



Making TMF Change Personal: Building Accountability into your Metrics Program

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AGENDA

- 01 **“Questions First”**
- 02 **Menti – Survey Question**
- 03 **The “Triple A” Perspective on TMF Oversight**
- 04 **Making TMF Performance Personal**
- 05 **Additional Considerations**
- 06 **Key Takeaways**

“Questions First” Approach to TMF Metrics



QUESTIONS FIRST

Define the questions
you want to answer

A common approach taken when defining metrics is to begin the process by asking “What metrics do we need?” I.e., a “metrics first” approach. This can result in (a seemingly endless) list of metrics that can shift focus from what’s important.



DATA LATER

Define the metrics
that answer those questions

In contrast, a “questions first” approach helps first identify the actual questions we want answered by the metrics, and subsequently we can identify appropriate metrics to answer those questions.

“Anything that is measured and watched, improves.” **Bob Parsons**

The “Triple A” Perspectives on TMF Health Standards

TOP 3 FREQUENTLY ASKED QUESTIONS



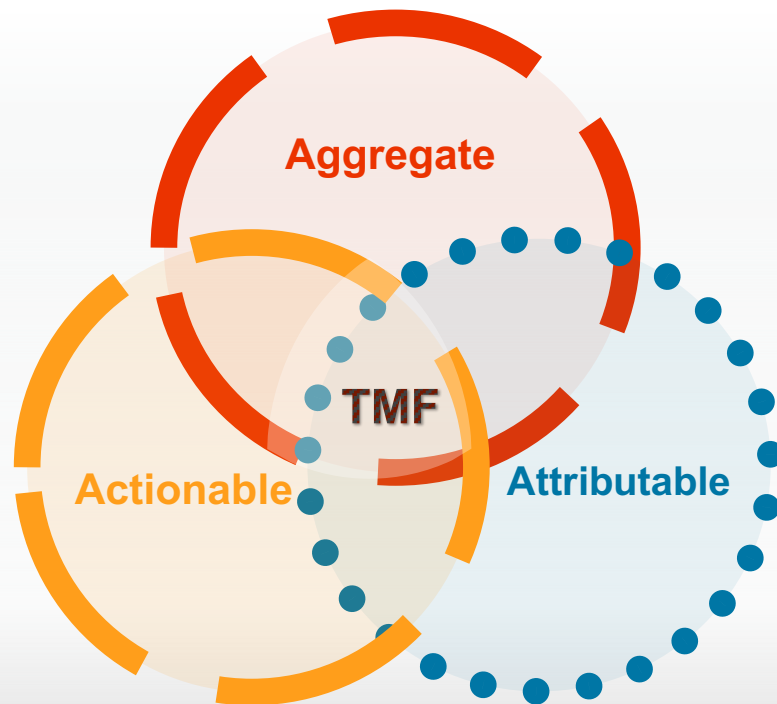
How Inspection Ready is my TMF?



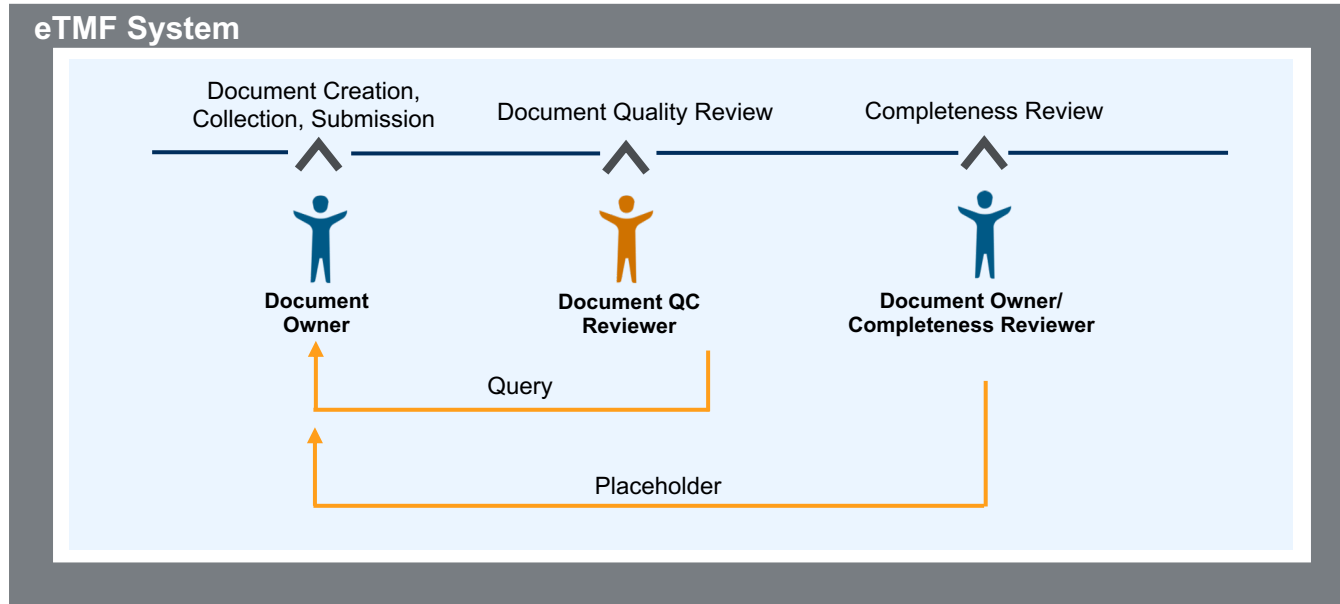
What actions are outstanding in order to ensure inspection readiness?



How are my team performing?



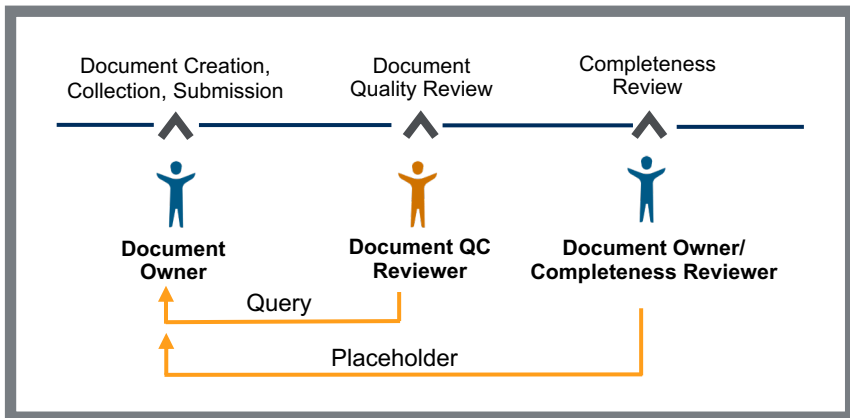
High-level eTMF Process





AGGREGATE

- ▶ **Study Level Focus**
- ▶ **Pont in Time, scheduled measurement**
- ▶ **Provide overall trending and compliance**
- ▶ **Industry standard of Inspection Readiness**
- ▶ **Measurement often tied to bonus/malus**



How Inspection Ready is my TMF?

- Are all documents present in the TMF?
- Are the documents filed in the TMF on time?
- Are the TMF documents initially filed quality documents?

Completeness % is calculated at a particular point in time by comparing applicable Final and Expected documents

Timeliness % is calculated at a particular point in time by comparing the number of applicable approved documents filed on time in the TMF to all applicable approved documents filed in the TMF

Quality % is calculated at a particular point in time by comparing the number of approved documents that meet the quality standard upon initial submission to the TMF to the total number of approved documents filed in the TMF



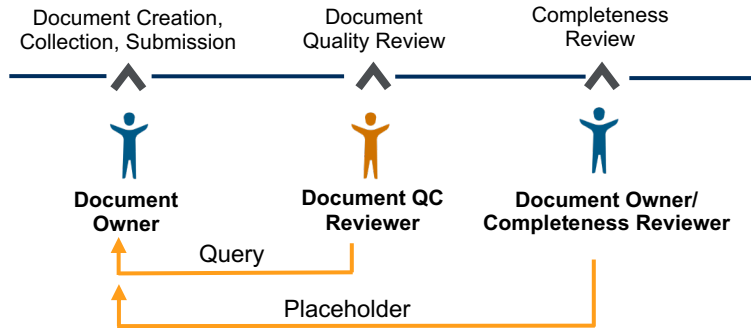
ACTIONABLE

- ▶ Study Level Focus
- ▶ Pont in Time, generated ad-hoc
- ▶ Provides visibility into pending actions
- ▶ Roadblocks to inspection readiness



What actions are outstanding in order to ensure inspection readiness?

- What queries are overdue?
- What Completeness Reviews are outstanding?
- Are missing documents being filed?
- Are tickets being resolved?



Outstanding Queries % is calculated by comparing the # of Queries that are open and aged compared to the total number of open queries

Overdue Completeness Reviews % are calculated by comparing Completeness Reviews that are overdue to the total number of active reviews

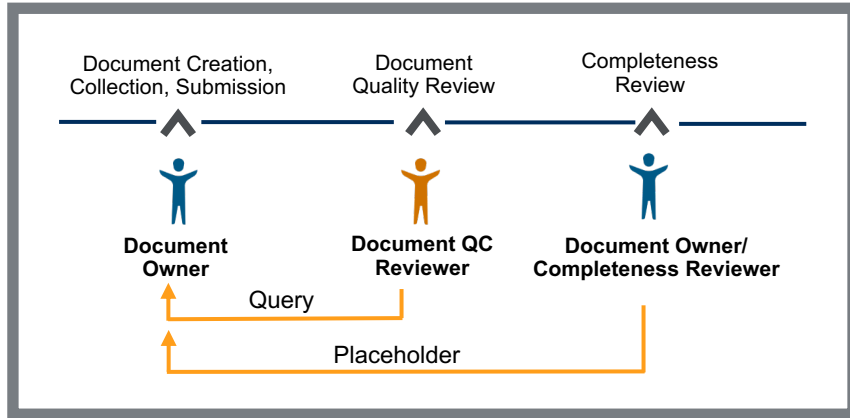
Overdue Placeholders % are calculated by comparing placeholders that are overdue to the total number of placeholders

Aged System Tickets % is calculated by comparing aged TMF tickets to overall TMF tickets



ATTRIBUTABLE

- ▶ Individual Level Metrics
- ▶ Cross user, site, Category and study
- ▶ Trending over set period, MoM, Annual review
- ▶ Creates accountability at the user level



How are my CRA's performing?

- Who is/is not filing documents in the TMF on time?
- Who is/is not submitting quality documents to the TMF?
- Who is/is not responding to queries on time?
- Who is/is not filling placeholders for their missing documents?

Timeliness of TMF Filing

The % of applicable approved documents filed on time in the TMF

Quality

The % of approved documents that meet the quality standard upon initial submission to the TMF

Timely Query Resolution

The % of assigned TMF Queries resolved within a timely manner

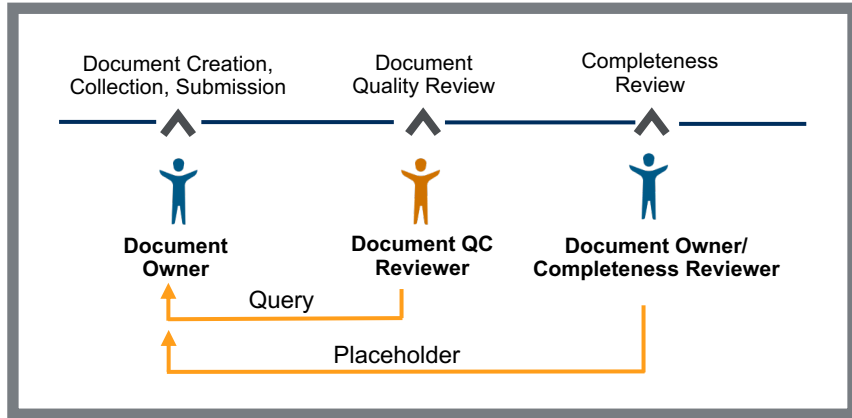
Placeholders

The % of placeholders resolved on time



ATTRIBUTABLE

- ▶ Individual Level Metrics
- ▶ Cross user, site, Category and study
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How are my Document QC Reviewer's performing?

- How efficiently are they reviewing documents?
- What is the accuracy of their Quality Review?

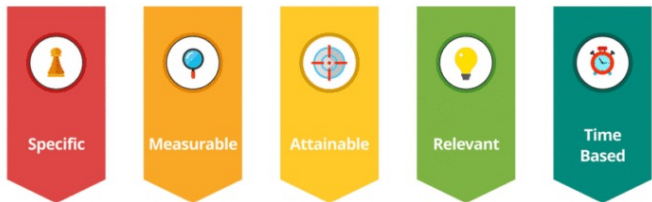
Quality Review Timeliness % is the calculation of an individual's TMF Documents Quality reviewed in a timely manner compared to all documents they quality reviewed

Documents Reviewed Per Hour is an individual's calculated rate quality reviewing TMF documents

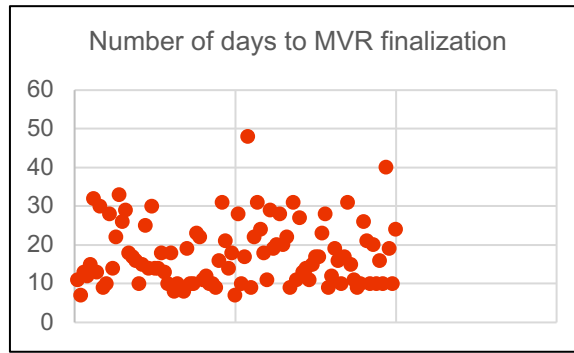
Document QC Reviewer Quality Sampling is an individual's error rate of quality review when sampling documents

Drive Accountability through SMART Goal Setting and Performance Management

SMART



E.g. CRA: Finalise 90% of visit reports within 10 business days of site visit

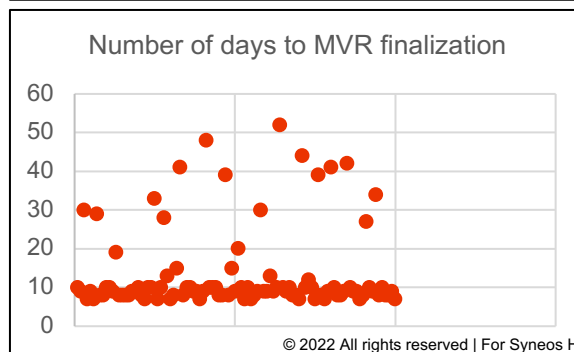


Before

Average: 17.51 days

<10 days or less: 38

>30 days: 8



3 months after:

Average 13.41 days

<10 days or less: 78

>30 days: 13

Drive Accountability through SMART Goal Setting and Performance Management

SMART



Level	Example Performance Goal
Document Owner (CRA)	Submit 90% of applicable documents within 30 days of document finalization/receipt
	90% of Documents meet the quality standard upon initial submission to TMF
Document QC Reviewer	Quality Review 90% of TMF documents within 7 calendar days
	95% of Documents Quality Reviewed meet the quality standard upon sampling

Individual TMF Performance Metrics in Practice

March
2022

Charlie the CRA submitted 140 of 150 TMF documents within 30 days of document finalization



120 of the 140 documents Charlie the CRA submitted to the TMF in March met the quality standard upon initial quality review

Jessica the Document QC Reviewer reviewed 2250 documents through the month of March. 2005 were reviewed within 7 calendar days of publication



According to a random sampling of Jessica's work, 98% of documents achieved the quality standard

Individual TMF Performance Metrics in Practice

March
2022

Charlie the CRA submitted 140 of 150 TMF documents within 30 days of document finalization.

Timeliness
93%

Quality
86%

120 of the 140 documents Charlie the CRA submitted to the TMF in March met the quality standard upon initial quality review.

Jessica the Document QC Reviewer reviewed 2250 documents through the month of March. 2005 were reviewed within 7 calendar days of publication

Quality Review
Timeliness
89%

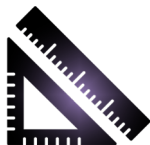
Quality
98%

According to a random sampling of Jessica's work, 98% of documents achieved the quality standard

Additional Considerations



TMF models and data availability



Tools, Resources and Administrative burden



General Data Protection Regulation (GDPR) and access restrictions (country dependent)

Key Take-aways



Questions First



Think “Triple A” (Aggregate, Actionable Attributable)



Build a Culture of Accountability through ongoing Performance Management



Thank you for your time

Questions?



Shortening the Distance from Lab to Life[®].

