Strengthening CRO Partnerships for TMF Quality and Efficiency

Steph Viscomi

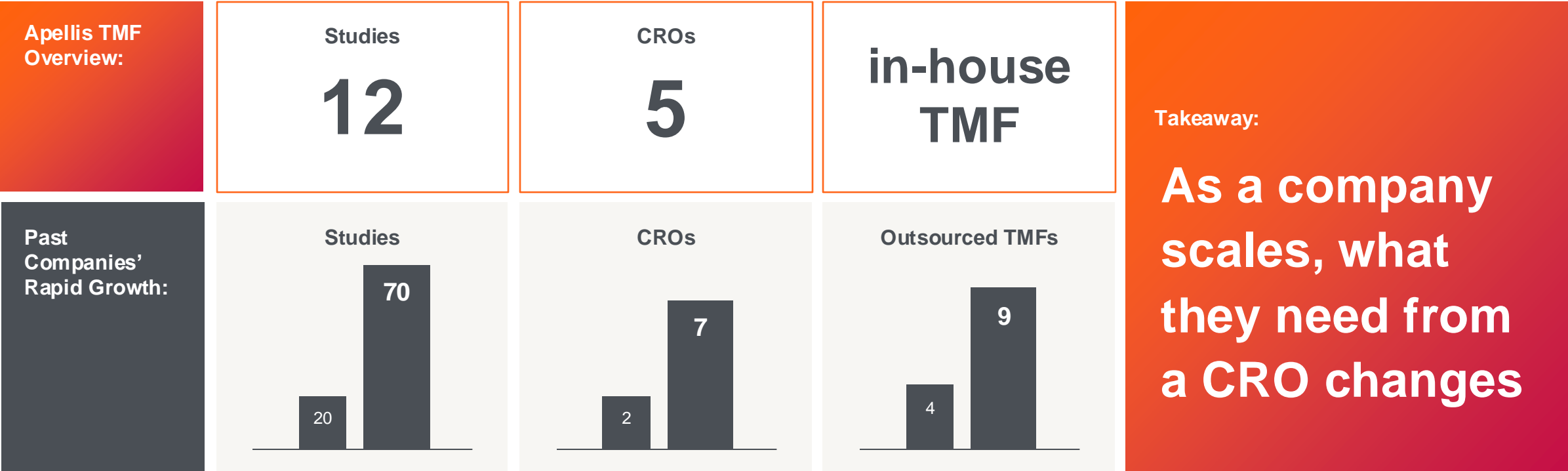*Director, Clinical Documentation & TMF*

April 2, 2025

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Disclaimer

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Strong CRO partnerships and a One Team mindset are foundational for growth and adaptability

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TMF Overview

Apellis TMF Overview:	Studies **12**	CROs **5**	**in-house TMF**	Takeaway: **As a company scales, what they need from a CRO changes**
Past Companies' Rapid Growth:	Studies 20 → **70**	CROs 2 → **7**	Outsourced TMFs 4 → **9**	

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Use a TMF Partnership Plan to set up CRO partnerships for success

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TMF Partnership Plan Overview

Defines the following

🧪 Studies in scope

📊 Metrics and goals

📄 Standard operating procedures

🖥️ System usage

🔍 Oversight expectations

📋 Communication requirements

📋 Inspection readiness

Partnership plan principles

> Create at beginning of partnership

> Establish one per CRO partner

> Include both sponsor and CRO

> Evolve over time
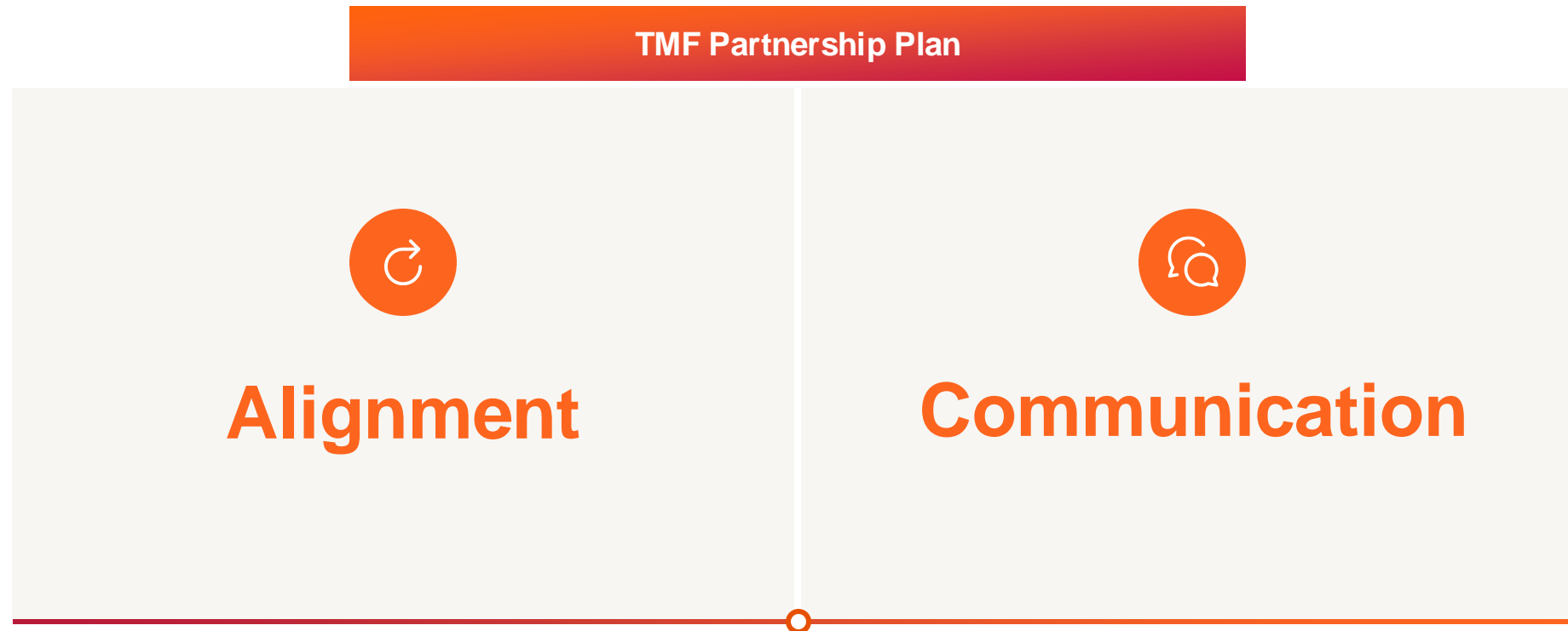
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Two Main Components of the Plan

TMF Partnership Plan

Alignment

Communication

"A partnership works when you carry each other"

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Two Main Components of the Plan

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Outline responsibilities

Define metrics

Provide visibility

Develop mitigation plans

Communication

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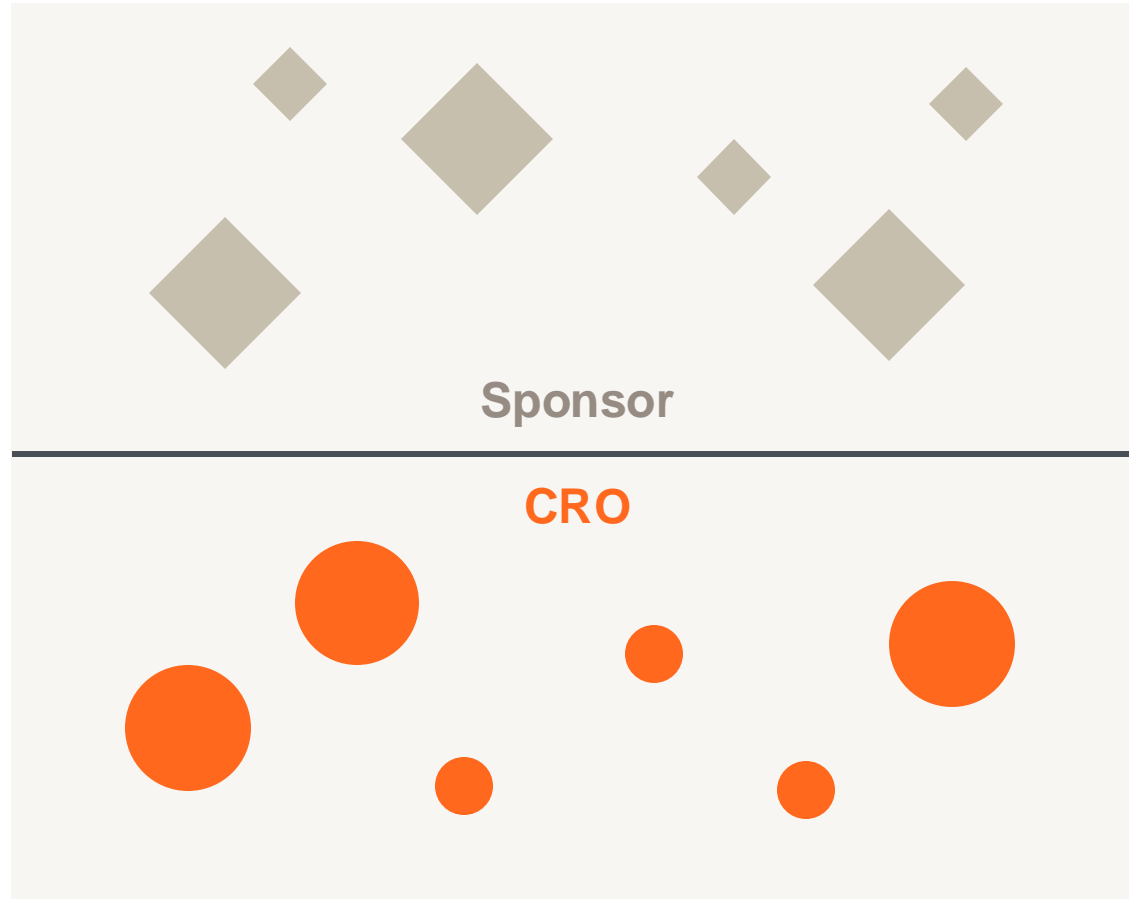
Outline Responsibilities Through Contracts

- **Implement** service-level agreements (**SLAs**)

- **Participate** in contract builds, revisions, and bid defenses
  (if you can)

- **Remain flexible** with contractual requirements based
  on the size of the sponsor and CRO

- **Set expectations** together at the very beginning,
  but strive for **adaptability**

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Outline Responsibilities Through Contracts

Takeaway:

Clear alignment on expectations and obligations enables pharma companies of all sizes to successfully partner with CRO(s) that meets their needs

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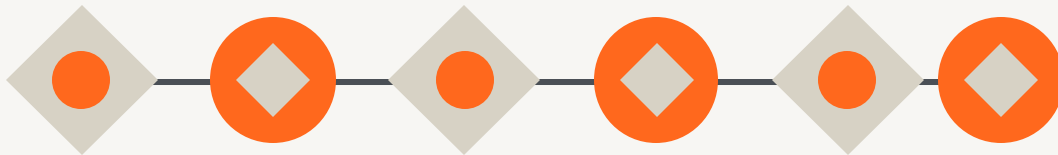# Outline Responsibilities Through Contracts

Alignment

Takeaway:

Clear alignment on expectations and obligations enables pharma companies of all sizes to successfully partner with CRO(s) that meets their needs

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Define Metrics To Ensure Accountability

Performance Metrics

- Document upload timing

- QC rejection reasons

- Query resolution speed

- QC cycle time
  (time from upload to QC)

- EDL pending decisions
  (EDL management)

Contractual Metrics

- Documents per month

- Completeness %

- Quality %

- Timeliness requirements
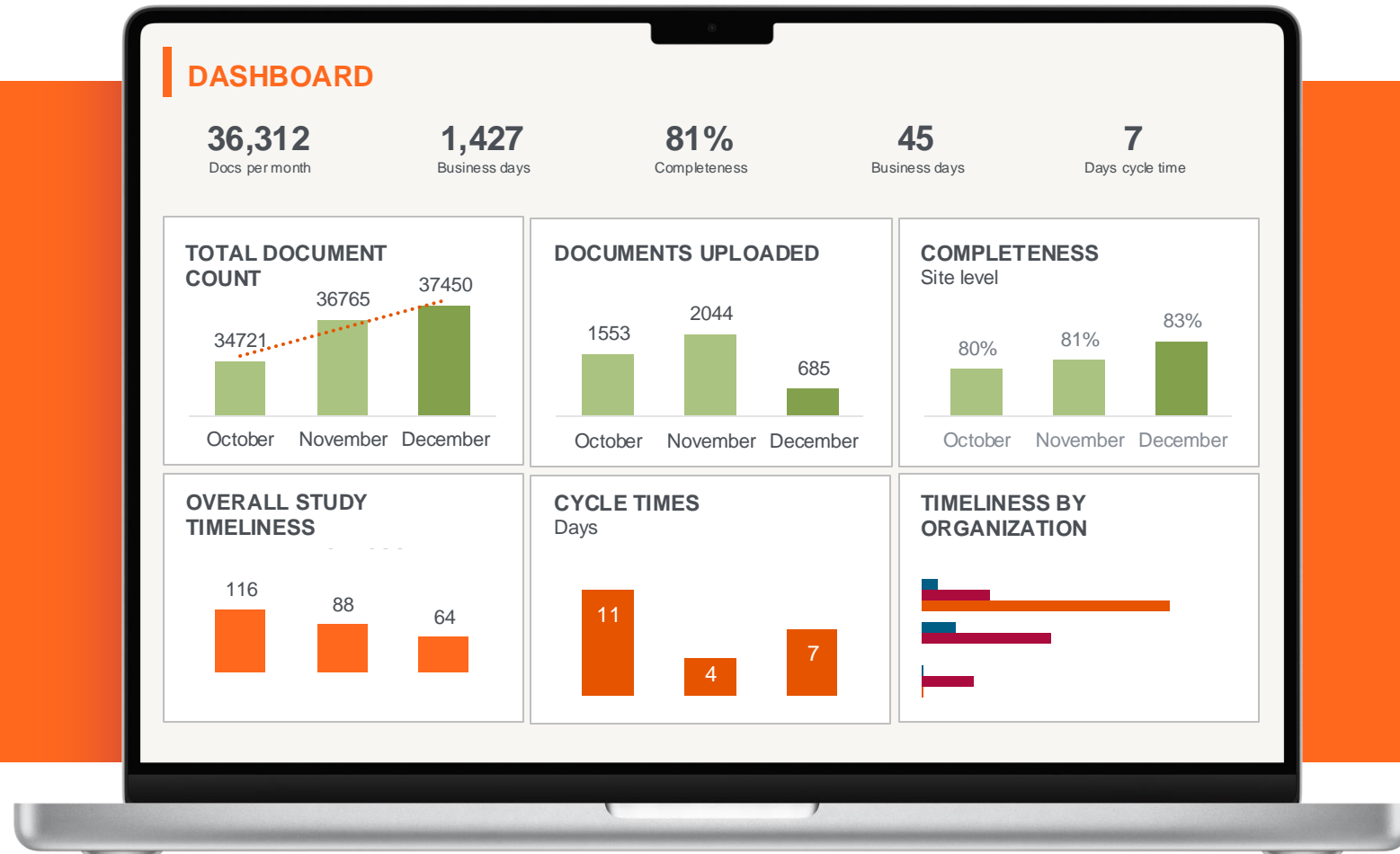
- eTMF system oversight

User Metrics

- Access level metrics

- Blinded vs. unblinded

- Global users

- Inactive users for
  90+ days

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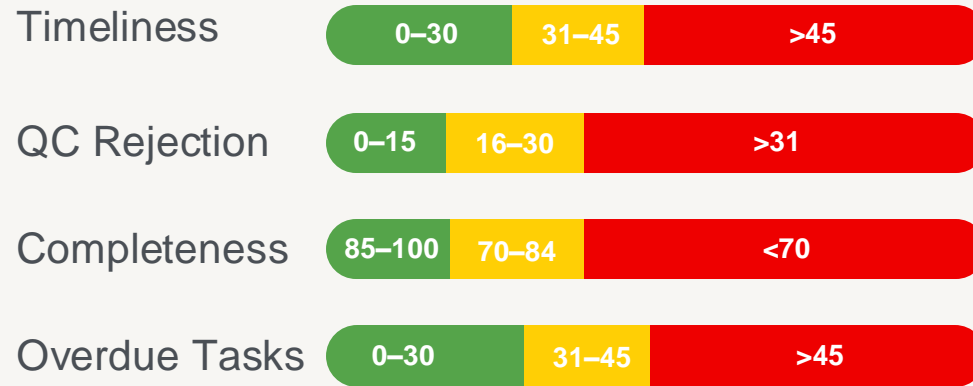# Provide Visibility Into Performance With Dashboards

Benefits

> Visualizes progress on key TMF activities across studies

> Consolidates data across internal and external systems

> Streamlines prioritization with metrics and deadlines
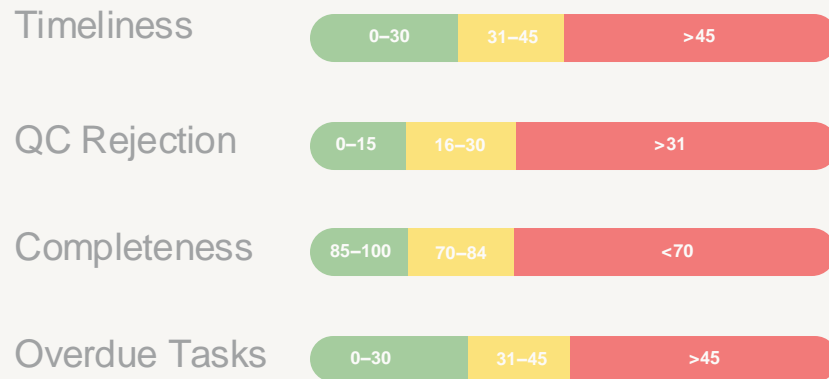
> Highlights need for process improvement

DASHBOARD

36,312	**1,427**	**81%**	**45**	**7**
Docs per month	Business days	Completeness	Business days	Days cycle time

TOTAL DOCUMENT COUNT

34721 36765 37450

October November December

DOCUMENTS UPLOADED

1553 2044 685

October November December

COMPLETENESS
Site level

80% 81% 83%

October November December

OVERALL STUDY TIMELINESS

116 88 64

CYCLE TIMES
Days

11 4 7

TIMELINESS BY ORGANIZATION

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Develop Mitigation Plans To Address Setbacks

Example Thresholds

Timeliness

0–30	31–45	>45

QC Rejection

0–15	16–30	>31

Completeness

85–100	70–84	<70

Overdue Tasks

0–30	31–45	>45

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Develop Mitigation Plans To Address Setbacks

Example Thresholds

Timeliness
| 0–30 | 31–45 | >45 |

QC Rejection
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Completeness
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Overdue Tasks
| 0–30 | 31–45 | >45 |

Example Escalation Plan

1 month → **2** months → **3** months

Issues identified

Raise at department level

No improvement / ongoing concerns

Establish root cause and corrective timeline

Ongoing issues with no resolution

Escalate to leadership

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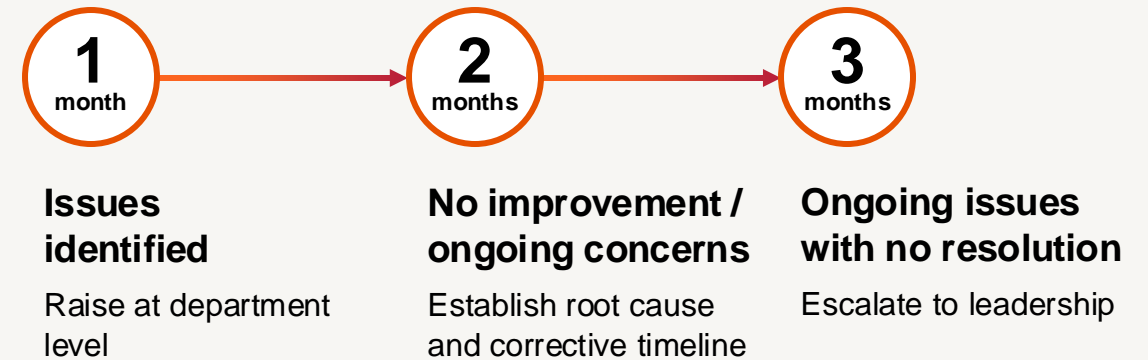
Inspection readiness and partnerships

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Healthy Partnerships Ensure Inspection Readiness

Communication

Metrics

Issue Resolution

Inspection Readiness

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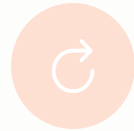# Two Main Components of the Plan

TMF Partnership Plan

Alignment
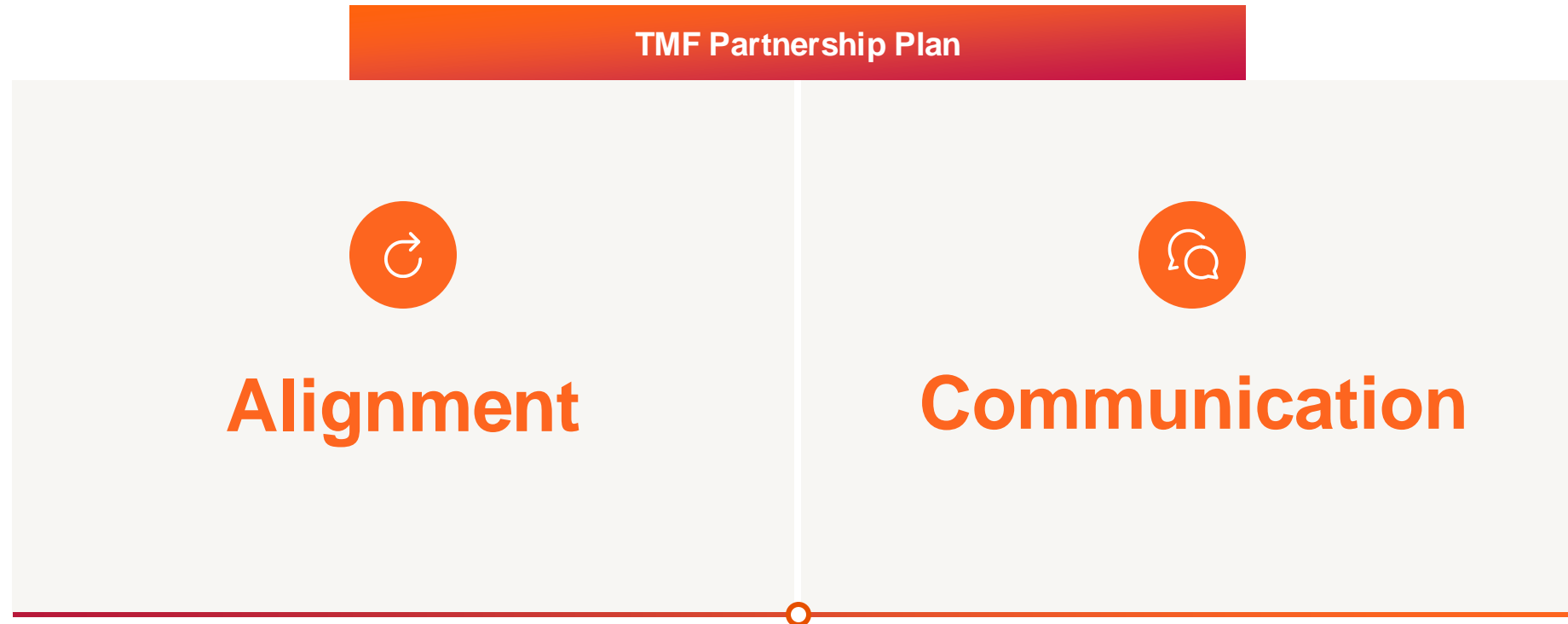
Communication

"A partnership works when you carry each other"

Two Main Components of the Plan

TMF Partnership Plan

Alignment

Communication

Create open dialogue

Streamline access

Seek input

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Create Open Dialogue with a "One Team" Foundation

How to establish:

- Set a standard of collaboration up-front
- Enable two-way communication
- Schedule governance meetings
- Create end-user experience as a team

Takeaway:

TMF stakeholders, internal and external, operate as one study team

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Seek Input by Surveying Stakeholders

QUESTIONS

1. Do you understand the purpose of the TMF?

2. Scale of 1-10 how comfortable are you using the eTMF system?

3. What challenges do you have with TMF processes (doc upload, quality review)

4. Do you feel that you know or know how to find the TMF health at any time?

5. Asking the team if the current metrics provided are useful? Why or why not?

6. What metrics are important to you as a study team at this milestone of the study?

7. How and when do you want TMF information disseminated to the study team?

Benefits

> Identifies successes and process gaps

> Improves CRO engagement

> Demonstrates commitment to end users

> Facilitates metric and strategy alignment

Streamline Access by Centralizing TMF Tools and Logins

TMF Central:

Meet the Team
- John Gant
- Nicola Vivaldi
- Tammy Gibbs
- Ted Sibelius

Upcoming QCs

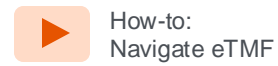| Date	TMF label	System
4/12/2025	John G.	V eTMF
10/01/2025	Angela H.	V eTMF

eTMF Access Requests

Jane Andersson ✓ ✗

Joseph Bach ✓ ✗

Metric Quick Links
- Timeliness Dashboard
- Completeness Dashboard

Learning Portal

How-to:
Navigate eTMF

Documents

Templates

Takeaway:

TMF Central improves usability and accessibility and enables consistent processes for end users.

Key Takeaways

One Team Mentality

1

COMMUNICATION

goes both ways

2

ALIGNMENT

on solutions,
not demands

3

IDENTIFICATION

of components
for a successful
partnership

4

COLLABORATION

through continuous
"**one team**" efforts

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