



2024 CDISC + TMF
EUROPE INTERCHANGE

BERLIN

24-25 APRIL: CONFERENCE & EXPO | 22, 23, 26 APRIL: TRAININGS

We are the (TMF) Champions:

A case study on how data can be used to strengthen collaboration, and back up a bold claim!

Presented by

Jason Weinstein, Associate Director TMF, DRM, Regeneron

Jacqueline Petty, Expert Services Lead, Professional Services, Cencora Pharmalex



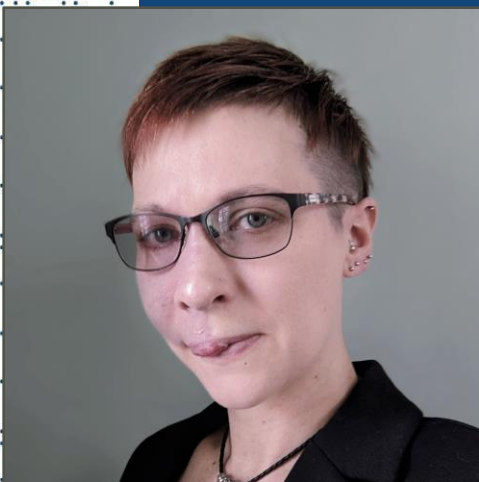
Meet the Speakers

Jason Weinstein

Title: Associate Director, TMF

Organization: Regeneron Pharmaceuticals

Jason is the Head of TMF Operations at Regeneron Pharmaceuticals. He has a decade of TMF experience that includes document migrations, regulatory inspections (FDA, PMDA, EMA), vendor oversight, TMF operations management, eTMF system management, and TMF health reporting. In his current role, Jason oversees document governance and processing, study team accountability and support, and the overall health of the TMF portfolio across Regeneron. Jason is also an active member of the CDISC TMF Reference Model.



Jacki Petty

Title: Expert Services Lead

Organization: Cencora Pharmalex

With a TMF career spanning 20 years, Jacki now primarily focuses on providing TMF expertise and oversight to customers, while also supporting internal learning and development. Through varied roles, she has had exposure to all aspects of TMF management while working alongside a variety of Sponsors and TMF stakeholders. Jacki currently acts as a TMF Programme Lead, providing critical oversight and supporting our team of TMF study resources at Regeneron.



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 author(s) have no real or apparent conflicts of interest to report.*



Agenda

1. The TMF Labyrinth
2. Proving Champion Status
3. Steps to Success
4. One Outcome... Double the Value
5. Supporting & Celebrating our Champions

The TMF Labyrinth...

- The ultimate goal of any Sponsor is to get drugs to market.
- Requires navigating the TMF labyrinth.
- Efficiently navigating is the key to being victorious!



TMF Leads Guiding the Way

- The labyrinth cannot be navigated without a helping hand.
- Requires a strong team of subject matter experts (SMEs).

Provide critical SME support

Raise the profile of the TMF

Share expectations

Guide functional groups

Facilitate TMF activities

- They help keep the study team moving towards our shared goal.

These SMEs are our TMF Champions!



Proving Champion Status

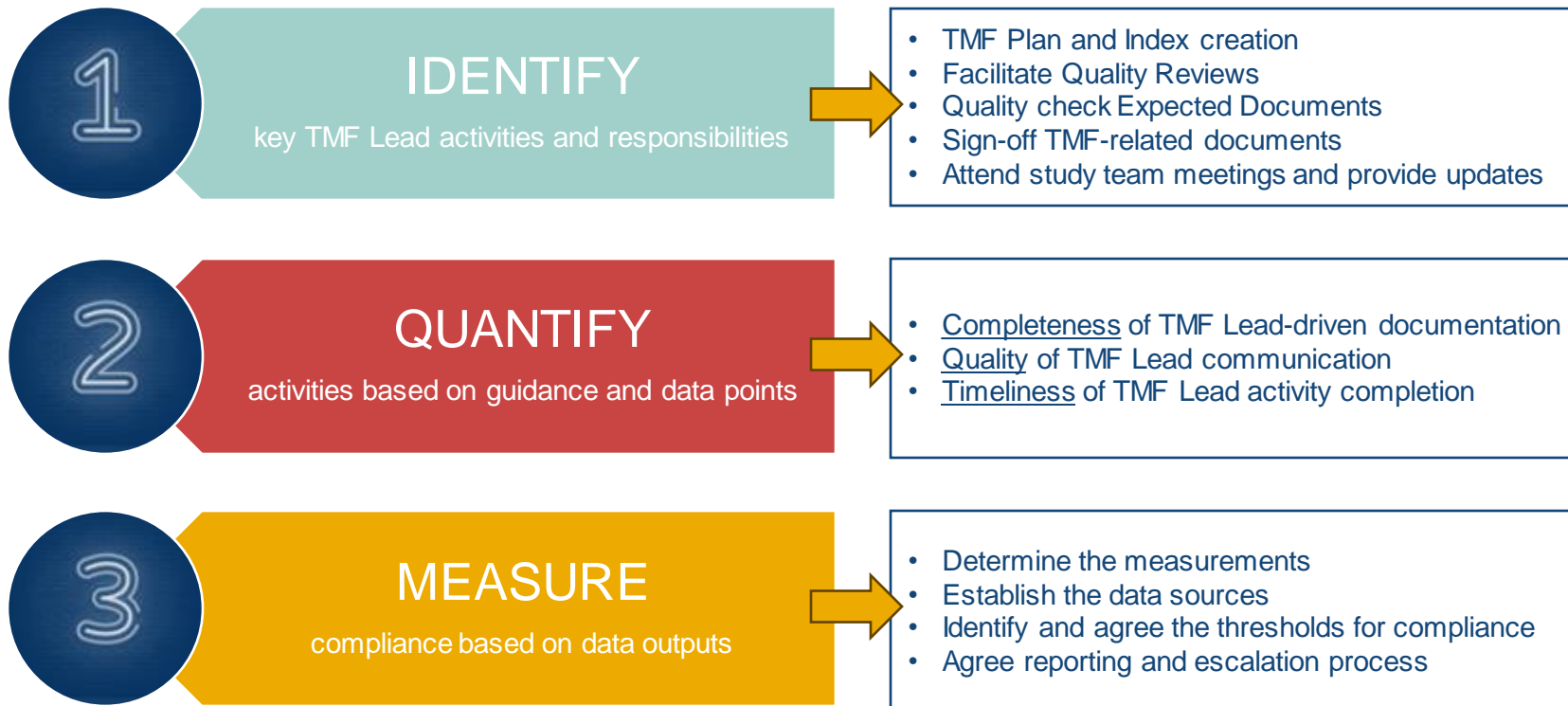
We know our TMF Leads are champions.

Our Study Teams know they are champions

However, *knowing* something and *proving* something are two different things.

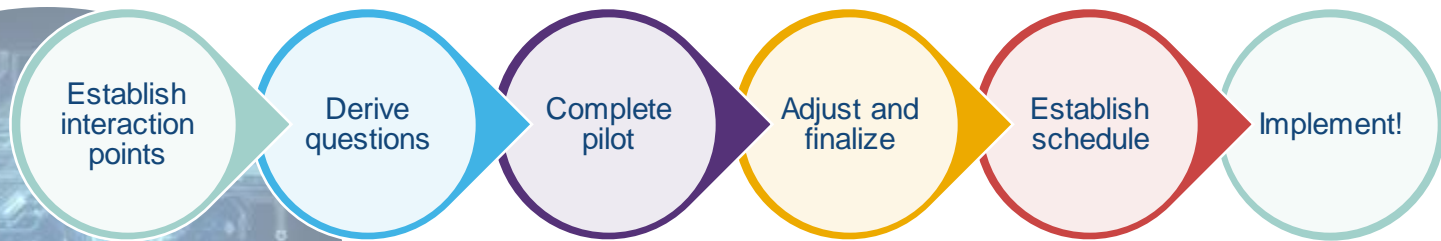


3 Steps to Success



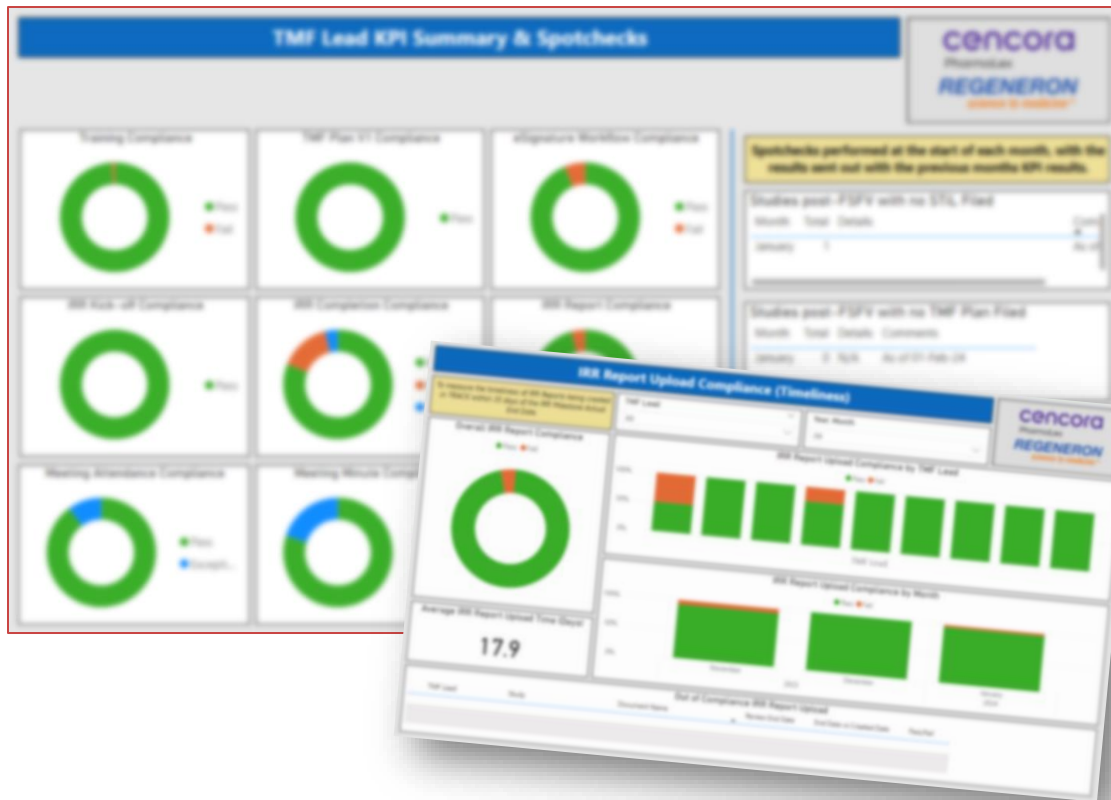
Thinking Outside the System

- Quantitative data is great, but isn't the full picture...
- How do we unlock the valuable *qualitative* data Clinical Study Teams hold on critical day-to-day interactions and activities?



Our answer was a targeted questionnaire, allowing response on 5 key areas of interaction, with additional free text feedback.

One Outcome...



Activity-driven Key Performance Indicators (KPIs)

Robust system-driven data

Insightful qualitative data

Clear, visual analysis

Actionable insights

Efficient, periodic reporting

Collaborative oversight

...Double the Value!

Sponsor



Vendor

Supporting our Champions



Head of TMF
Operations

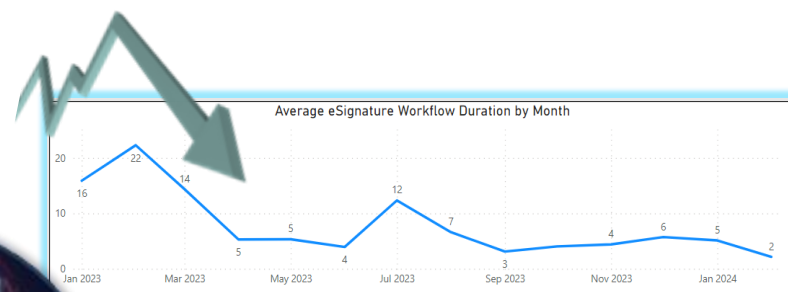
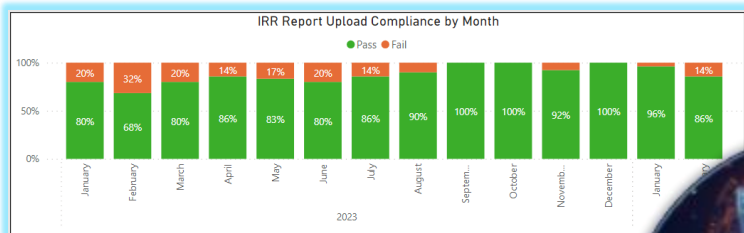


TMF
Programme
Manager



TMF Leads

Celebrating our Champions

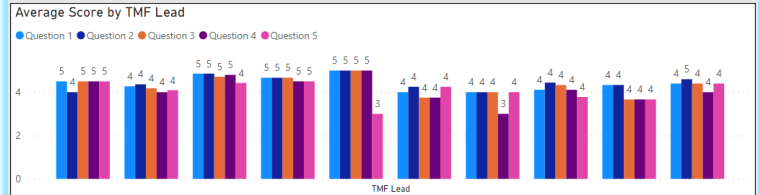
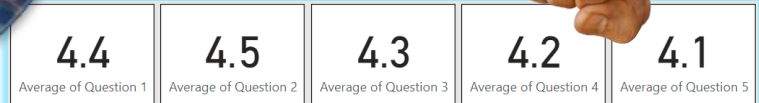
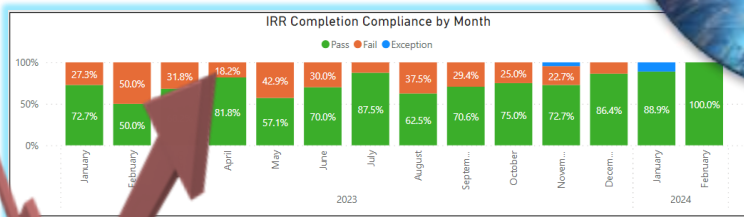


Improved & maintained compliance

Improved timeliness



Study team satisfaction





Thank You!

