

REFINING A RISK-BASED TMF MANAGEMENT APPROACH

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Standardized Risk-Based Approach Enables Better Oversight



40%

**Pilot Study Health
Score Improvement**



36%

**Starting Health Score
for New Studies**

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Astellas' Global TMF Team Manages More Than 50 Studies

Global TMF team:

12

including
5 TMF
compliance
managers

Study volume:

50+

global studies,
all phases

eTMF system:

**Astellas Vault
Clinical for all
studies**

TMF management:

50%

in-house

50%

CROs

Where We Started



Implemented a Risk-Based TMF Approach in 2021



Challenge:

- TMF Transformation
- Inspections found inconsistent frequency and percentage of documents in TMF checks



Goal:

- **Define** what and when to review, with consistent guidance for all studies
- Increase study team engagement

Start with the essentials to standardize TMF health checks and reduce inspection risks

Initial Outcome: Risk-Based Approach Reduces Effort for Study Teams



Reduced document QC
40% with classification
tiering and auto-approvals
for low-risk documents



Provided **guidance** for
quarterly functional area
TMF health checks

**A risk-based approach helps study teams
focus on what matters most**

What We Adjusted



New Additions



**TMF Compliance
Manager Role**



**TMF Health
Score**

**Take a collaborative approach to help study teams
embrace the process**

Health Score Weights Metrics Depending on Effort

Weighting Approach



Health Score Targets

90-100%
GREEN

80-89%
YELLOW

0-79%
RED

Health Score Comprised 10 Metrics

Completeness	Quality	Timeliness
<ol style="list-style-type: none">1. % docs present for study milestone(s)2. average of countries3. average of sites	<ol style="list-style-type: none">4. # days QIs overdue5. # overdue QIs6. # docs QC rejected >30 days7. # overdue QC workflows8. # in-progress workflows9. # in-progress >7 days	<ol style="list-style-type: none">10. # docs created >60 days

Pilot Studies Signaled Refinement Needed

Pilot: 13 pilot studies well below target score

Update 1: Refined weighting of health score

Update 2: Added a second timeliness metric

Timeliness (1)

docs created >60 days

Timeliness (2)

days for records submission

Continue to refine the health score and combine it with a scorecard to drive the right action

TMF Health Score Reporting Process



TMF COMPLIANCE MANAGER
Enter data into metrics
tab



AUTOMATED
Compare current to
previous



TMF COMPLIANCE MANAGER
Provide remediation
suggestions



AUTOMATED
Calculate TMF
aggregate score



TMF COMPLIANCE MANAGER
Perform quarterly
check with study
teams



TMF COMPLIANCE MANAGER
Compare periodic
scores

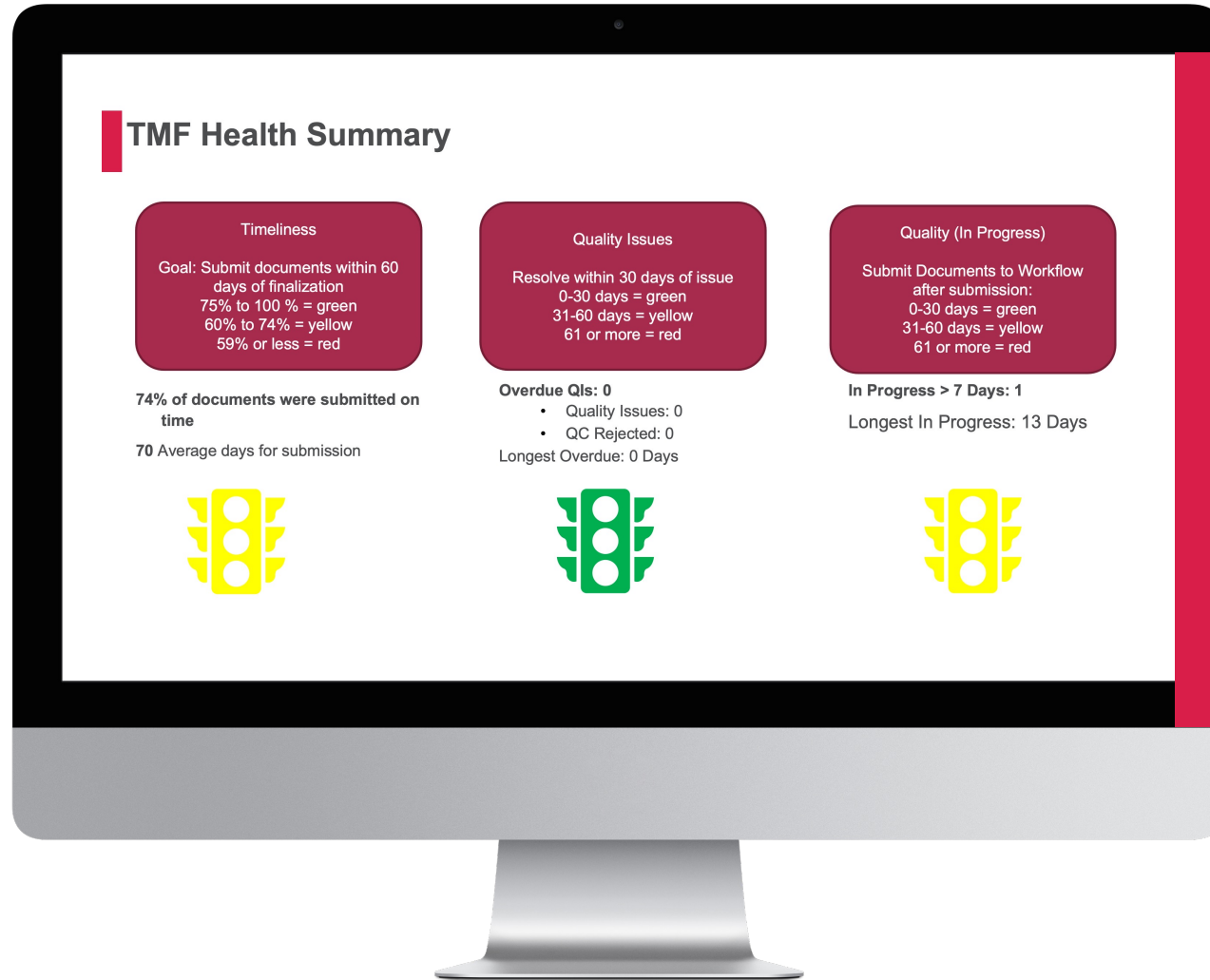
Sample TMF Health Scorecard: Overview

Study Number	Current Review	Previous Review	Comments	Metric Score	Total Points Possible = 300	Overall Timeliness Score	Overall Quality Score	Overall Completeness Score	Overall Score	Overall % Rating
Timeliness						44	90	137.5	271.5	91%
Average Days for Submission	70%	74	60 days or less = 30 (green); 61 to 90 days = 22 (yellow); 91 or more days = 0 (red)	22	30					
% of Records Created within 60 Days	74%	78%	75% to 100% = 30 (green); 60% to 74% = 22 (yellow); 59% or less = 0 (red)	22	30					
Quality										
Longest Quality Issue Resolution Timeframe	0	0	0-30 = 10 (green); 31-60 = 7.5 (yellow); 61+ = 0 (red)	10	10					
Total # Overdue Quality Issues	0	0	1-10 = 20 (green); 11-15 = 15 (yellow); 16+ = 0 (red)	20	20					
Longest Overdue QC Rejected	0	0	0-30 = 10 (green); 31-60 = 7.5 (yellow); 61+ = 0 (red)	10	10					
Total # of Overdue QC Rejected >30 Days	0	0	1-10 = 20 (green); 11-15 = 15 (yellow); 16+ = 0 (red)	20	20					
Longest In Progress Record Timeframe	13	144	0-30 = 10 (green); 31-60 = 7.5 (yellow); 61+ = 0 (red)	10	10					
Total # Number of In Progress workflows	1	2	1-10 = 20 (green); 11-15 = 15 (yellow); 16+ = 0 (red)	20	20					
TMF Completeness										
Study Level	90%	80%	90% or higher = 50 (green) 80% - 89% = 37.5 (yellow) 79% or less = 0 (red)	50	50					
Country Level Overall	87%	48%		37.5	50					
Site Level Overall	91%	55%		50	50					
Total Score				271.5	300					

Sample TMF Health Scorecard: Results

Timeliness Score (Max 60)	Quality Score (Max 90)	Completeness Score (Max 150)	Overall Score (Max 300)	Overall % Rating
44	90	137.5	271.5	91%

Sample Slide Shared With Study Teams



Give study managers an overview plus a detailed view of areas for improvement

Where We Are Now



Results: Significantly Improved TMF Health Scores

PILOT STUDIES



20%
starting average



41%
for most
current check

NEW STUDIES



56%
starting average



36-point
increase over pilot
study starts

Lessons Learned: How to Leverage TMF Health Scores

1

Centralize documents in primary eTMF

2

Balance between achievable and meaningful scoring

3

Encourage study teams to be hands on with TMF

4

Collaborative, not punitive, approach

Applications for Small Biopharma: Risk-Based Approach is Scalable

1

Start with classification tiering to provide study teams with guidance on areas of focus

2

Make dashboards and reports available to study teams, even if you don't have a compliance manager role

The risk-based tiering framework and dashboards focus the effort and reduce risk

Where We're Going



Next Steps in Refining Risk-Based Approach

Plan to:

1

Create a **central dashboard** for all studies and scores

2

Aim for studies to reach **90% threshold** in consecutive checks to move to bi-annual TMF health checks

3

Use the TMF health score as a **study team's objective**

Questions?

Key Takeaways

1

A risk-based approach improves TMF health

2

Study teams' buy-in is central to success

3

A risk-based approach is cultural