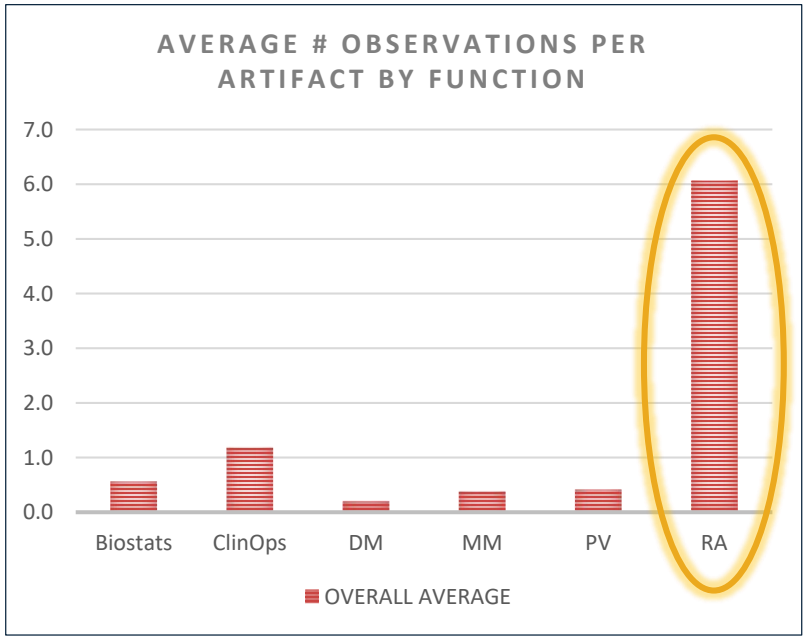
FACILITATES MORE PRECISE CUSTOMIZATION OF SECTIONS AND/OR ARTIFACTS FOR RISK-BASED REVIEW THROUGH COMPREHENSIVE TREND ANALYSIS.

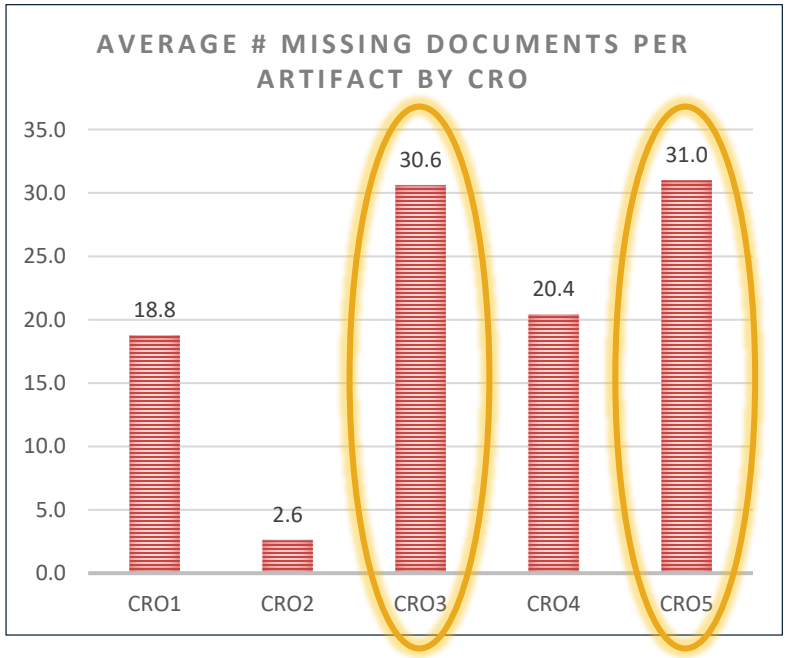


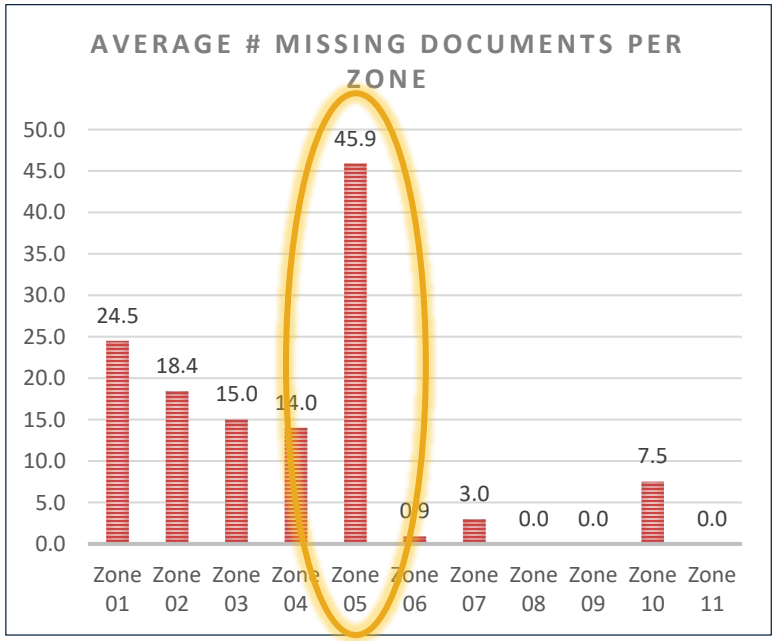
PROVIDES INSIGHTS THAT CAN ASSIST IN DETERMINING WHETHER ORGANIZATIONAL PROCESSES AND GUIDANCE REQUIRE UPDATES.

Spotlight on: Heatmaps (2)

Reviewing Heatmaps at the Portfolio Level allows a shift…
Instead of asking 'is this study ready' it moves to 'where does Readiness consistently break down'?







Individually, the studies didn't trigger reason for escalation, but together they highlight where risk is.

Spotlight on: Quality Review (1)

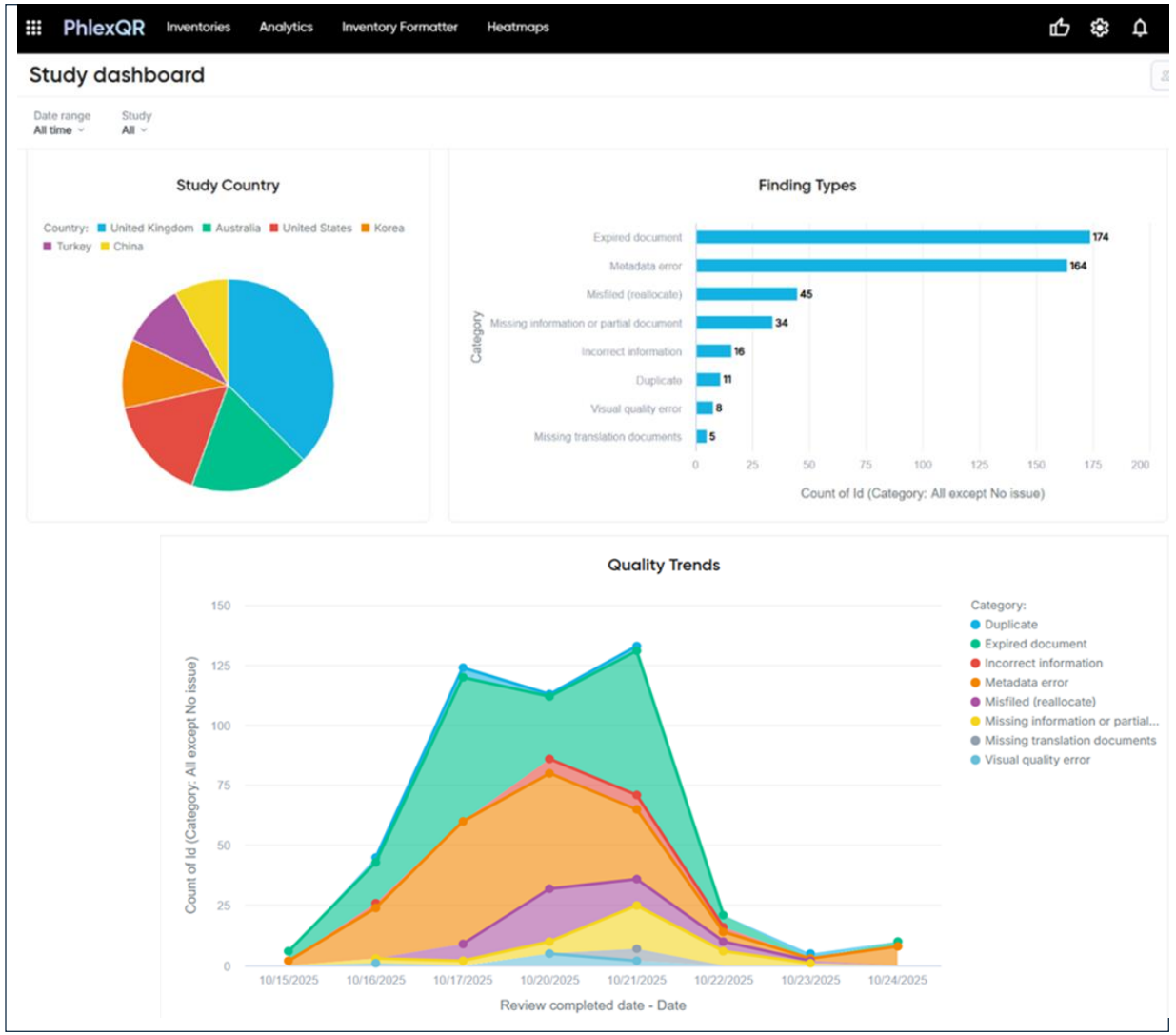
Having a Quality Review (QR) Dashboard allows real-time overview of TMF quality across studies, countries, and artifact types.

This can help leaders to spot risks, issues, and trends, to proactively improve overall management, compliance, and inspection readiness.

The dashboard helps to demonstrate that quality risk is:

Measurable → **Predictable** → **Actionable**

How could you use this data to develop a robust risk-based approach?



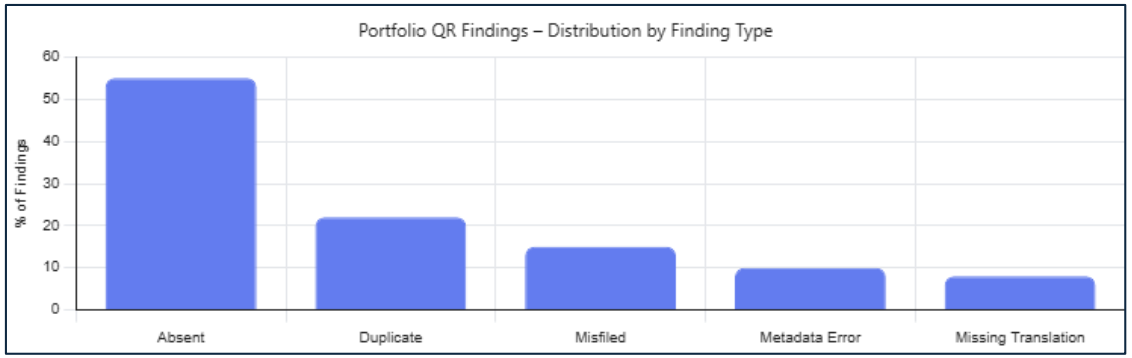
Spotlight on: Quality Review (2)

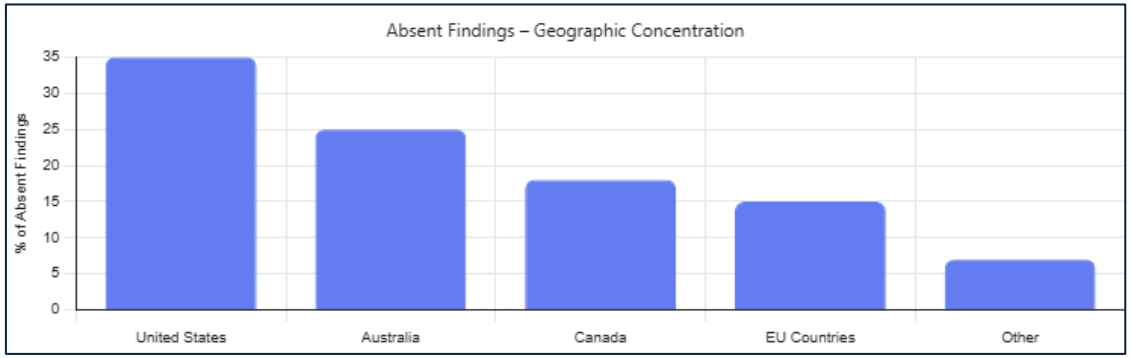
Quality Reviews often uncover issues that teams resolve quickly at study level - the finding is closed, and everyone moves on.

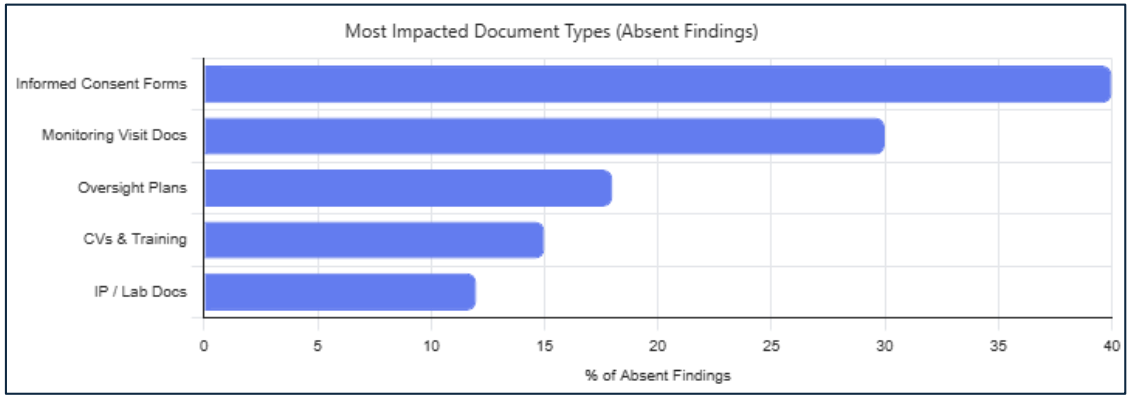
When QR results are aggregated across studies, patterns emerge: the same types of findings appear with similar root causes and similar mitigating actions.

At study level, these are handled efficiently, but at portfolio level, it becomes clear we're not learning from them.

Once patterns are visible, we can stop fixing the symptom repeatedly and instead address the underlying process or training gap.







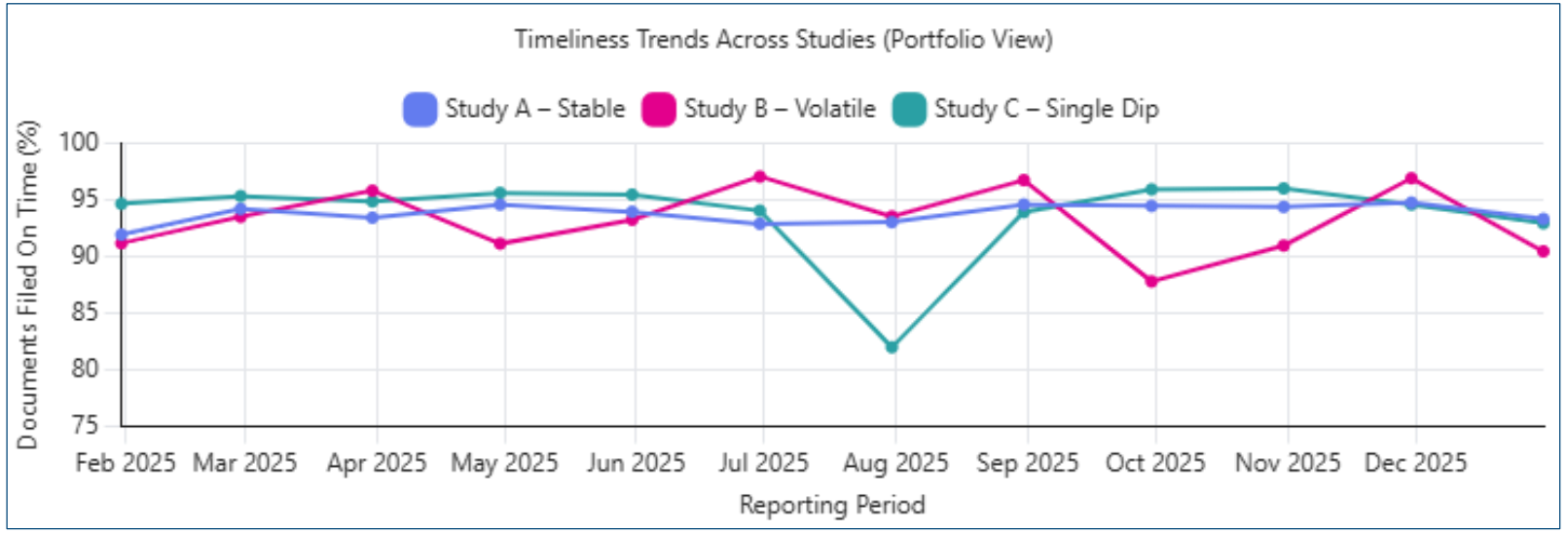
Spotlight on: TMF Health (1)

- TMF Document Quality (RFT)
- QC Query Types
- Aging QC Queries
- Deletion Requests

- Overall TMF Completeness
- Completeness by Milestone
- Completeness by Country/Site
- Overdue Milestones/Placeholders

- Document Upload Timeliness
- Document Approval Timeliness
- QC Query Resolution Timeliness
- Quality Review Timeliness

Spotlight on: TMF Health (2)



Volatile	Single Dip	Stable
Structural Pressure	Event-based	Predictable
Higher Risk	Explainable	Controlled
Lack of Control	Not systemic	Well-managed

Stability matters more than a single miss!

Staying Focused

Resource Optimization & Decision Making

Anticipating workload spikes across studies before pressure builds

Allowing proactive resource rebalancing across teams, regions, or vendors

Highlighting where additional effort does not improve outcomes

Supporting informed trade-offs between speed, quality, and capacity

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Inspection Readiness

Portfolio trends demonstrate effective sponsor oversight

Enables consistent readiness - not last-minute scrambles

Shows control, not just compliance

Turns metrics into a coherent inspection story

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Getting Started

Start small – establish 3-5 meaningful portfolio level metrics

Focus on trends over numbers

Standardise your definitions

Use metrics to support decisions

Review regularly

Thank You!

Questions?

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Rethinking TMF Quality: Moving Beyond Document Timeliness

Nina Louise Arberg, Senior Clinical Document Manager, Ferring Pharmaceuticals

Chris Jones, Head of CDM Business Operations, Novartis

Franciska Darmer, Global Head of Clinical, Base Life Science

Torsten Stemmler, Head of Inspection Unit, BfArM

Speakers

Nina brings 8 years of experience in biopharma having worked with both paper and electronic Trial Master Files, supporting global clinical trials.

Specializing in oversight of outsourced TMF activities, quality oversight, inspection readiness, and ensuring compliance with ICH-GCP and regulatory expectations.

Nina Louise Arberg
Senior Clinical Document Manager
Ferring Pharmaceuticals

Speakers

A committed, driven, pragmatic leader with 30+ years of experience in pharmaceutical records management and archiving.
For the past 10 years have specialized in Clinical Document Management.
Focussed on compliance, process improvement, risk-based decision making and developing team capabilities.

Chris Jones
Head, Clinical Document Management Business Operations
Novartis

Speakers

Franciska brings over 25 years of experience in the life science industry, having worked with pharma, technology vendors and global IT services teams. Specialized in guiding companies through digital transformation across R&D and with strong focus on eTMF management acceleration and performance though technology enablement.

Franciska Darmer
Global Head of Clinical
BASE Life Science

Speakers

Dr. Torsten Stemmler earned his PhD in Biology (Neurobiology and Psychophysics) from the University of Bremen, Germany, in 2011. Following his doctoral studies, he pursued postdoctoral research at RWTH Aachen, focusing on visual perception.

His career took a dynamic turn when he retrained as a Data Manager, developing database solutions at the University Hospital Aachen.

In 2017, he brought his expertise to the Federal Institute for Drugs and Medical Devices, where he serves as a GCP Inspector, ensuring compliance with Good Clinical Practice standards.

Dr Torsten Stemmler
Head of GCP Inspection Unit
Federal Institute for Drugs and Medical Devices (BfArM)

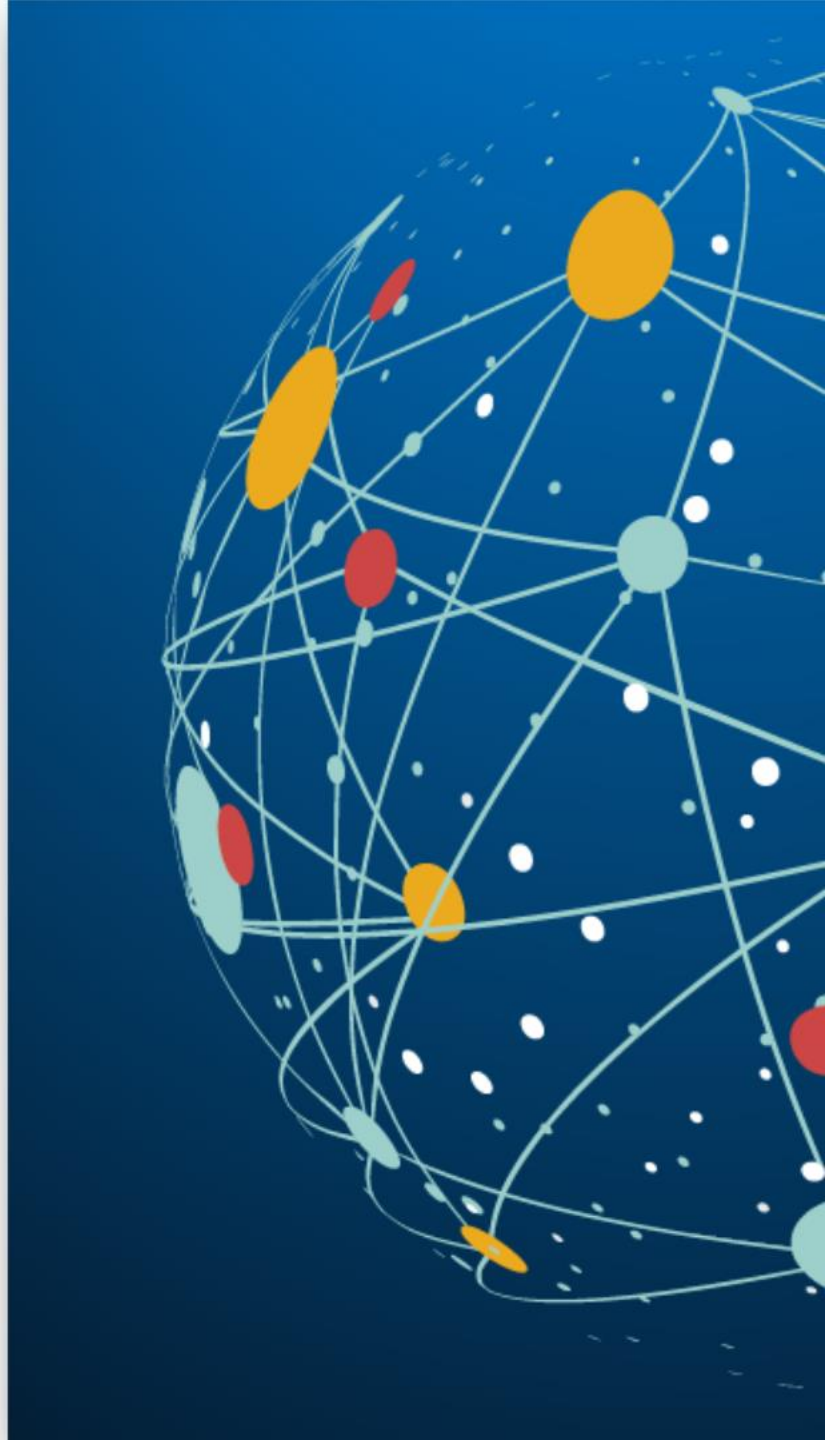
Agenda

1. TMF Document Timeliness: Is It Still a Valid Quality Measure?

2. Shifting the Focus: From Document Timeliness to Milestone Timeliness

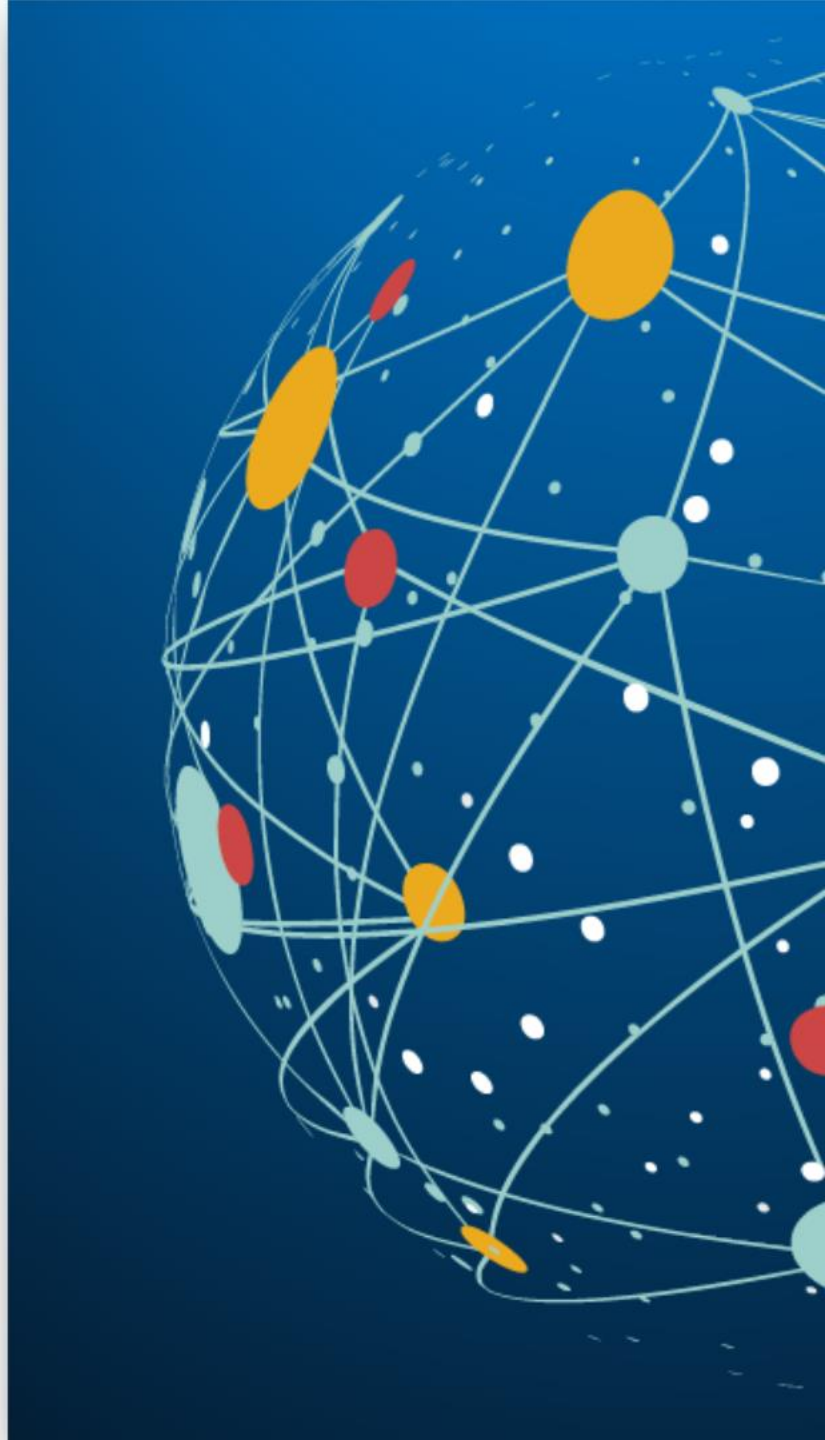
TMF Document Timeliness: Is It Still a Valid Quality Measure?

- Does document timeliness add real value as a quality indicator?
- Does document timeliness still matter?



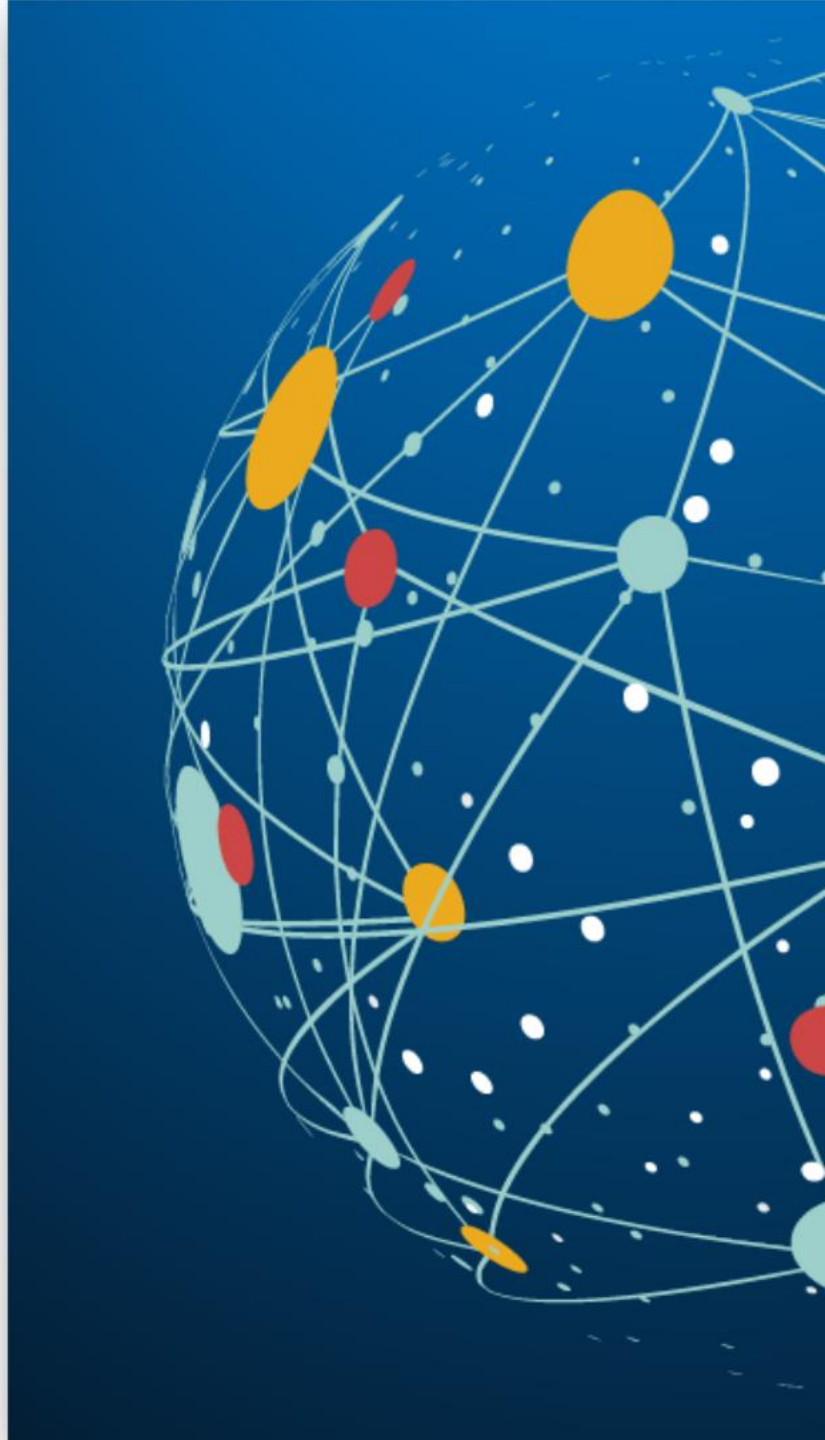
Poll

Is document timeliness addressed in your company's SOPs?



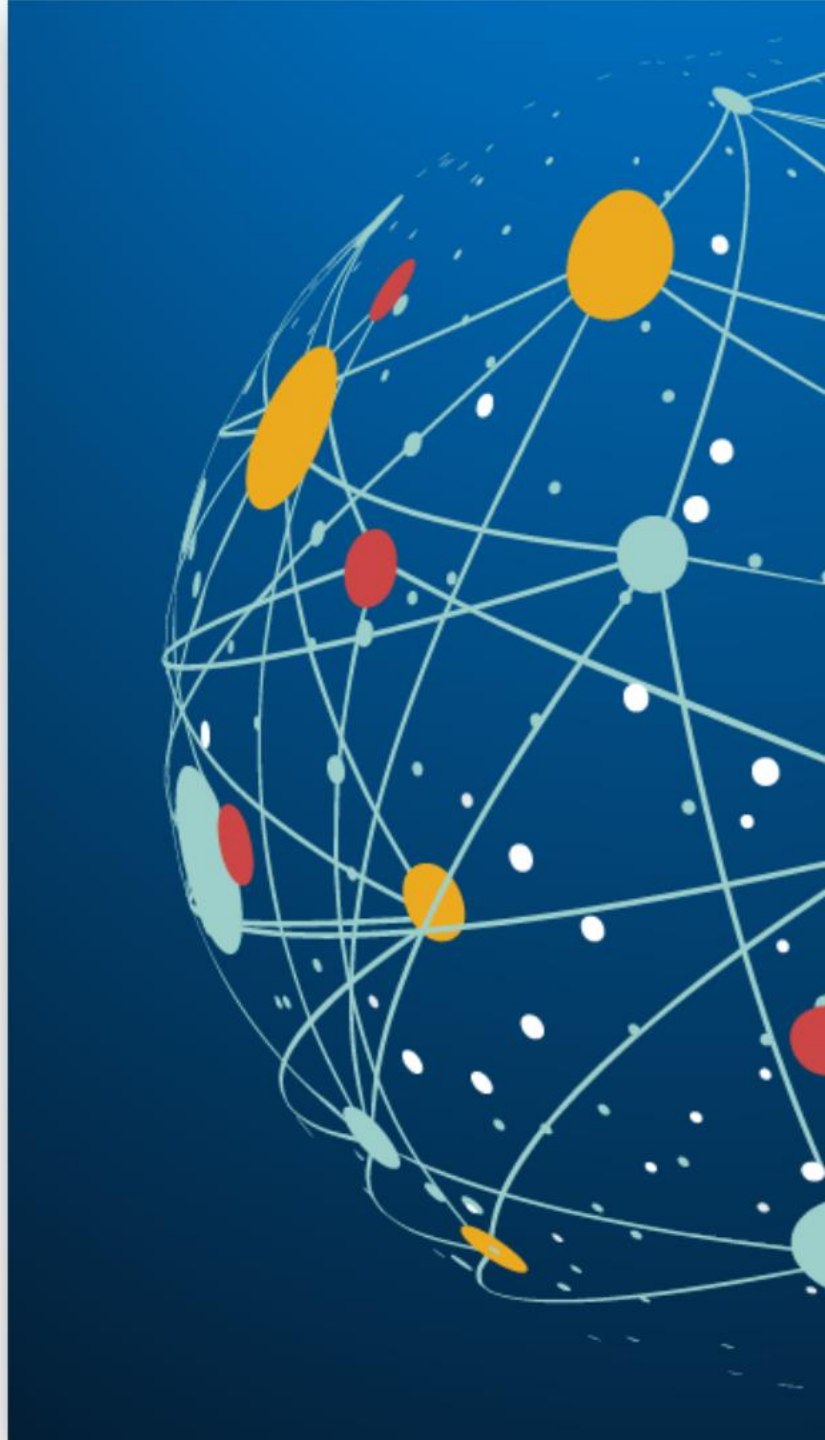
Poll

Is document timeliness used as a TMF Quality indicator in your company?



Shifting the Focus: From Document Timeliness to Milestone Timeliness

- Does milestone timeliness better reflect TMF Quality?
- What should be considered when using milestone timeliness as a TMF quality indicator?



Questions?

Thank You!