

Optimizing Outsourced Models

Improve sponsor-CRO collaboration and increase oversight for inspection readiness

March 2022

CONFIDENTIAL

Agenda

- 1** Seagen Overview
- 2** Developing a New Model
- 3** Relationship-Building Between Sponsor and CRO
- 4** Programs for eTMF Health
- 5** Oversight Performance Metrics
- 6** Business Results
- 7** Key Takeaways

Our Vision

To be a global oncology leader
improving the lives of people
with cancer through innovative
targeted therapies

Julie

TUKYSA clinical trial participant

Seagen

Company Overview

23+
Years

As a dedicated
biotechnology company
focused in oncology

12
Locations

Seattle area,
San Francisco,
Canada, Switzerland,
and Europe

~2,500
Employees

The majority involved
in research and
development

Nasdaq:
SGEN

Publicly traded

4

**Marketed
Cancer Therapies**

9

**Pipeline
Programs**

2

**Proprietary Technologies:
ADC and SEA**

Developing a New Model



TMF Rescue

- Close to end of study and submission



Leadership Buy-in

- Align with goals
- Measure business impact with metrics



Goals

- Increase visibility
- Ensure real-time oversight

Relationship-Building Between Sponsor and CRO



Clear system expectations with pre-requisite for vendor selection



Clear TMF health expectations from outset



Ongoing visibility into what Seagen assesses

Programs for eTMF Health

Seagen Expectations

	Level	Completeness
Start-up	Study	100% key plans* and essential documents present by First Site Active (FSA)
	Country	100% EC approvals and associated translations present by FSA
	Site	100% essential documents present by Site Activation
Conduct	Study	> 90% essential documents present
	Country	
	Site	
Closeout	Study	100% all documents present by TMF lock
	Country	
	Site	

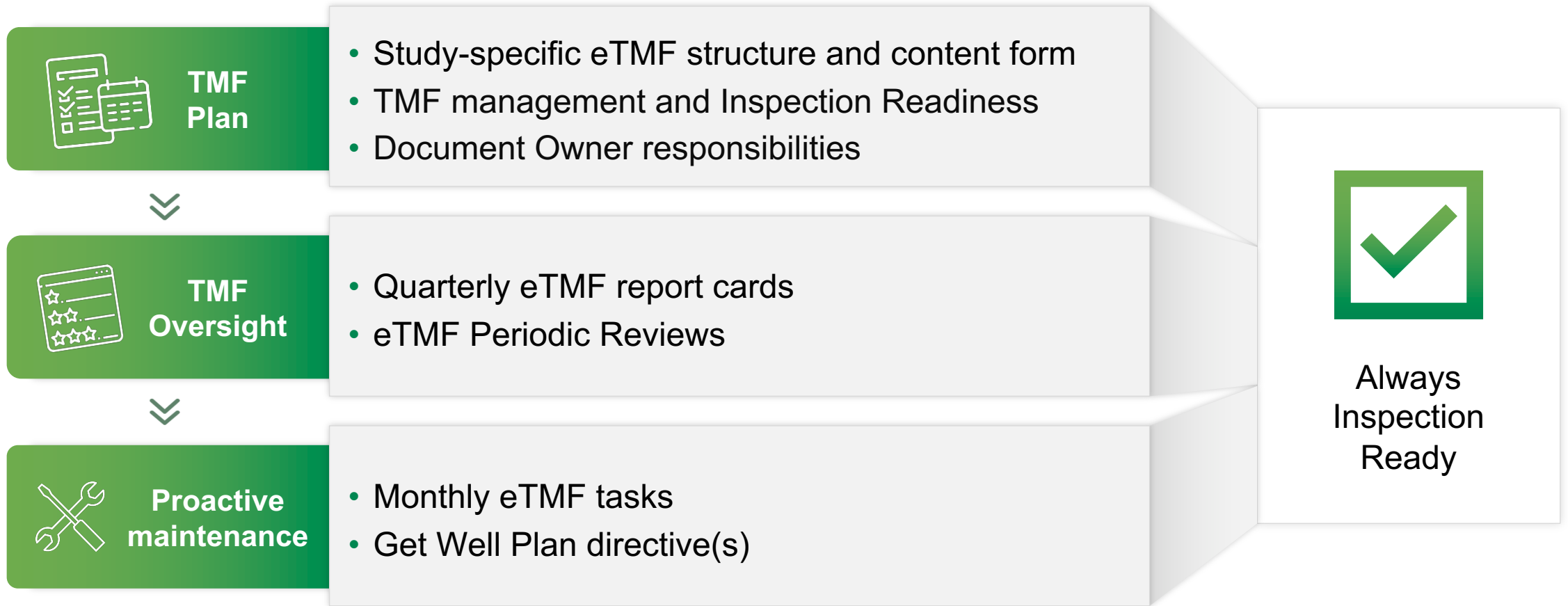
Quality & Timeliness

> 90% documents meet ALCOAC and Seagen guidelines at initial submission to eTMF

> 90% essential documents approved in eTMF within **30 days** of document finalization

Programs for eTMF Health

Activities to Monitor and Improve TMF Health



Programs for eTMF Health

eTMF Report Cards

High Level eTMF Health		<ul style="list-style-type: none">• Green Light > 90%• Yellow Light 75-90%• Red Light <75%
Findings		<ul style="list-style-type: none">• Exemplifies control over eTMF• Metrics are INDICATORS• Speaks to special scenarios
Get Well Plan		<ul style="list-style-type: none">• Risk Based Approach• Mitigation/Remediation• Accountability (e.g., re-training)

Programs for eTMF Health

Proactive Monthly Maintenance

Monthly eTMF Health Maintenance (examples)

- EDL maintenance
- Quality Issues
- Documents ≠ Approve
- Get well plan recommendations



Study eTMF Metrics
Global Level



Study eTMF Metrics
Country Level



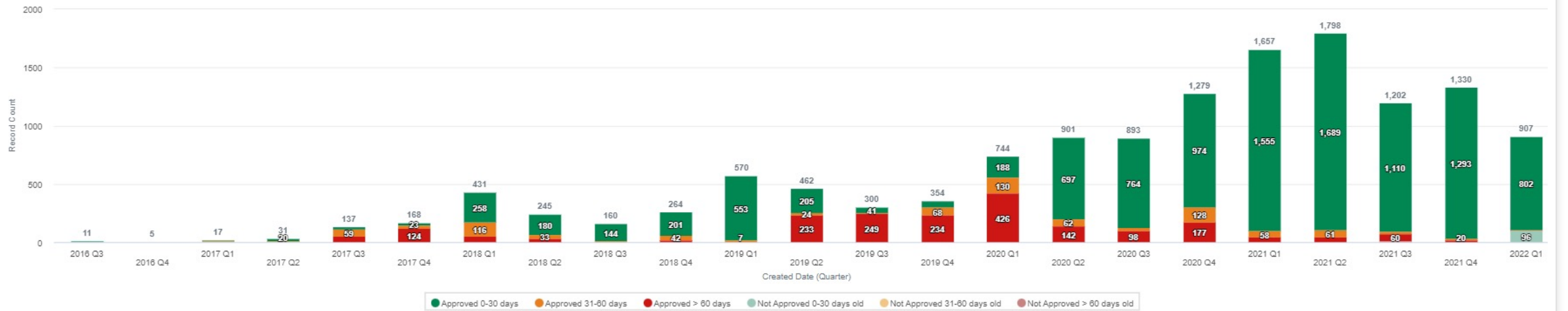
Study eTMF Metrics
Site Level

Oversight

Reports/Dashboards

Document Creation to First Approval by Quarter - Global

As of 3 minutes



Oversight

Reports/Dashboards



Business Results



Visibility and Global Metrics

- Previously, global metrics were not available
- Current state provides visibility across study, program, and portfolio



Improved Collaboration

- Master plans at program level
- Consolidated trainings across vendors
- Engaging office hours
- More solution discussions instead of escalations

Key Takeaways

1

Leadership
team buy-in is
essential

2

Develop a
robust TMF plan
and expectations

3

Create meaningful
dashboards for
vendor oversight
and visibility

Q&A

