



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

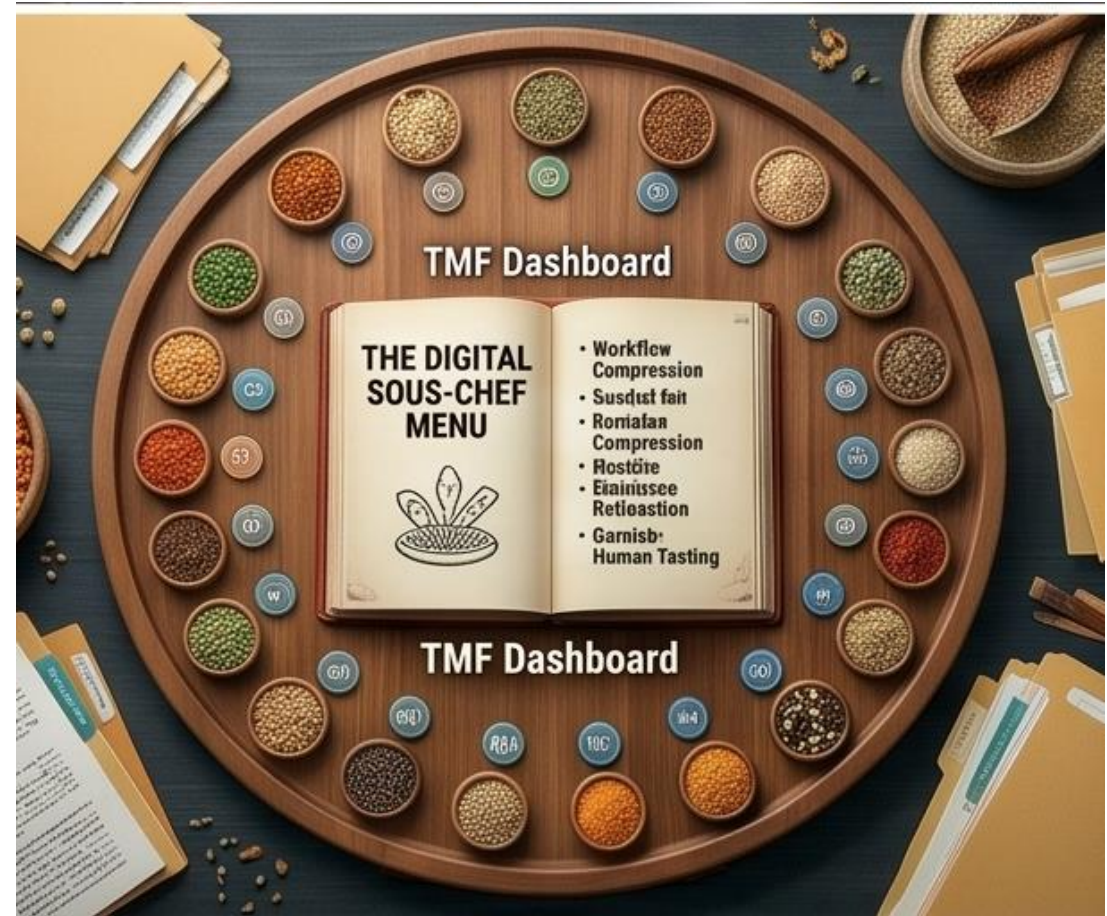
The Digital TMF Sous-Chef: How AI Preps the Mise-en-Place for TMF Excellence

Pallavi Tadimeti

Associate Director, TMF Operations at Blueprint Medicines, a Sanofi Company

Agenda

- Setting the Kitchen: Why TMF needs a Sous-Chef
- Mis-en-place for TMF
- Prepping your Station
- Tasting & Quality Control (Human-in-the-loop)
- Menu engineering: What to automate first?
- Recipe cards for Tasty Outcomes
- Chef Notes from the Kitchen!



Speakers



Pallavi Tadimeti

Associate Director,
TMF Operations

Blueprint Medicines, a
Sanofi Company

Pallavi Tadimeti is an Associate Director of TMF Operations at Blueprint Medicines and a passionate advocate for modernizing Trial Master File practices. With 11+ years of experience in Biotech and Pharmaceuticals, spanning TMF operations and inspection readiness, she has led impactful eTMF transformations, and enterprise governance.

Known for her collaborative leadership style, Pallavi works across functions and with CRO partners to drive continuous improvement and sustainable, inspection-ready TMF ecosystems using practical, scalable solutions—and brings a collaborative, data-driven approach to TMF excellence. She is especially interested in how innovation and emerging technologies, including AI, can shape the future of TMF management.

Your Digital Sous Chef: How AI Preps the Mise en Place for TMF Excellence

Elevating TMF operations through intelligent automation and human expertise

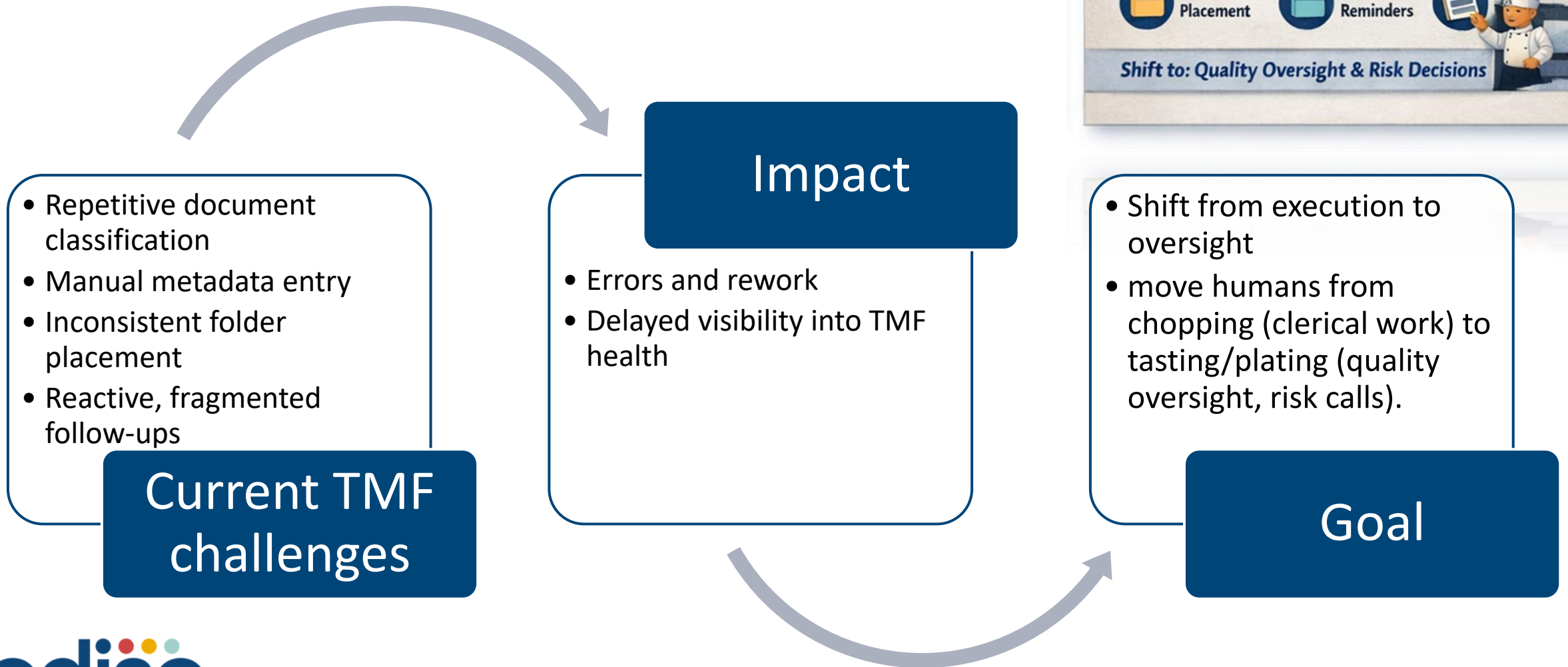
AI as the **Digital Sous Chef** supporting TMF operations

TMF Lead : **Head Chef** directing strategy and quality

Outcome: Faster execution, higher quality, inspection readiness



Setting the Kitchen: Why TMF Needs a Sous Chef



Mise- en-Place for TMF

AI capabilities:

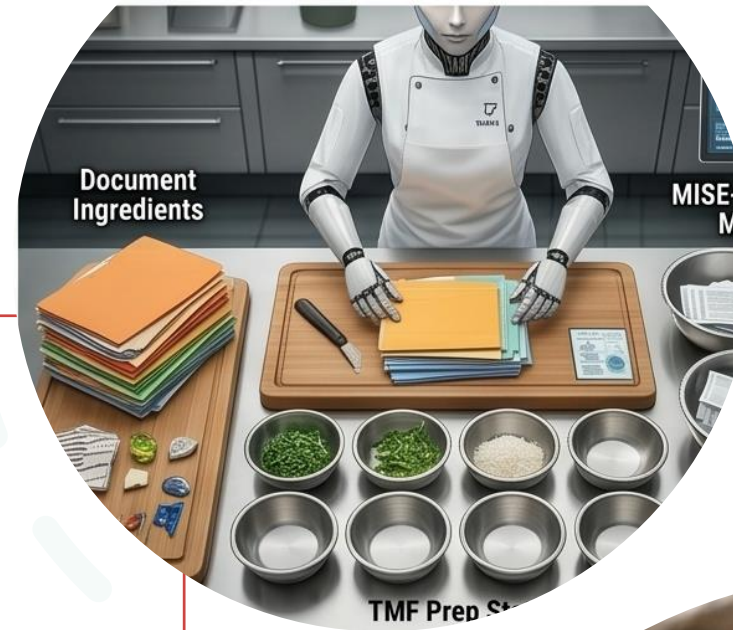
- Automated document classification
- Metadata extraction and tagging
- Compliant filing

Benefits:

- Reduced human error
- Faster quality control cycles
- Real-time TMF

Outcome:

- Proactive issue detection and correction



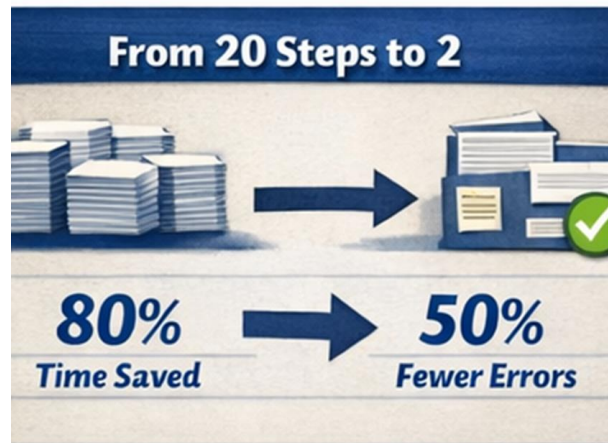


Prep Station (Personal Productivity)

Everyday sous chef tasks in your inbox & calendar

- Tone check for an email before you “plate” communication.
- Weekly task list generated from meeting notes.
- Auto reminders created by triaging Outlook messages.

Increase Efficiency, Reduce Labor!



Classification recipe:

“Classify incoming TMF documents by Reference Model category and propose metadata (title, date, site, country, artifact) with confidence scores.”

QC recipe: “Identify likely misfiles/duplicates and missing signatures; return a checklist with severity and recommended actions.”

Comms recipe: “Draft a status email to study team summarizing TMF completeness %, open queries, and upcoming milestones in 150 words.”

The Entrée: Predictive Intelligence (systemic AI support)

Taste before plating—catch risks early

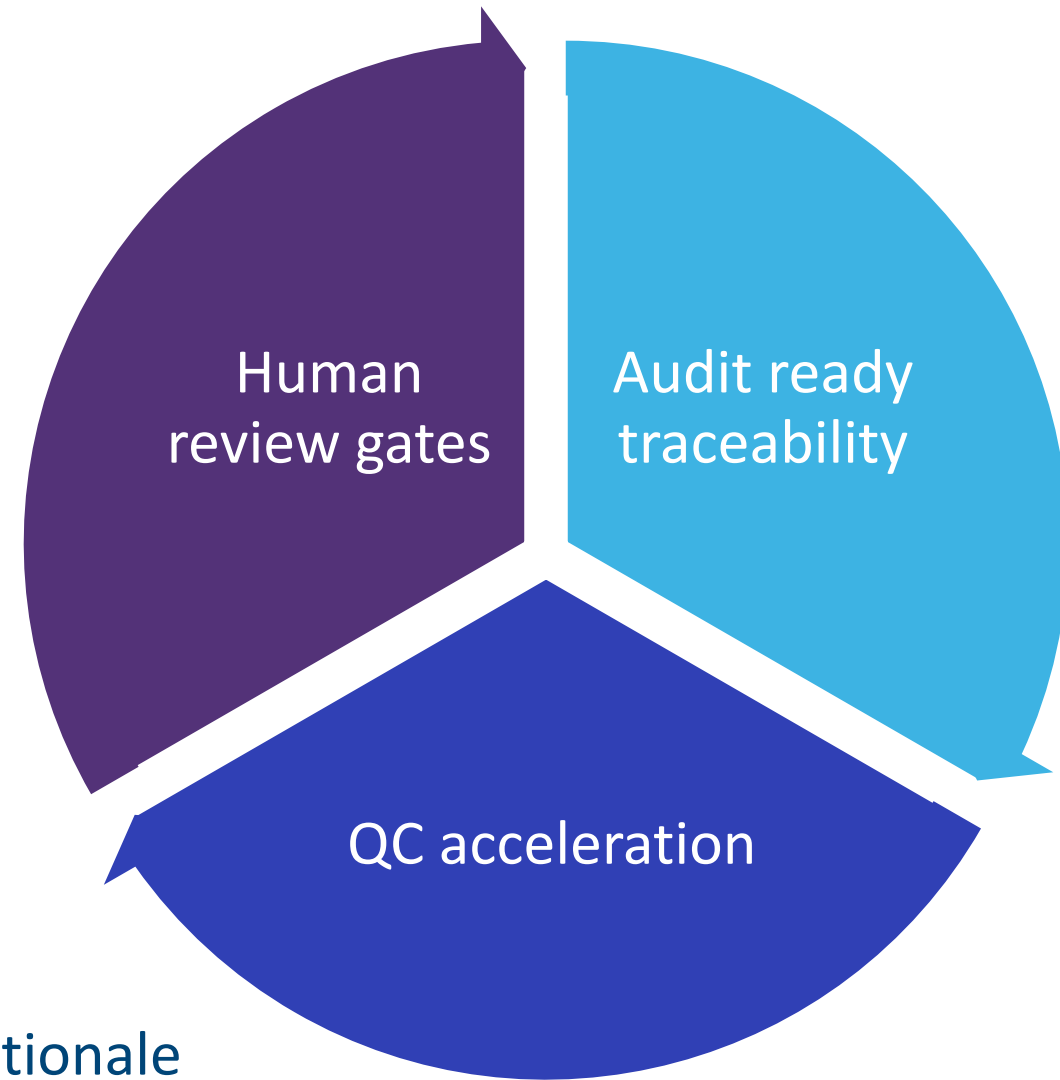
Early warning signals: missing signatures; site performance risk; timeliness gaps.

Actionable alerts drive targeted follow up (who/what/when).



Tasting & Quality Control (Human in the Loop)

Balance autonomy
with oversight



Record rationale
for
decisions.

Head chef signs off

Menu Engineering: What to Automate First

Pick dishes with high prep to impact ratio

High Volume

Classification/ Metadata



Low Risk

Medium Volume

Reminders/ Task Lists



Medium Risk

You're building a workflow that integrates with the system you already have, starting with the use cases that deliver the most value at the lowest friction.



To turn your TMF operations into a Michelin-star kitchen, we've reimaged your project management prompts as Recipe Cards.

Managing projects can often feel like trying to herd cats while juggling flaming torches.

To lower the temperature, you can use AI as a "Digital Chief of Staff."





The "Status Report" Automator

Use Case: When you need to update stakeholders but don't want to spend an hour formatting an email.

The Prompt:

"Act as a Senior Project Manager. Based on these three bullet points: [Insert: Task A done, Task B delayed due to tech glitch, Task C starting tomorrow], write a professional status update email.

Tone: Transparent but solution-oriented.

Structure: > * Current Health (*Green/Yellow/Red*)

Wins this week

Roadblocks & Mitigations

The 'Big Goal' for next week."





The "Pre-Mortem" Risk Scout

Use Case: Before launching a new phase or project to catch blind spots.

The Prompt:

"I am starting a project focused on [Insert Project Goal]. We are using a team of [Number] and have a deadline of [Date].

Imagine it is six months from now and the project has failed. List the top 5 most likely reasons why it failed (technical, cultural, or logistical) and provide one 'Preventative Action' for each risk."

Output: Project plan





The "Conflict & Tone" Refiner

Use Case: When you need to send a firm "nudge" to a teammate without sounding like a villain.

The Prompt:

"I need to tell a team member that their deliverable is 2 days late and it's holding up the entire pipeline. I'm feeling frustrated, but I want to stay supportive and professional.

Rewrite this draft to be clearer and firmer while maintaining a 'one-team' collaborative spirit: [***Insert your angry/messy draft here***]."



Pro-Tips for the Chef's Kiss!

Context is King

Always tell the AI what your industry is (e.g., "Hospitality" vs. "Healthcare").

The 80/20 Rule

Let the AI do 80% of the heavy lifting, then spend 20% of your time adding the "human touch" and verifying facts.

Chain of Thought

If the first result is too generic, reply with: "Make it more concise and prioritize the budget implications."

The Golden Rule

Never put "raw" AI output into the TMF world without a human "taste test."

Fresh Ingredients

AI is only as good as the data you feed it. Ensure your prompt includes the specific version of the TMF Reference Model .

Mise-en-Place

Use AI to do the 20-step "prep" (sorting, flagging, extracting) so you can focus on the "artistry" (clinical judgment & compliance).



Thank You!

Which part of your "TMF Menu" is currently causing the most kitchen fires?

