



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

Keeping People in the Loop: Empowering TMF Teams Through AI and Automation

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Disclaimer

- *The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of CDISC, Phlexglobal, or Regeneron.*



Agenda

1. The TMF Landscape: Why Change Is Necessary
2. Identifying & Implementing Automation Opportunities
3. Empowering People: Upskilling & Change Management
4. Results: Engagement, Ownership & Innovation
5. Key Takeaways & Your Next Steps

Speakers



Jason Weinstein
Head of TMF Operations
Regeneron Pharmaceuticals



Dionne Manicom
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The TMF Landscape: Why Change Is Necessary

Setting the Scene



Identifying the Automation Opportunity

- **How We Identified Automation Potential**

- Reviewed all TMF activities to identify high-volume, rule-based tasks
- Engaged TMF team members directly: “What tasks drain your energy every day?”
- Prioritized by frequency, error risk, and associate time cost

- **Key Principle**

- Automate tasks, not people — free capacity for meaningful work

Up to 40% of TMF team time is spent on repetitive, low-complexity tasks

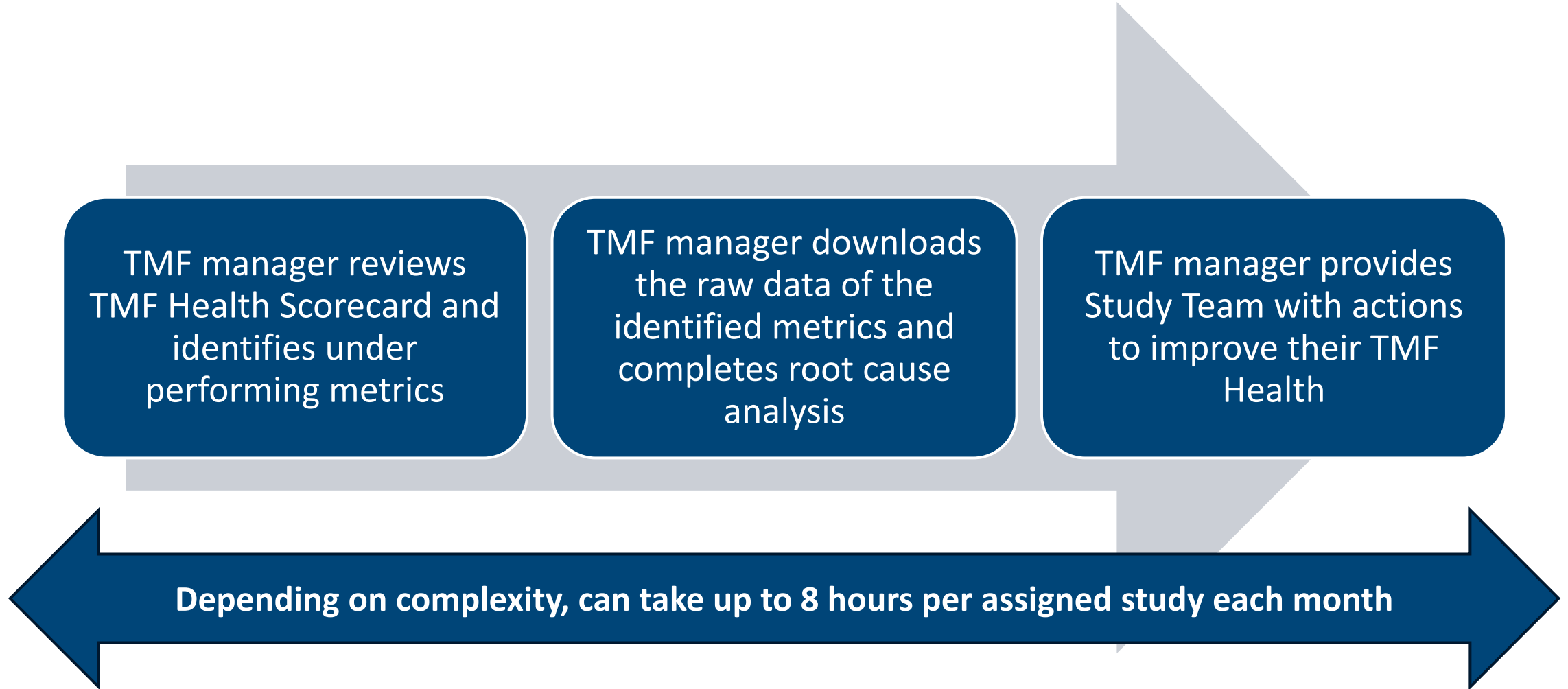


Starting our AI Journey...

- **Document Processing and QC**
 - Auto-classify
 - Automatically apply required metadata
 - Automate simple QC
- **TMF Health Root Cause Analysis**
 - Analyze TMF health data
 - Provide recommendations to improve TMF health
 - Allow TMF managers to interrogate feedback



Manual Process for TMF Health Analysis





Information Overload



Identifying & Implementing Automation Opportunities

Building a Robot

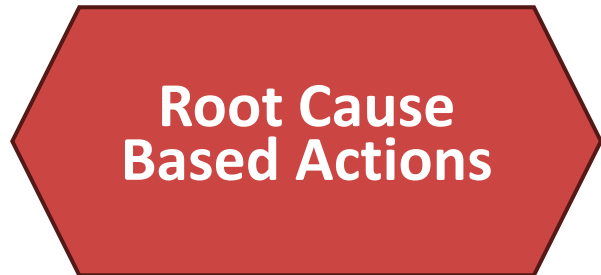
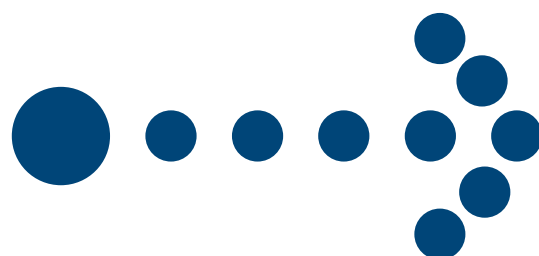
eTMF Data



TMF Metric
Details



REGN Specific
Training



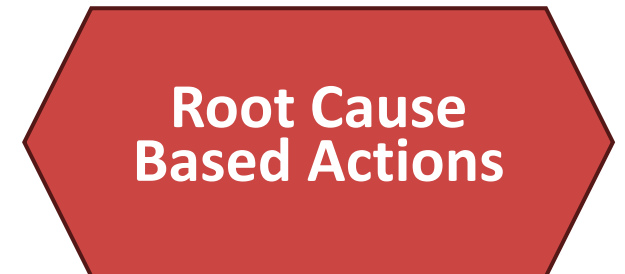
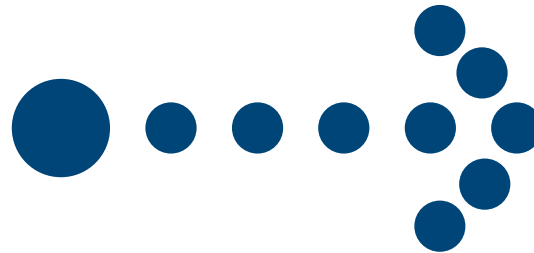
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Empowering Our People

A People-Driven Transformation

Proactive Communication



Transparent roadmaps shared with all team members early



Regular town halls: What's changing, why, and what it means for your role



Emphasize the Benefits



Culture of Innovation and Upskilling

Embrace Change

Pilot with Sr TMF managers as
“automation champions”

Celebrate learning from failures, not
just successes



Challenges

Expected and Unexpected

Expected Challenges

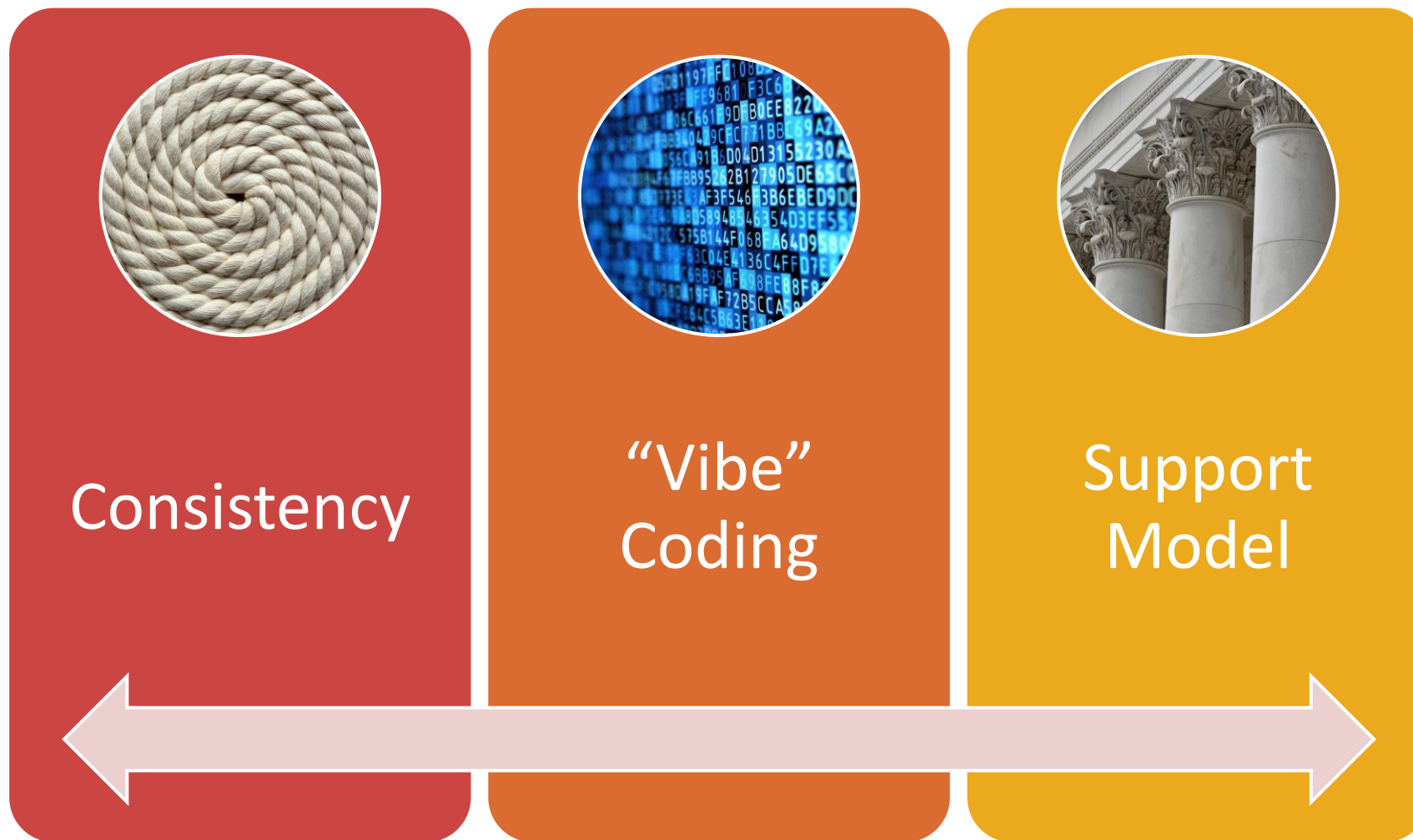
TMF Data Integration

- Data Definitions
- Data Mapping

Validation

- Is it required?
- Do we have a process?

Unexpected Challenges





Expected Results & Outcomes

Measuring What Matters

**Greater Study Team
Engagement**

TMF Manager Time Saved

**Expected
Results**

**Consistency Across TMF
Operations**

Improved TMF Health

Expected Impact Highlights



Greater Study Team Engagement

- Clearer definition of action ownership leads to a more engaged study team
- Actions will be tracked at the study level



Improved TMF Health

- Reduced ambiguity will lead to increased compliance
- Focusing on actions that have the greatest impact



Next Steps

Short Term and Forward Looking

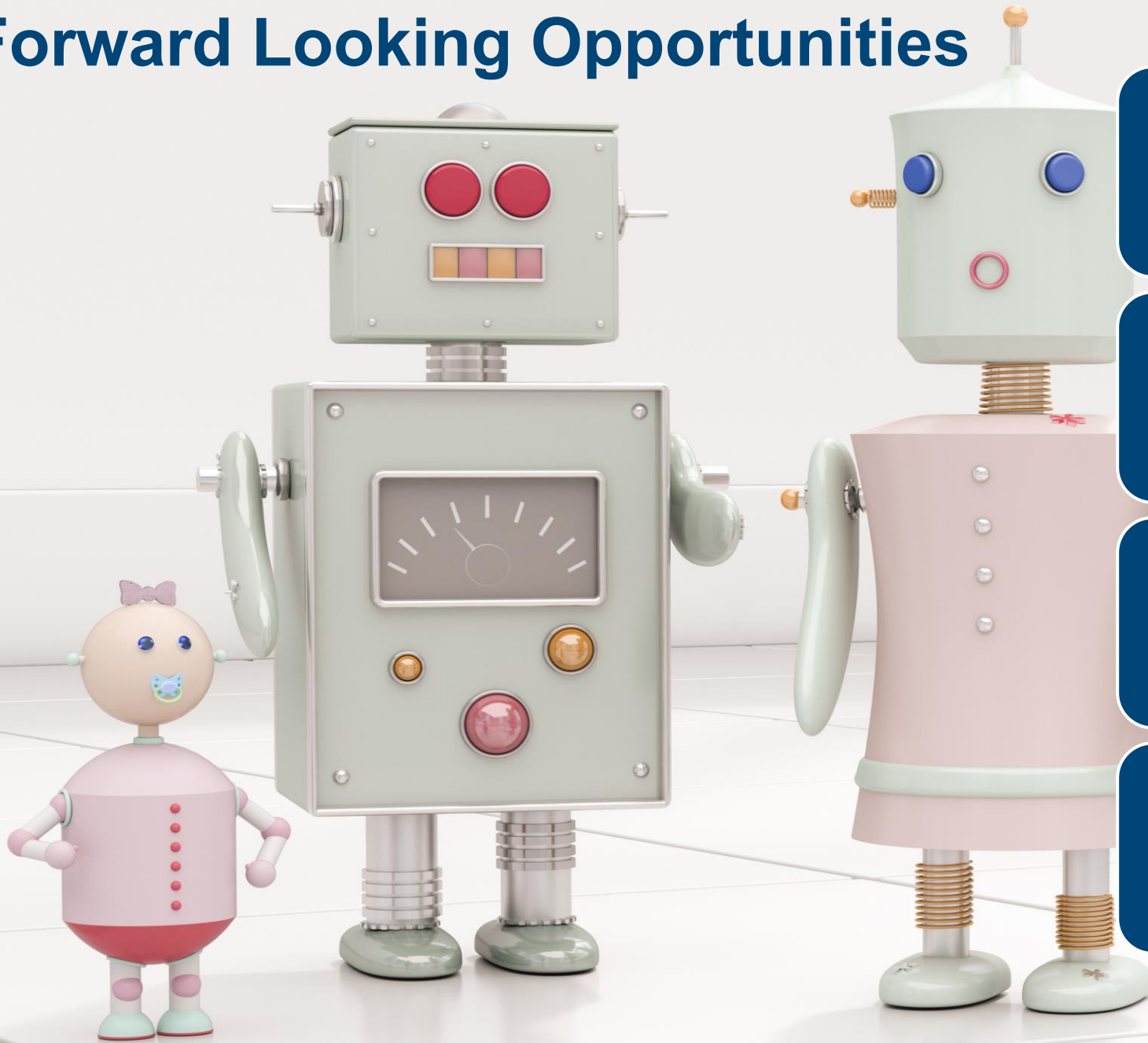
Short Term Actions

Update/Refine THIAA Consistency

Pilot with TMF Managers

Monitor THIAA for AI Drift

Forward Looking Opportunities



Proactive TMF Health Feedback

TMF User Q&A Chat

Natural Language Search for Inspections/Audits

Predictive Metrics



Questions?

