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THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



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Rethinking AI for TMF: From Overhyped Automation to Pragmatic Success

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Agenda

1. The Perception
2. Why We Envisioned AI/ML for TMF Migration
3. The Chosen AI/ML Adoption Approach
4. Outcome – Automated Reality vs Expectation
5. What did we do next
6. From Ambition to Outcome
7. AI in perspective
8. The Real Question

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- 19+ years in Document Management
- 10+ years specializing in Clinical Document Management including TMF
- Automation and AI evangelist and thought leader
- Focused on streamlining processes, improving quality, and enabling efficient, scalable ways of working



The Perception



Helpful? Yes. Fully automated? **No.**

TMF AI, when done right:

Less grind. Not magic.





Why We Envisioned AI/ML for Migration

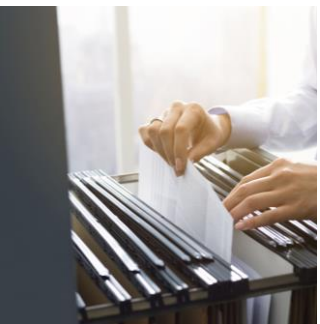


Challenges of Legacy System

Legacy electronic Document Management System was unstructured and misaligned with TMF Ref model. Audit and Inspection observations.

The scale of the migration

~24 Mn documents of ~17K studies



Limitations of Manual Processing

Manual review and classification using large vendor workforce proved inefficient, error-prone, inconsistent and caused delays.

300+ vendor resources



Vision for AI/ML Automation

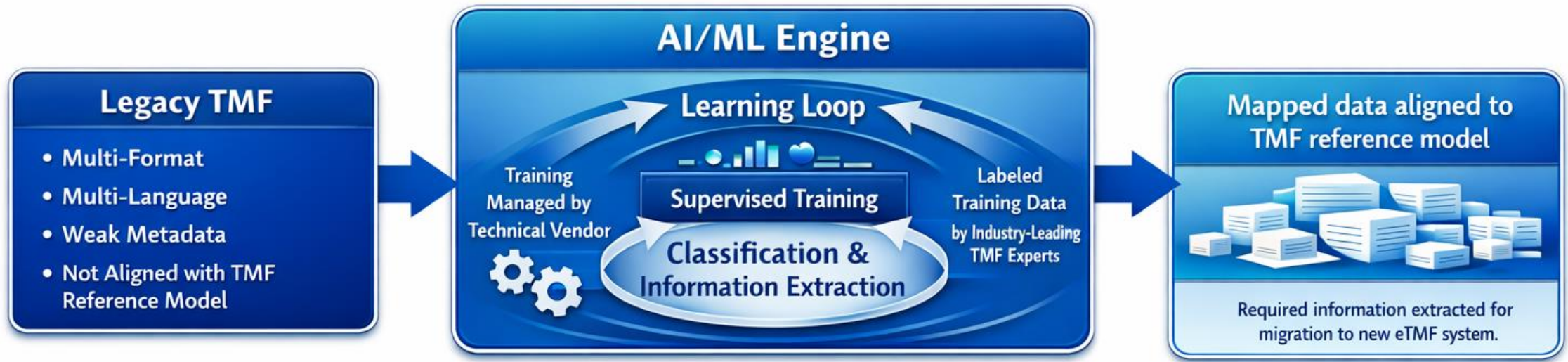
Adoption of AI/ML tool for Classification and information extraction aimed for consistency, scale and efficiency.

Way ahead of matured AI/ML tools in TMF

Partnered with vendor with functioning AI tool in another domain

Bold target of 100% automation and 98% accuracy.

The Chosen AI/ML Adoption Approach



Outcome – Automated Reality vs Expectation

- ✓ Automated classification of ~70% of documents with high confidence, significantly reducing manual effort
- ✗ High false positive rate undermined trust in the outputs
- ✗ Non-templated documents led to confident misclassifications due to hallucinations and overgeneralizations
- ✗ Site level handwritten documents caused considerable challenge in classification and information extraction



What did we do next ...

Strategic reset

Moved away from an AI/ML-only vision to prioritize accuracy, risk control, and predictable outcomes, redefining delivery and governance.

Hybrid execution model

Combined business rules, targeted AI/ML, and manual intervention for a more resilient process.

Risk-based classification

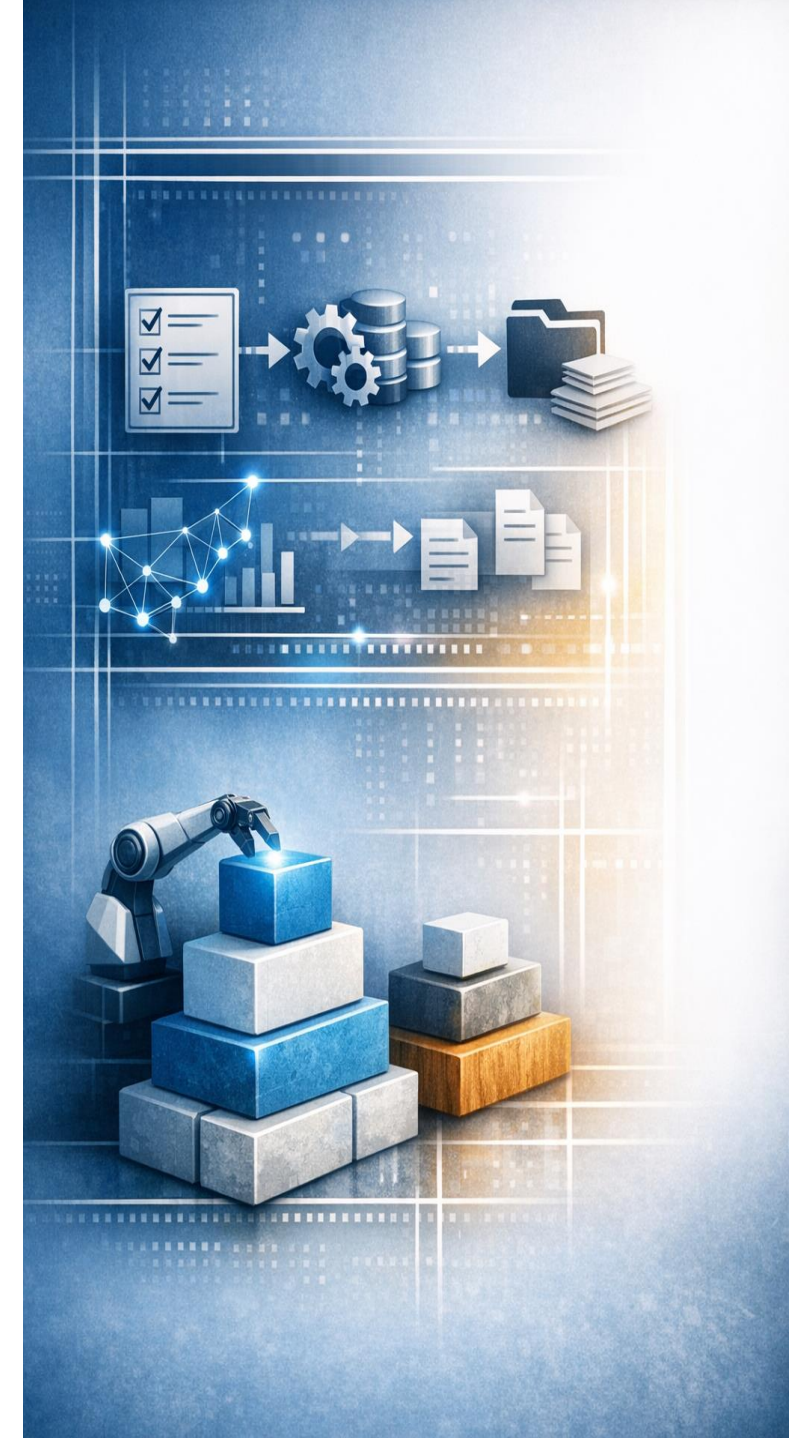
Anchored document classification on metadata-driven rules to reduce false positives.

Selective AI/ML use

Used AI/ML only where it adds clear value (critical metadata extraction) to cut manual cleanup and costs.

Measured impact

Delivered high-quality migration with significant cost savings and deferred manual non-critical fixes.



From Ambition to Outcome

Agility over Perfection

This was not a story of flawless automation, but of adapting quickly, making hard choices, and resetting direction when assumptions proved unrealistic.

Outcome-Driven Execution

Success came from prioritizing what mattered most: migrating massive document volumes, protecting business continuity, and meeting regulatory expectations.

Pragmatic Hybrid Model

Effective delivery required a deliberate mix of rules, targeted AI/ML, and human accountability — not full automation.

Mature Governance in Practice

Disciplined decision-making, risk control, and accountability turned a struggling AI-led initiative into a predictable, successful outcome.



AI in perspective: power, limits, and responsibility

Balanced AI Perspective

AI is powerful yet not magical; it requires careful context to avoid hype.

Success Conditions

Success needs managing the hype around AI, realistic expectations (a healthy skepticism), precise problem framing, disciplined execution, and selective application.

Controlled Framework Alignment

AI must follow standardization, traceability, and quality within a controlled governance framework.

Innovation Guided by Judgment

Impact arises when AI innovation complements human judgment, not replaces it.



The Real Question

Success with responsible AI in regulated environments doesn't come from pursuing full automation – it's about having the discipline to ask three questions:

- Where does AI accelerate?
- Where can rules stabilize without AI ?
- Where must humans remain accountable for judgement ?

In regulated environments, that balance is not a limitation - it is what makes innovation credible, scalable, and trusted.

AI gave us 70% automation with surprises. Humans and rules blended with AI gave us 100% delivery with trust. In regulated environments, trust always wins.

So, the next time someone pitches you 100% AI automation, ask yourself—are we chasing the magic, or are we ready to do the grind that actually delivers ?

Choose accordingly....



Thank You!



Questions?

