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THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



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Shifting the Lens: Capturing TMF Clarity Through a Portfolio View

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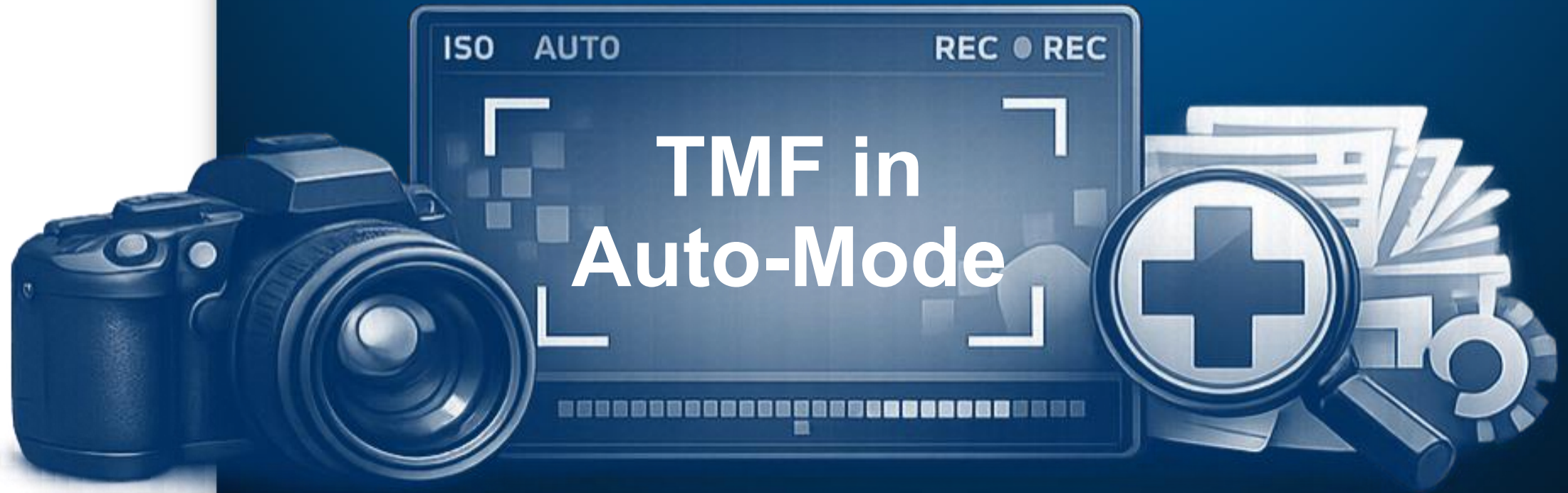
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Agenda

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

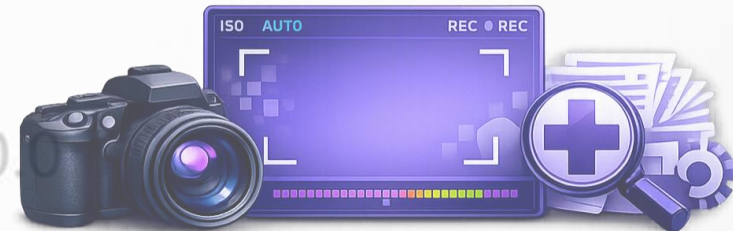




Most organizations feel reasonably comfortable with their TMF Metrics.

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.





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

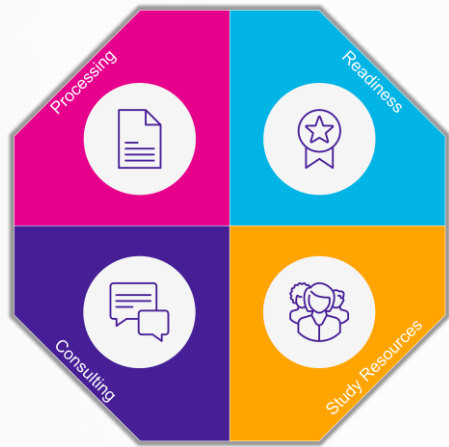
Early signals of risk long before escalation thresholds are reached

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





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

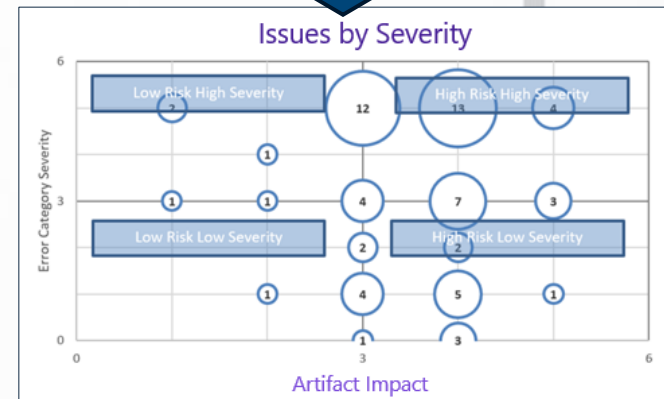
- Ongoing oversight of TMF Health Metrics, as monitored across Studies

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	4	19%	22	31%	36	50%
1 Spain	10	2	20%	3	33%	5	50%
2 United Kingdom	3	1	33%	1	33%	1	33%
3 United States	6	1	17%	1	17%	4	67%
TOTAL	19	8	17%	26	31%	115	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.

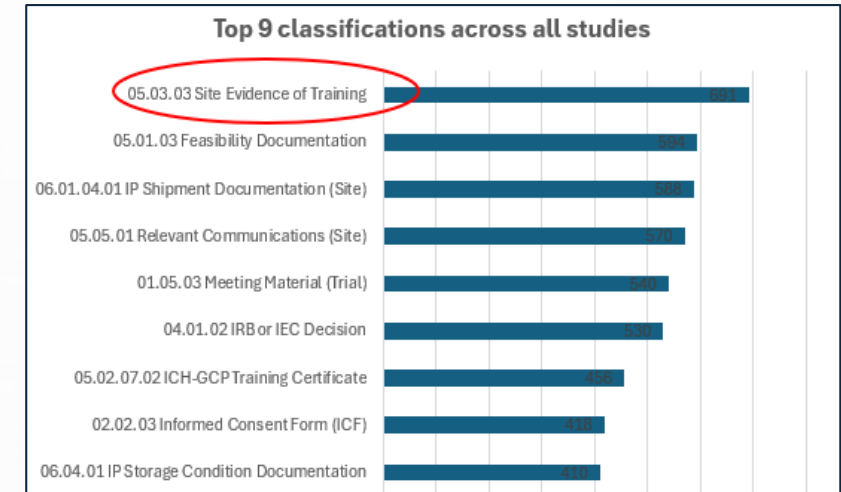
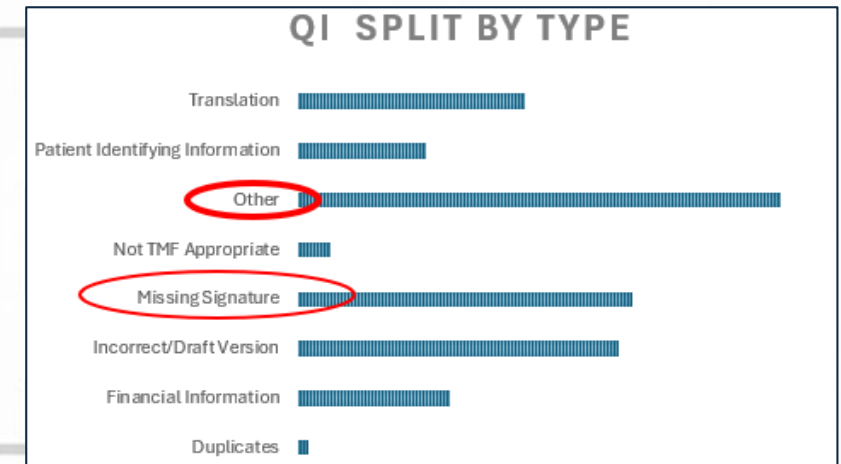
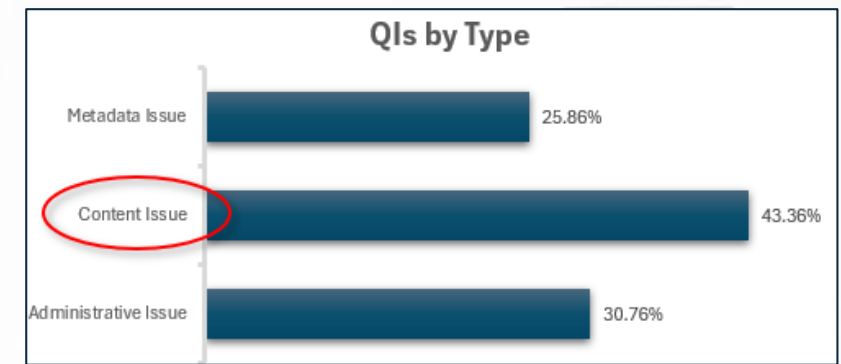
Spotlight on: Processing (2)

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

Distinguishes volume-driven pressures from genuine quality risks.

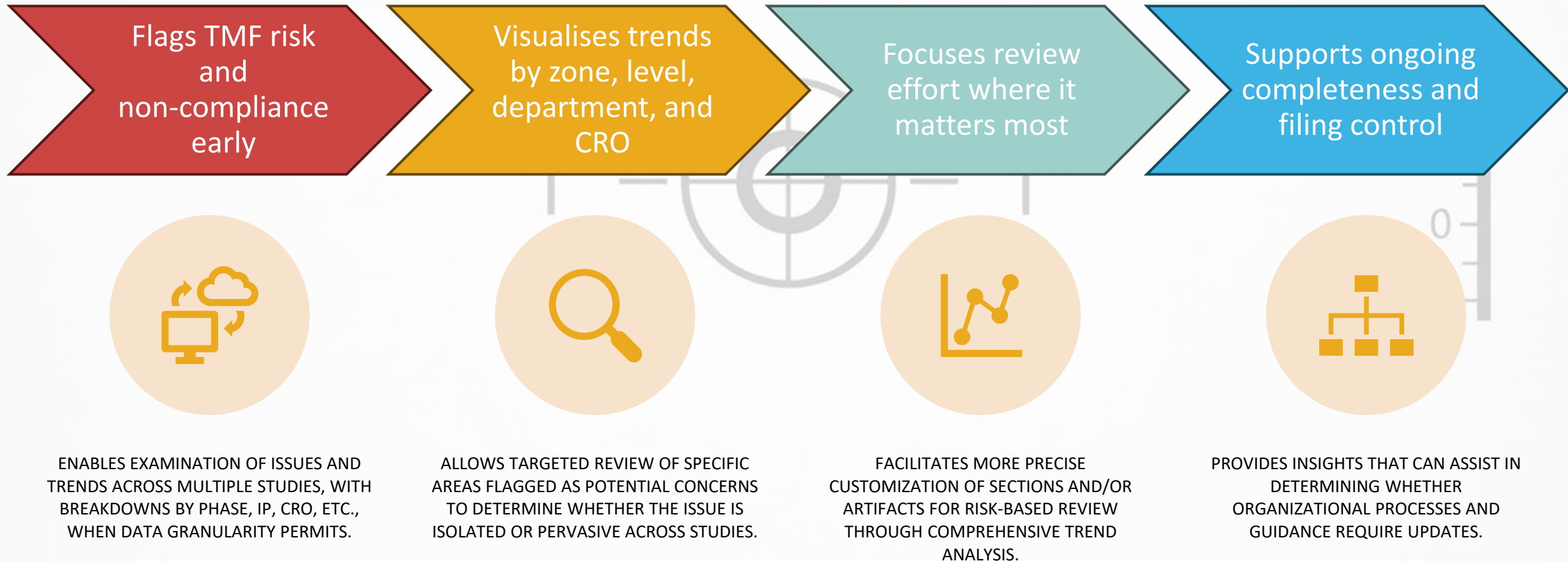
Pinpoints areas where quality control efforts should be concentrated to minimize rework.

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





Spotlight on: Heatmaps (1)

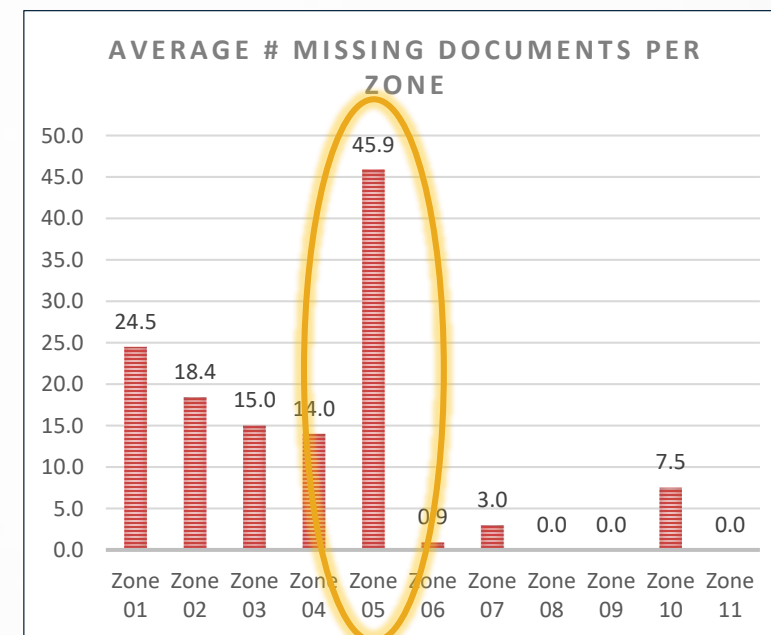
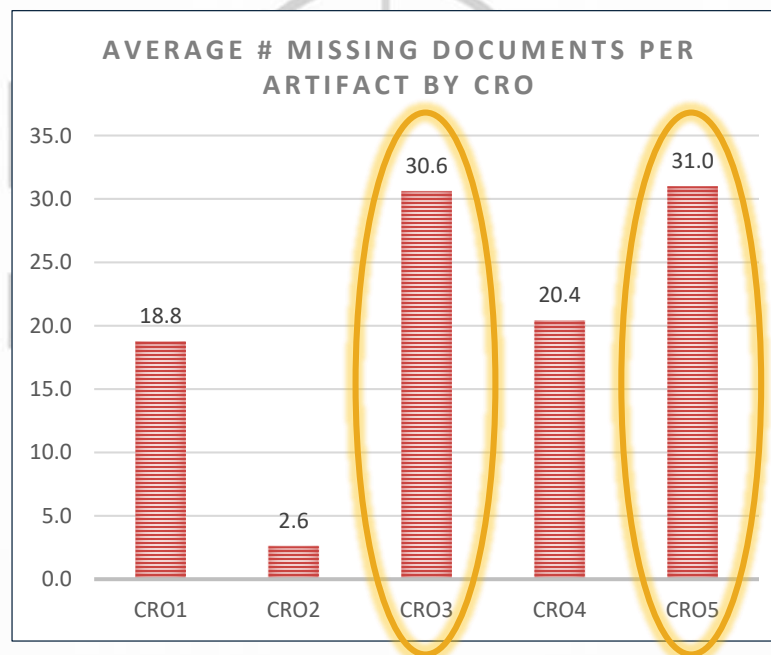
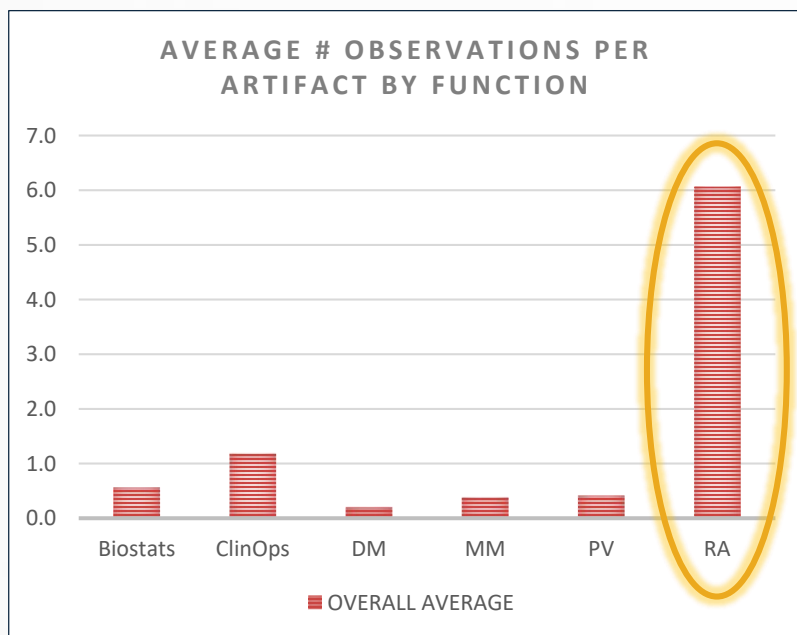




Spotlight on: Heatmaps (2)

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)

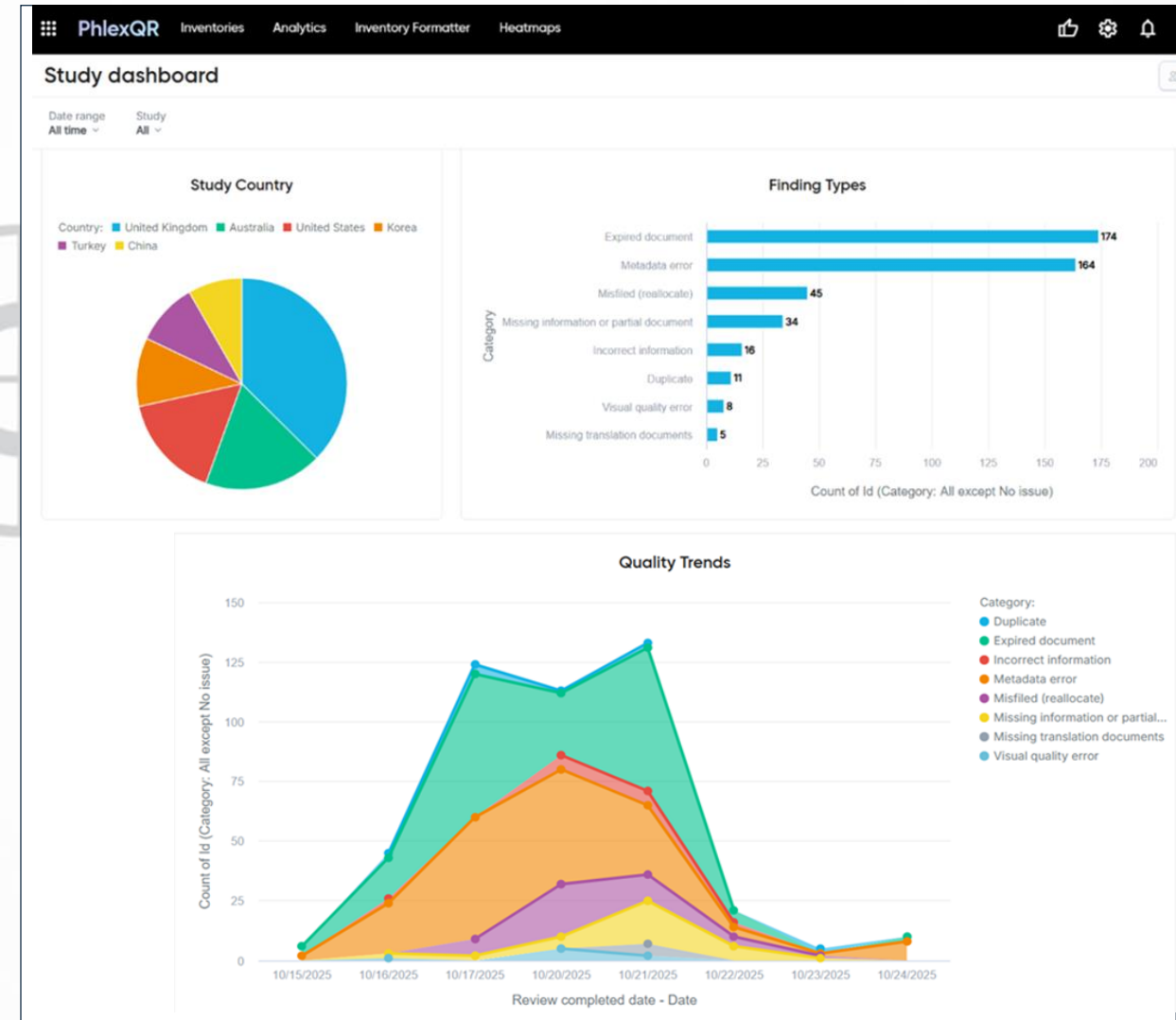
Having a Quality Review (QR) Dashboard allows real-time overview of TMF quality across studies, countries, and artifact types.

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:



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





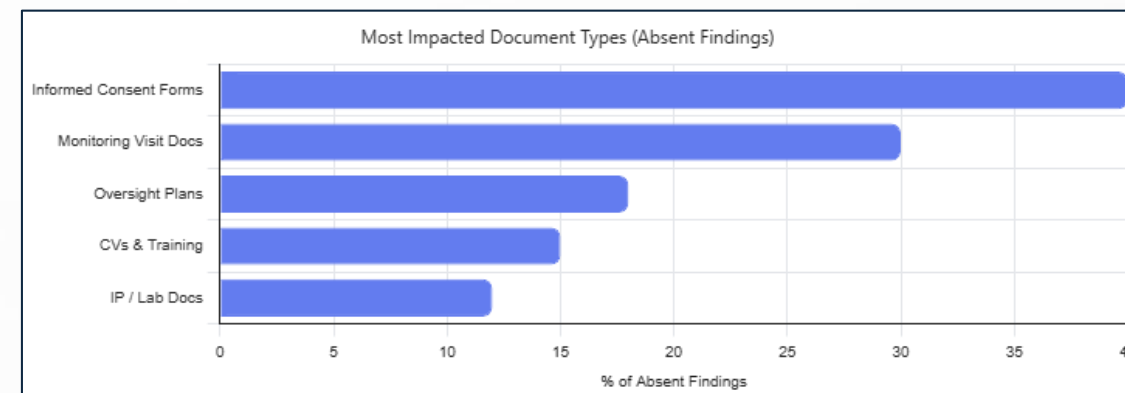
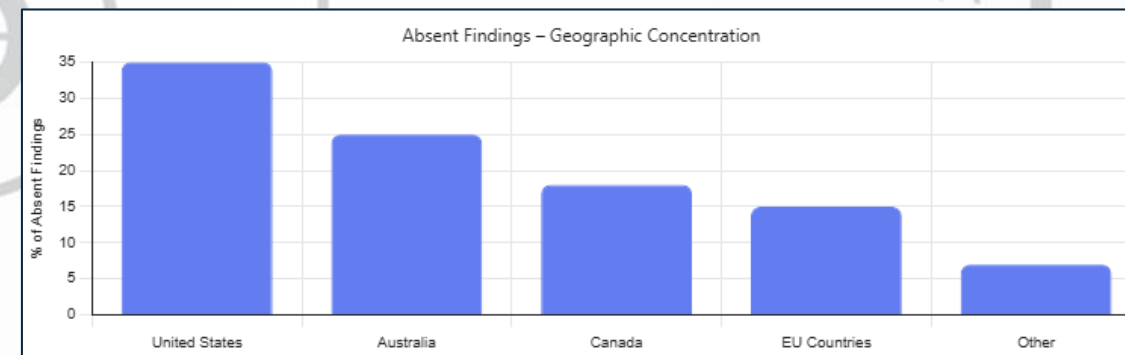
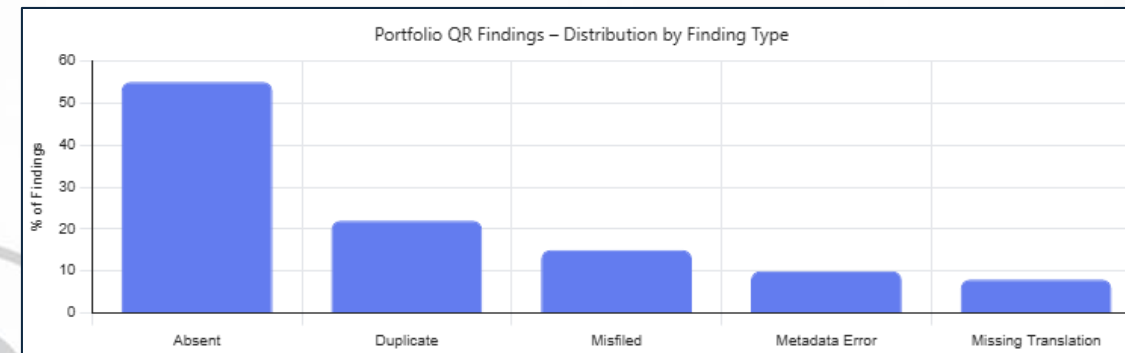
Spotlight on: Quality Review (2)

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.

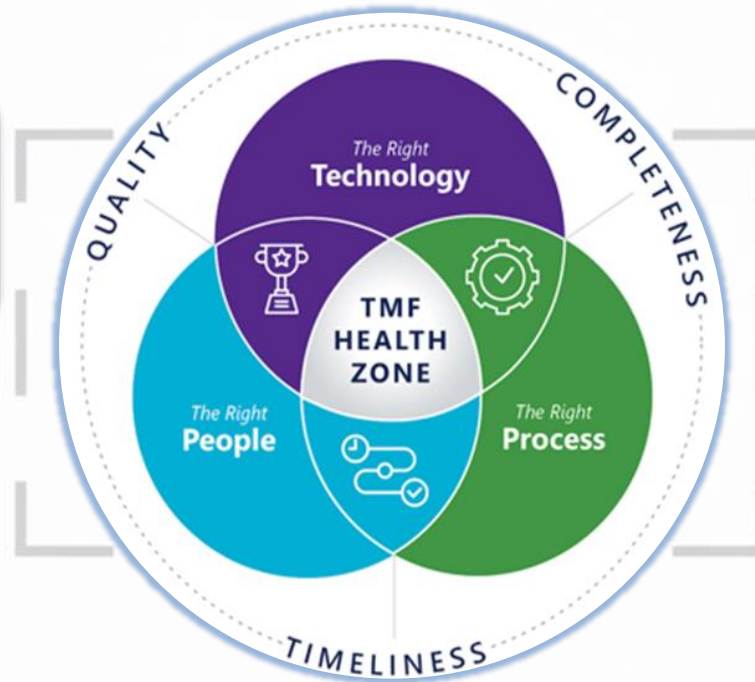
Once patterns are visible, we can stop fixing the symptom repeatedly and instead address the underlying process or training gap.





Spotlight on: TMF Health (1)

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

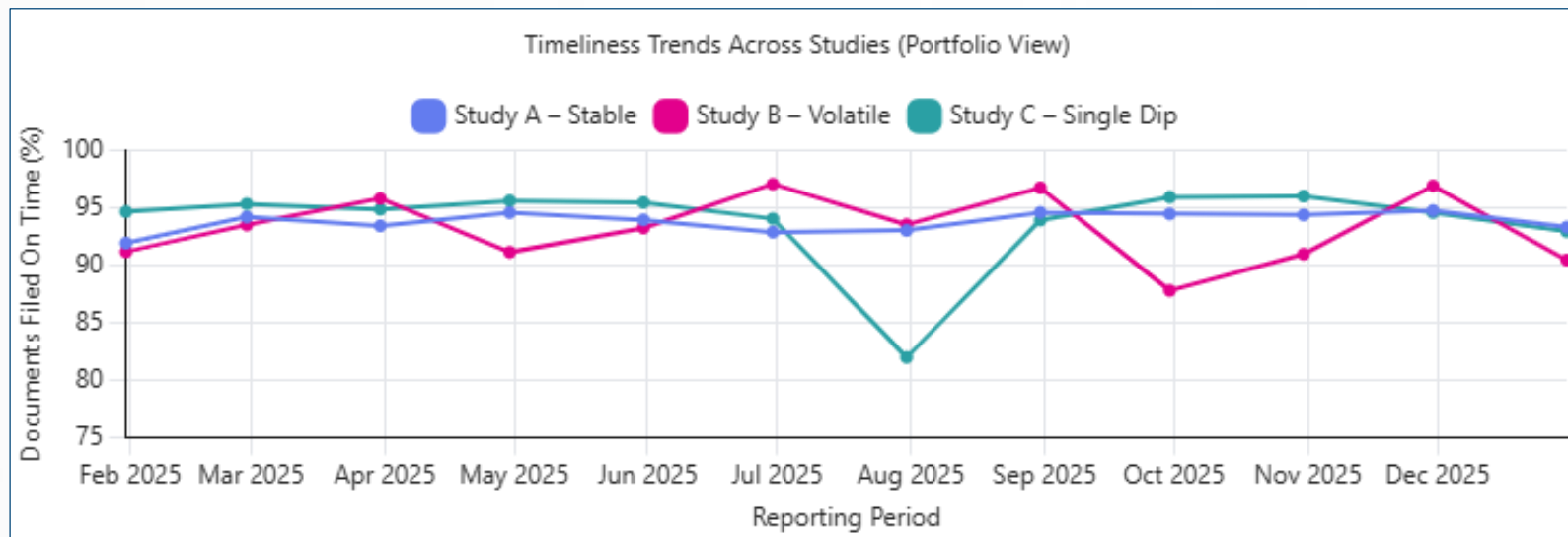


- Overall TMF Completeness
- Completeness by Milestone
- Completeness by Country/Site
- Overdue Milestones/Placeholders

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



Spotlight on: TMF Health (2)



Volatile

Structural Pressure

Higher Risk

Lack of Control

Single Dip

Event-based

Explainable

Not systemic

Stable

Predictable

Controlled

Well-managed

***Stability matters
more than a single
miss!***





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



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



Getting Started

Start small – establish 3-5 meaningful portfolio level metrics

Standardise your definitions



Focus on trends over numbers

Use metrics to support decisions

Review regularly



Thank You!





Questions?

