



Elevate Your TMF Inspection Readiness with a Focused Preparation Program

Presented by –
Hobson Lopes, Assoc Dir, Records and Archives Management, Regeneron

Meet the Speakers

Hobson Lopes

Title: Associate Director, Records and Archive Mgmt.

Organization: Regeneron Pharmaceuticals

Hobson has more than 12 years of industry experience and is currently the Associate Director of Records and Archive Management including records management/archival, quality/inspection prep, and translations.



Ramya Iyer

Title: Sr. Manager, TMF

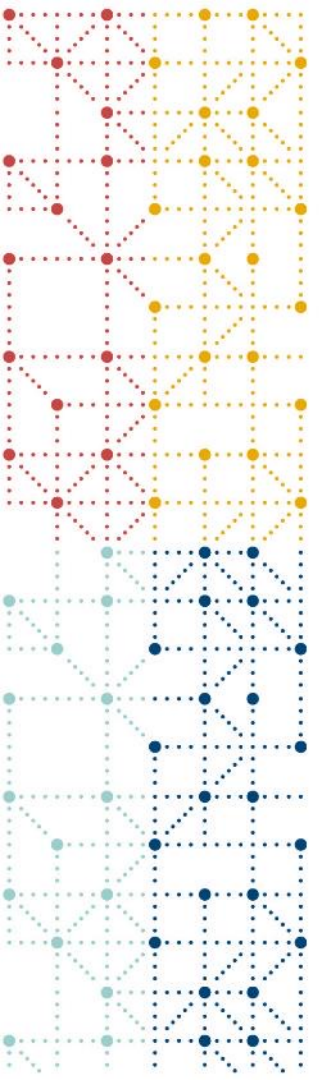
Organization: Regeneron

Over 10 years of industry experience, currently serving as a Sr. TMF Manager at Regeneron Pharmaceuticals, where I lead Document Governance, Quality, and Inspection Readiness processes.



Disclaimer and Disclosures

The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of Regeneron or CDISC.



Agenda

- Inspection Preparation
- Inspection Preparation Program
- Positive TMF Culture
- During Inspection
- Outcome and Takeaways

A soccer ball with black and white panels is shown hitting a white goal net. The background is a blurred green field. On the far left edge, there is a vertical decorative strip with a grid of dots in blue, red, yellow, and teal colors.

Inspection Preparation ~
Preparing for the BIG Game!

Always Inspection Ready Mindset!



Continuous and Consistent mindset towards Inspection Readiness



Emphasizing Documentation through procedural documents



Ongoing Quality Checks, reconciliation (especially at critical events)



Performing regular Risk identification and Risk assessments



Building a robust TMF management process that is not affected by turnover

What's in it for me!



- Regulatory Compliance
- TMF is central – one source to tell the story of the study
- Continuous Improvement culture
- Our common goal – WIN for science, medicine
- WIN at the big game – Inspection Success

Preparing for the Big Game!

Focus on a study/program that is:

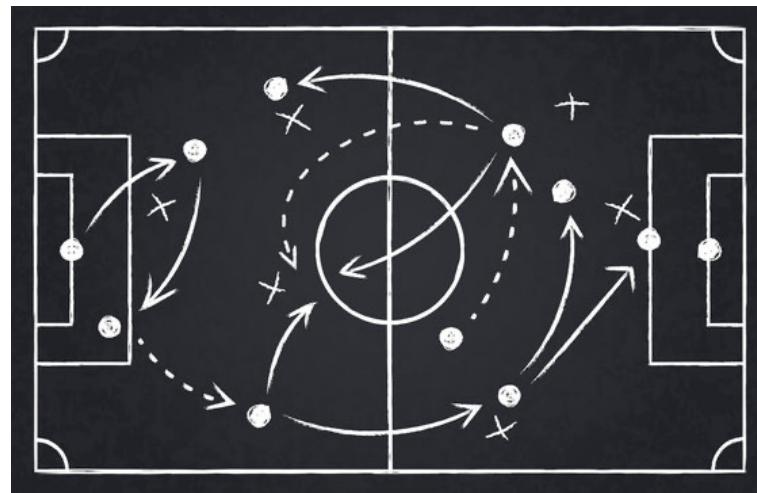
- Pivotal/Potential for Inspections
- Slated for submission

Timelines

- Work backwards
- Carve out enough time to get TMF in shape
- Build stamina for a long game

Game Plan

- **TMF Readiness**
 - Filing Consistency
 - Completeness
 - Searchability
 - SME Training
- **Strengths and Weakness**
- **TMF Deep dive – Know your Playbook**
- **Drills/Practice/Scrimmages**
- **Elevate Team Spirit/Confidence**

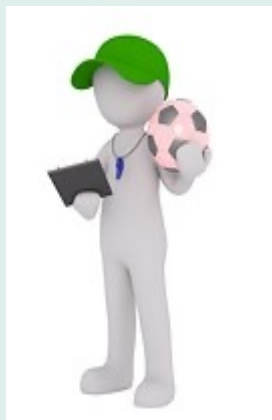


Meet the Key Players

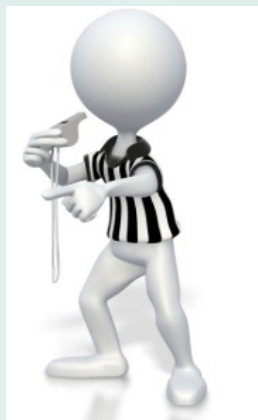
Clubs (Study Team)



Coaches (TMF Inspection Lead)



Referees (Inspectors)



Maintenance Crew (Everybody Else)



Fans (Patients)



All Hands-On Deck (Or should we say Feet !!)



Time to get the Playbook Out!

Aka deep dive into TMF



Identify documentation gaps

Documents for major events
Quality events
Logic and Cross-checks



TMF Index accuracy

Consistency
Application of metadata
Reflected in Index
Enhance Searchability



Assess compliance

Support from IT/Systems to confirm
access was managed per SOP
Are all users trained in TMF
Processes



Assess the Past Performance



TMF compliance

QC Trends (leverage findings from past Quality checks)

Are their still open items

Confidence level on issue resolution



Assess upload timeliness,

Timepoints with upload peaks

Do we know the reason behind the peak

Ensure study team can speak to them



Identify Strengths and Weakness

Aide in implementing Risk Based Approach

Strengths

- Kudos to the Study Team
- Keep the momentum going
- Perform light oversight
- Indicates good Readiness Practices

Weakness

- Numbers speak!
- Past Findings
- Additional training needs
- Need to increase drills and checks
- Indicates high focus for Inspection Preparation



Time to roll up your sleeves!



Eye on the goal



Start Early



**Leverage lessons
learned from the
playbook**



Have an action plan



Time to roll up your sleeves!



Cross Functional SME Readiness

Do they know their portion of the TMF?
Can highlight locations when requested
Can speak to any gaps/lack in documentation



Drills – Mock Runs

TMF Focused interview
Increase comfort around TMF



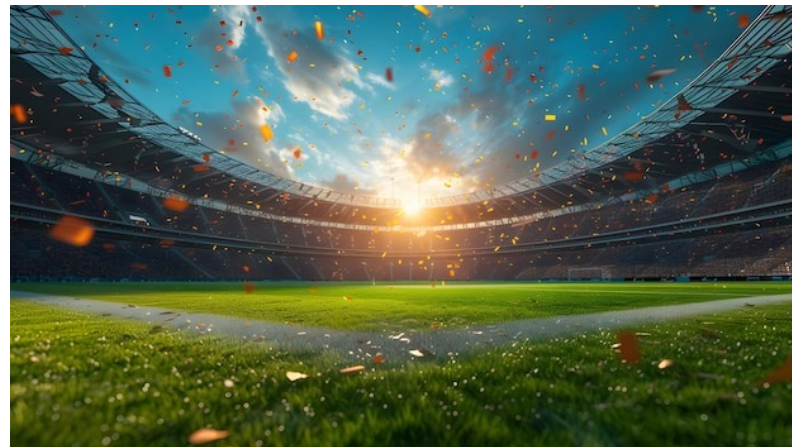
Storyboarding

Differentiate between TMF issues vs documentation issues
Capture any unique decisions, scenario pertaining TMF



Success Markers

- Significant improvement on TMF Metrics
 - Completeness
 - Timeliness
 - Quality
- TMF Action Plan – No Pending Actions there!
- Increased confidence with Functional SMEs for their part of the TMF
- Process in place to address TMF requests and teams are trained as needed



Example:

- Average of 7-10% improvement with EDLs within 6 months
- Average of 15-20% improvement with Upload Timeliness within 6 months

It all starts with building Positive TMF culture



Build Morale - Positive TMF Culture



Build team spirit



Effective Cross functional Collaborate



TMF is a goal that you can score!



Ownership and Accountability



Best Practices, Training and Resources



Goes beyond preparing for the big game!

The Ultimate Motivation Factor!



Game Time



Game Time



LAST CHECKS IN
PLACE



STAGE
DOCUMENTS



EFFECTIVE
COMMUNICATION
PLAN IN PLACE



IDENTIFY YELLOW
FLAGS AS THE
GAME
PROGRESSES



STRATEGY TO
ADDRESS TMF
REQUESTS



TMF ACCESS FOR
INSPECTORS IN
PLACE, IF
REQUESTED
#ClearDataClearImpact



Coach on the Sidelines

Read the Game

- Improvise game plan
- Leverage reports

Collaborate with cross functional SME

- SME awareness of potential requests
- Streamlining the process to manage inspection requests
 - Who gets the requests for TMF documents?

VAR – Over the Shoulder or Direct Access

- Ongoing reporting
- TMF request tracking

Support Staff

- IT – System backup, scheduled maintenance
- AV – Space for collaboration, meeting tools (Teams, Zoom)



Outcome



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Takeaways!



Don't forget AIR!



It always takes a village and TMF is the village center

Cross-collaboration is key



Identify potential yellow cards during the Game Strategy

Avoid any Red card!



It's a marathon not a sprint!



Thank You!

