



2024 CDISC + TMF  
US INTERCHANGE

**PHOENIX/SCOTTSDALE**

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## **TMF Training Driven by Metrics**

Dawn Niccum  
Executive Vice President, Quality Assurance  
inSection Group



## Meet the Speaker

Dawn Niccum, RN/MSN, RQAP-GCP, CCRA, PMP

**Title:** Executive Vice President, QA & Compliance

**Organization:** inSeption Group

Dawn Niccum heads Quality Assurance at the inSeption Group. She is an expert in the development, management, and implementation of clinical trial systems including the TMF. Dawn is a Steering Committee Member for the CDISC TMF Reference Model, Chairs the Educational Governance Committee, and is a Steering Committee Liaison for the ISF Reference Model Initiative. She has presented as an SME at numerous conferences on clinical quality systems and inspection readiness. Dawn is educated as a Registered Nurse and holds Masters' degrees in Regulatory Affairs and Quality Control and Nursing Education as well as certifications in clinical research, GCP quality assurance, and Project Management.



# 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 CDISC.*
- *The speaker has no real or apparent conflicts of interest to report.*



# Agenda

1. TMF Metrics Basics
2. Linking Training to Metrics



# TMF Metrics Basics

# Pillars of TMF Health



TIMELINESS



COMPLETENESS



QUALITY

# Choosing Appropriate Key Performance Indicators

## Timeliness

- Percentage of records submitted within expected timelines.
- Timeline from record upload into system and steady state (e.g., approved or final)

## Completeness

- Percentage of expected steady state records in their respective TMF repository.

## Quality

- Percentage of records approved with no quality issues.
- Number of Quality Issues per Quality issue type.

## Use

- Number of users with credentials for that has logged into the system in the last 90 days
- Number of users that have never logged into the system within 30 days of becoming an “active” user



# Setting Thresholds

- Determine the upper and/or lower limit of your threshold.
  - What is ideal?
  - What shows that the process is in jeopardy?
  - When would the process be considered out of control?
- Use built-in reporting tools (if available) to watch trends
- Provide metrics to the study team on a regular basis



# Knowledge is Power

## Metrics help identify:

- Systemic Issues
- Root Causes
- Opportunities for Increase Efficiency
- Gaps
- Overall health of the TMF



# Poll Question

Which of the pillars is most critical to overall quality of the TMF?

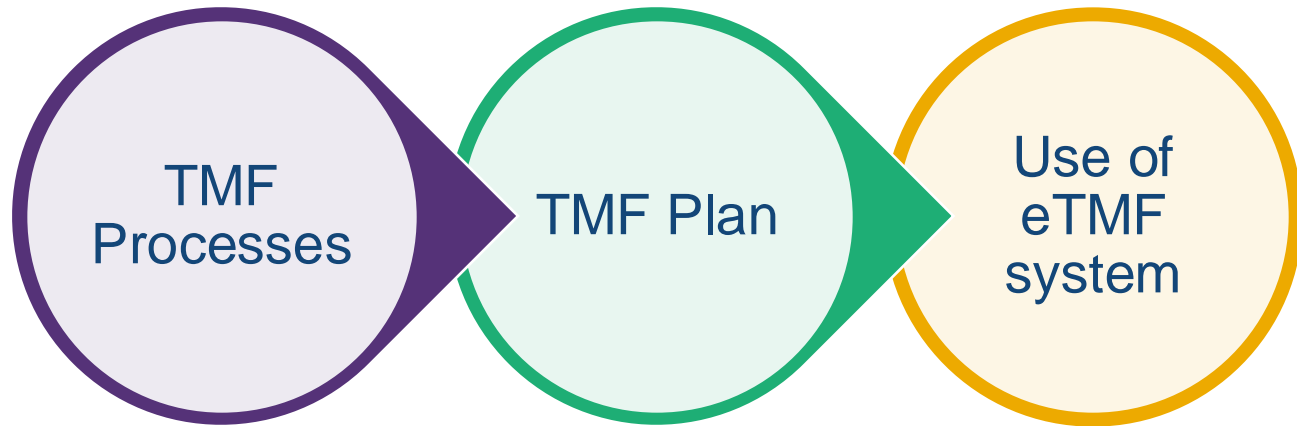
1. Timeliness
2. Completeness
3. Quality
4. All are equally important





# Linking Training to Metrics

# Typical Training



# Targeted Training



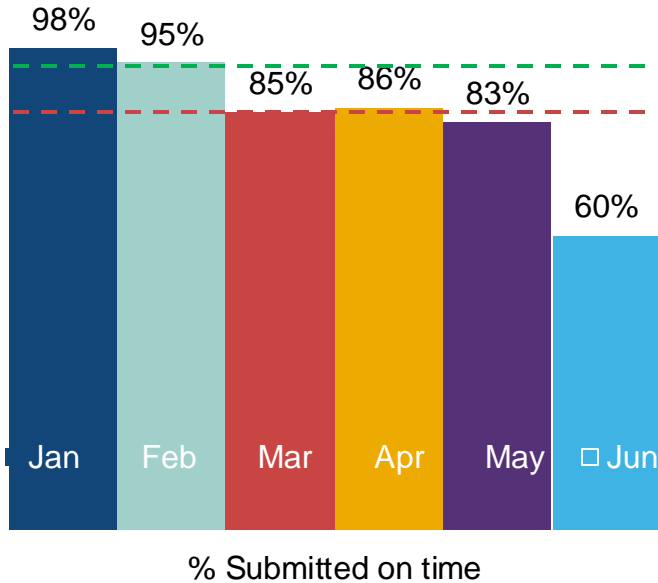
- Targeted training builds on basic training
- Not “retraining”
- Training material focused on the issue at hand.



# Training Methods

- Targeted training is ideally live with embedded engagement with the trainees
- Use of examples helpful to drive key messages
- Involve peers of trainees who are doing well
- Material is not a reiteration of previous training

# Case Study - Timeliness



- Metric

- Percentage of records submitted within 30 calendar days of finalization or collection.
- Target = 95%
- Lower Limit = 85%

- Review of Metric

- Trend shows downward compliance
- Contributing factors
  - End of study start up
  - Majority of late records are from CRAs - May and June were primarily site records



# Timeliness Training

- Create workshop to address the contributing factors
  - Why were the CRAs submitting records late?
  - Determine solutions
- Focus training on the importance of timely submissions to maintain an “inspection steady” TMF
- Share the metrics with the CRAs after the workshop – looking for improvement





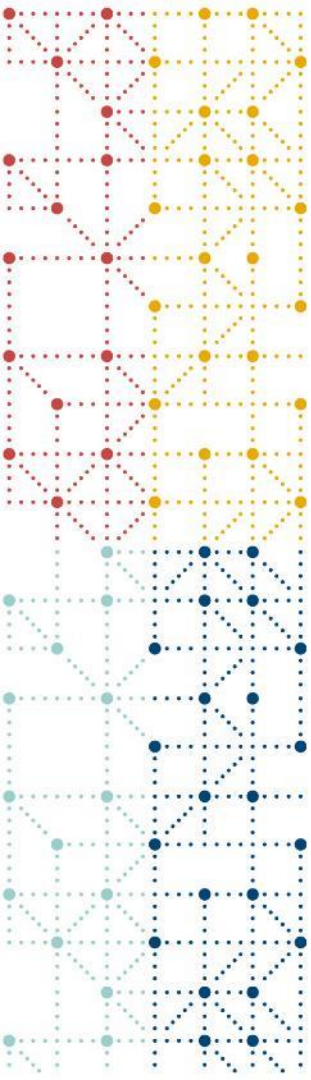
# Incorporating Additional Training

- Consider adding additional content to initial training
- After training workshop, share outputs across teams
- Continually evaluate training program to identify gaps



# Summary

- Continuous training enables study team members to be successful at keeping the TMF “inspection steady”.
- Metrics can drive training that addresses specific issues
- Continuous improvement is the cornerstone of a robust Quality Management System and expected by the regulators



# Thank You!

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