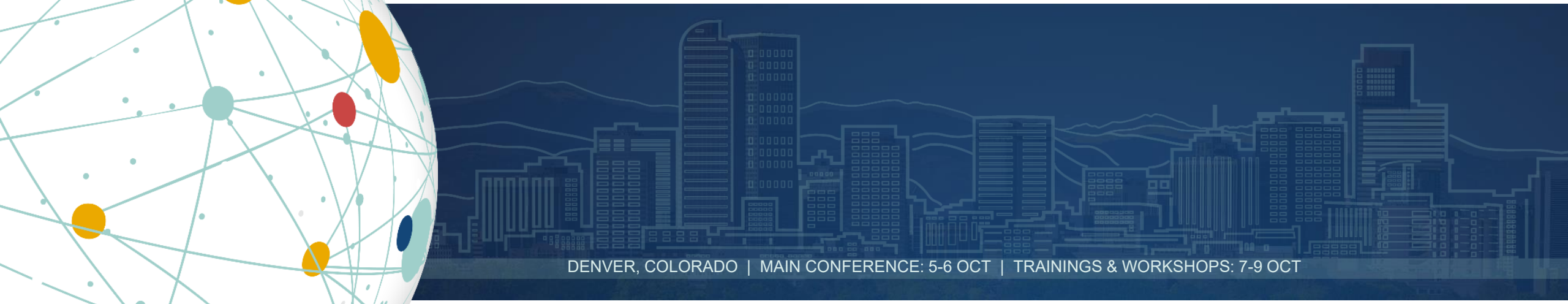


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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



From AI Hype to TMF Reality: Early Lessons from Implementing AI Agents

Pawel Rucki, Head of Clinical Product Development, Base life science
Jamie Toth, Sr. Director, Global TMF Management & Records at BeOne Medicines, USA.
Nisi Nazim, Associate Director, TMF Systems, BeOne Medicines, USA

DISCLAIMER

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 or the company of which the presenters are employed.

Agenda

1. **The Hype Phase**
   Why everyone wants a moonshot
2. **Charting the Course**
   TMF evolution and the reality check
3. **Blast Off**
   Standing up the crew and going live
4. **Through the Atmosphere**
   Turbulence: roles, adoption, change
5. **Trajectory**
   Objectives, guardrails and tuning
6. **Mission Control**
   Governance, oversight and telemetry
7. **Lunar Orbit**
   Proven use cases and rollout
8. **Moon Landing**
   Where we see real value
9. **The Next Frontier**
   Releases 2 and 3

Speakers



Pawel Rucki
Head of Clinical Product Development
Base life science
Pawel Rucki is Head of Clinical Product Development at BASE Life Science. He has spent over 12 years in clinical operations, spanning clinical systems implementation, inspection readiness, records management and archiving, and CRO oversight. He now leads product direction for BASE's clinical operations portfolio, with a current focus on applying AI agents to TMF quality and completeness, and the governance and validation model needed to run them under GCP.



Jamie Toth
Sr. Director, Global TMF Management & Records
BeOne Medicines, USA
Jamie is a Steering Committee member for the CDISC TMF Reference Model Working Group and the Incoming Chair Elect. She is on the Board of Directors for the Health Sciences Records and Archives Association (HSRAA) and on the Board of Directors for the Association for GxP Excellence (AGxPE).
Jamie has over 18+ years experience in Clinical Systems.



Nisi Nazim
Associate Director, TMF Systems
BeOne Medicines, USA
16 years' experience in the Clinical Systems domain responsible for delivering system enhancements, process improvements as well as leading migrations for the electronic Trial Master File (eTMF).

The Hype Phase

"We didn't go to the moon because it was easy. We went because it required discipline, innovation, and execution."

- Adapted from John F. Kennedy, 1962

AI in TMF is no different.

The Hype Phase

OUR VISION:

01 Automation across the TMF

02 Issues Caught Earlier

03 Inspection-Ready, Steady TMF

04 A Scalable Foundation



Charting the Course

"We choose to go to the Moon in this decade and do the other things, not because they are easy, but because they are hard."

— John F. Kennedy, 1962

TMF Evolution: 2022 – 2027

2022
Transformation

- Identified areas for transformation, including system and process and built team

37,000 docs

2023
Implementation

- Launched new eTMF and globally harmonized processes
- Migrated records
- Risk tiering of records

49,000 docs

2024
Optimization

- Continued migrations
- Began integrations
- Fully implemented risk tiering of records

92,000 docs

2025
Maximization

- Additional integrations
- Decommission of old eTMF
- FQC risk-based approach

60,000 docs

2026
Elevation

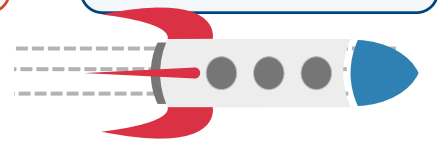
- More integrations
- AI Release 1

YTD 68,000 docs

2027
Acceleration

- AI Releases 2 & 3
- CDISC TMF Standard Model V1

AI 'MISSION DESIGN'



2024
Use cases defined

Late 2024
RFI started

2025
RFP and vendor demos

Nov 2025 – Mar 2026
Senior mgmt approvals

April 2026
Kick off and workshops

Q4 2026
Go-live

Ignition Timeline

Charting the Course

The Reality Check

Turbulence on ascent

- Classification accuracy
- Metadata quality
- Validation requirements
- Change management
- User adoption

The Crew

The people side of change

- Roles evolving toward meaningful TMF work
- Maintaining lists and placeholders
- Sending documents to the inbox
- OCM: SteerCo, F2F, CCRB, newsletters

AI's impact to people

Set expectations early on what AI will and won't do

Global TMF roles evolving into Functional QC

Service-provider QC work diminishing

Blast Off

"Liftoff. We have liftoff."

— NASA launch commentary, Apollo 11, 16 July 1969

We are go for launch



Through the Atmosphere

"Failure is not an option."

— Gene Kranz, NASA flight director

Through the Atmosphere

Mission Control



Steering Committee

Representation across all R&D

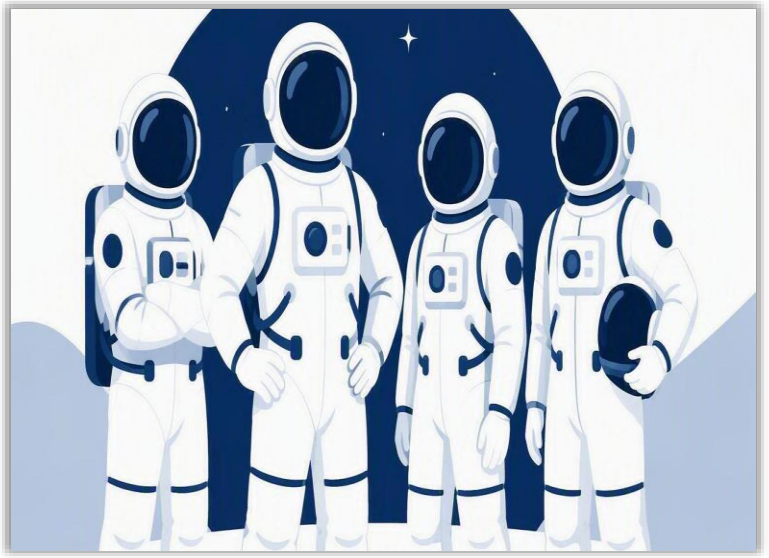
Bridge



Core Team

Cross-functional, Cross-regional,
IT, CSV/QA, Training
Service Provider

Space Crew



TMF Representatives / End Users

AI's Impact to People



1

Set expectations early

Remind people up front what AI will do — and what it won't.

2

Roles are evolving

Global TMF roles are changing as work shifts into Functional QC.

3

QC work is shrinking

Service-provider QC volume diminishes as automation takes on review.

Trajectory

"A moonshot is won with small mid-course corrections, not one big burn"

Source: NASA, Apollo 11 Mission Report, translunar midcourse corrections, July 1969

Mission Objectives

PRIMARY OBJECTIVE

KEEP THE TMF INSPECTION-READY

SECONDARY OBJECTIVES

01 **Log on arrival**
Classification and metadata

02 **Clear before filing**
ALCOA++ records quality

03 **Sweep on schedule**
Functional Quality Checks

Flight Simulator

Prototype → **Review** → Requirements → Risk assessment

We built clickable prototypes on a developer platform before writing any requirements

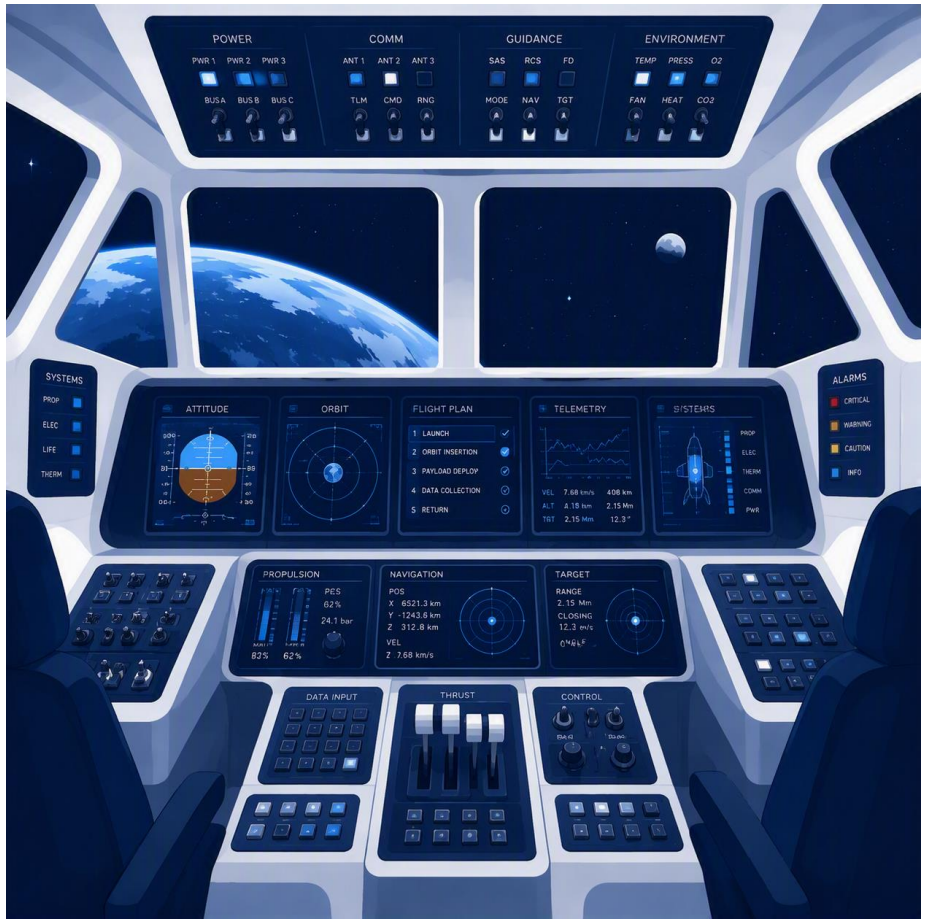
The TMF team commented directly on the screens. Sixteen rounds, each rebuilt and back within 24h

Written afterwards, from the screens that had already survived review

The prototype showed where the agent hands off. That is where the human-in-the-loop controls were placed



Built to Be Steered



ADAPTING MEANS CHANGING A SETTING, NOT THE SYSTEM

TUNED

- **Thresholds** - when a signal becomes an issue
- **Tolerances** - how much variance is accepted

VERSIONED

- **Prompts** - what each agent looks for
- **Model version** - which model is in service

Mission Control

"Apollo never flew itself – a room full of people watched every parameter."

Source: NASA, Apollo Flight Operations, Mission Control Center, Houston

Mission Control and Autopilot

WHEN	HANDOVER TO	HUMAN-IN-THE-LOOP
Any Major finding at any risk tier	**QC workflow** document is QC rejected	Whether the finding stands, and how it is resolved
High or Medium Risk Records are stopped for review	**Review before filing** nothing files unverified	Whether the AI graded it right, and whether it missed anything
Low Risk Records are allowed to proceed	**No one, before filing** agent files autonomously	Nothing at the gate. Sampled post-approval review is the control



Telemetry and Response

MEASUREMENTS

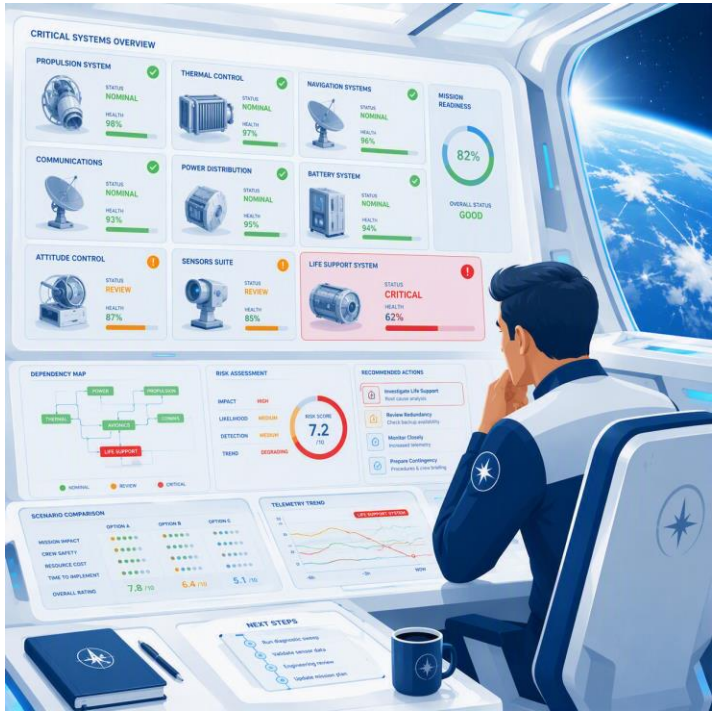
We mine the agent's and the human's audit trail to see where the agent's output gets corrected, and how often. Frequent correction raises a signal.

ASSESSMENT

The signal is assessed both ways: is the agent wrong, or is the human over-correcting? Nothing is decided before that question is answered.

RESPONSE

The agent may need recalibration, a check may need retuning, or the people may need training. AI makes mistakes. So do humans.



Lunar Orbit

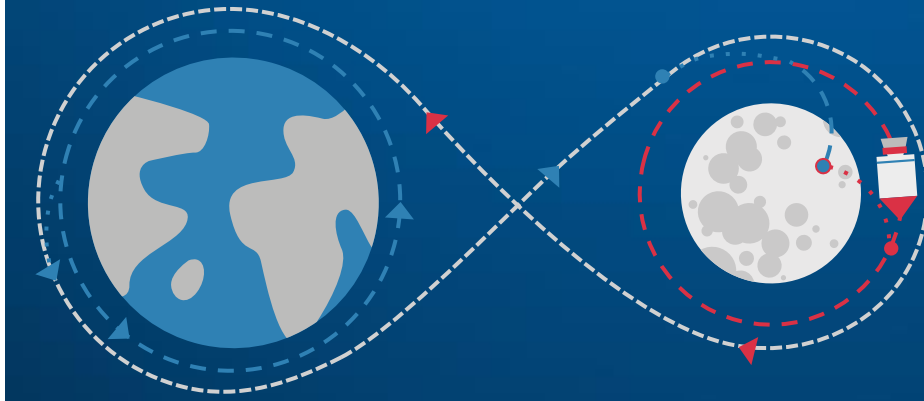
"The sky is not the limit; it's just the beginning."

— popular aviation saying (author unknown)

Lunar Orbit

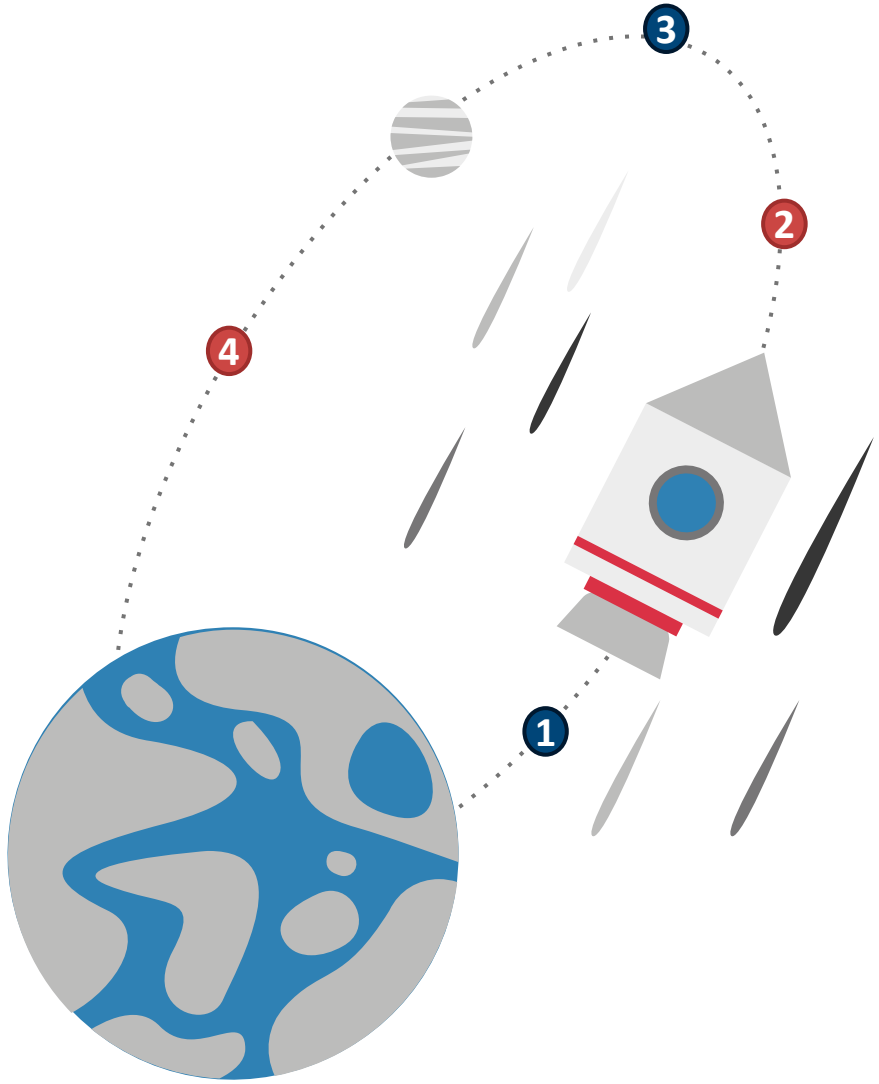
Proven Use Cases

- Document classification
- Metadata extraction
- QC support
- TMF health analytics



Process

1	Mapping out As Is and To Be considering AI and HITL
2	Evaluating existing TMF KPIs and metrics
3	Reviewing static TMF Index holistically
4	Aligning with RBQM on risk-based strategy



Things each of us would tell the next team

BeOne	Base
Please participate if you have been nominated to be on the project	Educate the team on what AI can actually do, before expectations are set
Change doesn't happen over night – it takes time and reiteration...just like AI!	Plan for access and test data as a workstream, not a task
Plan – plan – and plan some more!	Give the prototype to somebody who was not on the project
Always anticipate the next move and be prepared!	Don’t underestimate the development timeline and configuration of the primary system

Moon Landing

“Landing is harder than launching.”

Source: NASA, Apollo 11 Mission Report, lunar module descent, July 1969

Moon Landing

J

WHERE WE ANTICIPATE REAL VALUE

- Time savings
- Improved quality
- Reduced manual effort
- Faster inspection readiness



The technology was never the hardest part of this program. Governance, people and process are what bring it safely down.

Come to CDISC Barcelona May 2027 to hear about the landing!

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Next Frontier

“The moon isn't the destination. It's the first landing.”

Source: NASA, Moon to Mars objectives, Artemis program

The Next Frontier

WHERE WE GO FROM HERE

RELEASE 1

Building the foundation

RELEASES 2 AND 3

Planned for 2027 …



Thank You!



Questions?

