



# cdisc® 2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

## From Flirting to Commitment: Tailoring Your Risk-Based TMF Strategy

Rob Jones, Head of Clinical, Arithmos



ARITHMOS  
Consulting | Technology | Services

## Speakers



**Rob Jones**

Head of Clinical  
At Arithmos

Head of Clinical at Arithmos  
overseeing and getting hands on  
with Essential Documents, Clinical  
Operations, AI and clinical  
systems

A true romantic and devoted to his  
true love, Seth his border Collie



ARITHMOS



# Disclaimer

- The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official position of Arithmos, CDISC, or any regulatory authority.
- The content is provided for informational purposes only and should not be considered regulatory, legal, or compliance advice.

# Agenda

- 1.Introduction
- 2.Five Methods
- 3.Wrap Up
- 4.Questions

# Introduction

Getting flirty

# What does Risk mean to you?

## Key Concept:

Identify what matters most in relation to criticality and quality, and focus your time and resources there, apply proportionate attention to everything else

- ICH E6(R3): 'Risk' Appears 89 times across 86 pages
- ICH E8(R1): Risk identification, evaluation and control embedded throughout
- Regulators across the world: Embracing risk-proportionate oversight at all levels



# Risk-Based takes real time to get right

## Risk-based done WELL:

- Reduced burden, better quality

## Risk-based done POORLY:

- Increased burden, duplicates workload

## TRUE COMMITMENT:

- Putting in the work when it matters

We have all been flirting with Risk for years, now is the time to get serious



# Five Method

The relationship journey

# Method 1: Flirting with metrics

## How its defined:

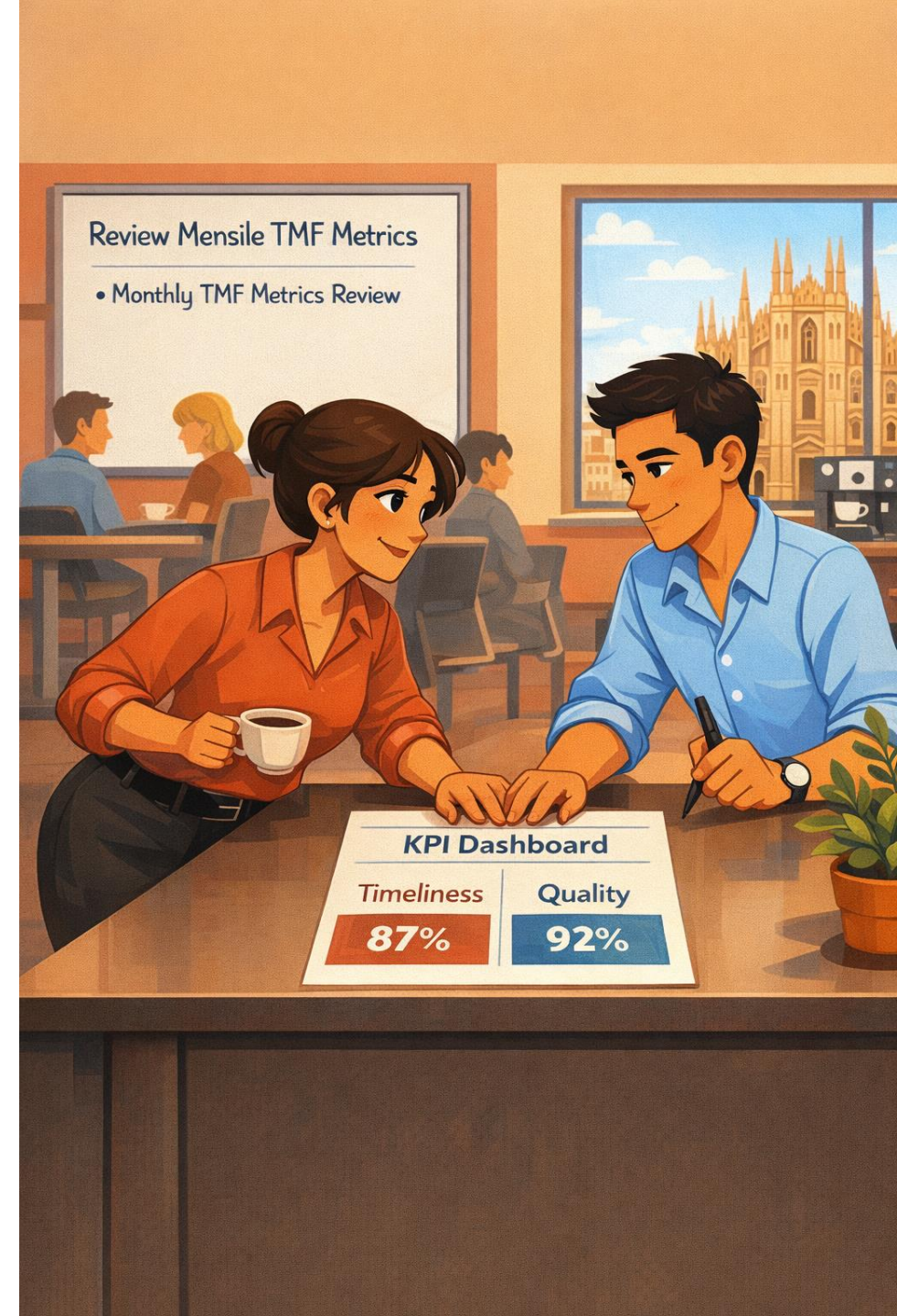
- Track routine TMF metrics monthly
- Set KPI thresholds at three stages
- Define 2<sup>nd</sup> line metrics approach when thresholds are passed

## Real World Example:

- Study 1: All KPIs are green, no additional reports run
- Study 2: First Timeliness Amber result in 6 months, run report again in 2 weeks
- Study 3: Third month in Red for Quality, run additional reports, path to green

## Pros and Cons:

- ✓ Proactive issue identification
- ✓ Data driven and objective
- ✓ Reduces alert fatigue
- ✗ Requires eTMF analytics
- ✗ Involves a baseline for thresholds
- ✗ Staff need time for escalation



# Method 2: DTR (Down to Relationship/Risk)

 How its defined:

- Assign risk score to filing index
- 4 levels; Low, Medium, High and Essential
- Used to define future approaches and record importance



## Real World Example:

- Varying filing timelines for Essential Records
  - Essential: 15 days
  - Others: 30 days
- Build future QC and Periodic Review processes



## Pros and Cons:

- ✓ Foundation for other methods
- ✓ Objective framework
- ✓ No technology need
- ✓ Upfront categorization work
- ✗ Requires rationale
- ✗ Removes one-size-fits-all
- ✗



# Method 3: QC, but with a safety net

## How its defined:

- Use the risk score to define QC intensity
- Various levels from 0% QC to 100%
- Keep your periodic reviews to catch misses

## Real World Example:

- Standard approach: 100% QC of all submitted documents
- Risk Based QC
  - High Risk: 100%
  - Medium Risk: 40%
  - Low Risk: 0% or automated

## Pros and Cons:

- ✓ Immediate workload reduction Scales with volume
- ✓ Requires sophisticated systems
- ✗ Reactive workload increase is expected
- ✗



# Method 4: Real trust in your reviews

## How its defined:

- Tailored review frequency based on study design
- Milestone, Quarterly, Semi-Annually
- Record type specific checks
  - Cross
  - Logic
  - Metadata

## Real World Example:

- Phase I trial, 9 months: Milestone based review
- Phase III trial, 5 years, start quarterly, eventually semi-annually
- FDA 1572, check across CVs, Medical License etc.

## Pros and Cons:

- ✓ Reduction in review fatigue
- ✓ Efficiency across portfolio
- ✓ Scalable
- ✓ Encourages critical thinking
- ✗ Requires record governance
- ✗ Reactive workload increase is expected
- ✗ Must have trust



# Method 5: Long term commitment to oversight

## How its defined:

- Utilize vendor performance across multiple studies
- Vendor specific metrics made up from all studies
- Provide vendor insight to proactively identify risks in other studies



## Real World Example:

- Metrics indicate monitoring issue with CRA in Italy for study A
- Study B is about to go live in Italy, increase training proactively
- Increase oversight in study C

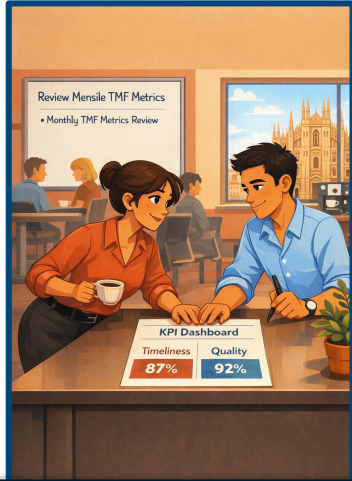


## Pros and Cons:

- ✓ Leverage existing data
- ✓ Predictive versus reactive
- ✓ Catch systemic issues early
- ✗ Requires large volume of data to be synthesized
- ✗ Dependent on mature vendor management
- ✗ Only valuable at scale



# Summary



**You can't skip ahead, trust and commitment to the process is essential for organic growth**

# Wrap Up

Finding the one

# Why organizations get stuck

"We aren't ready for this yet"

"I don't know what to do, there is only me"

"We have always done it this way and it's been ok"

"Our partners have their own process and don't want to follow ours"

"But what if we make a mistake?"



# Real commitment is working hard for what matters

Less work overall  
Lower quality standards  
Doing the bare minimum



Less work on Low-Risk  
More work on High-Risk  
Times of increased intensity



Work Smarter | Evolve Resources | Dynamic Focus

Perfection in every aspect of an activity is rarely achievable or can only be achieved by use of resources that are out of proportion to the benefit obtained.

*ICH E8(R1) Section 3.2 Critical to Quality Factors*



# Questions?





**Thank You!**

