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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

DENVER, COLORADO | MAIN CONFERENCE: 5-6 OCT | TRAININGS & WORKSHOPS: 7-9 OCT

Redefining TMF Strategy with Agentic AI

Jim Horstmann, Senior Product Manager, Veeva Systems

Meet the Speaker



Jim Horstmann

Senior Product Manager,
Veeva eTMF, Veeva Systems

With 14+ years dedicated to eTMF applications in Life Sciences, Jim focuses on optimizing user experience and simplifying document management. He is passionate about using emerging technologies and data insights to drive higher TMF quality and industry innovation.

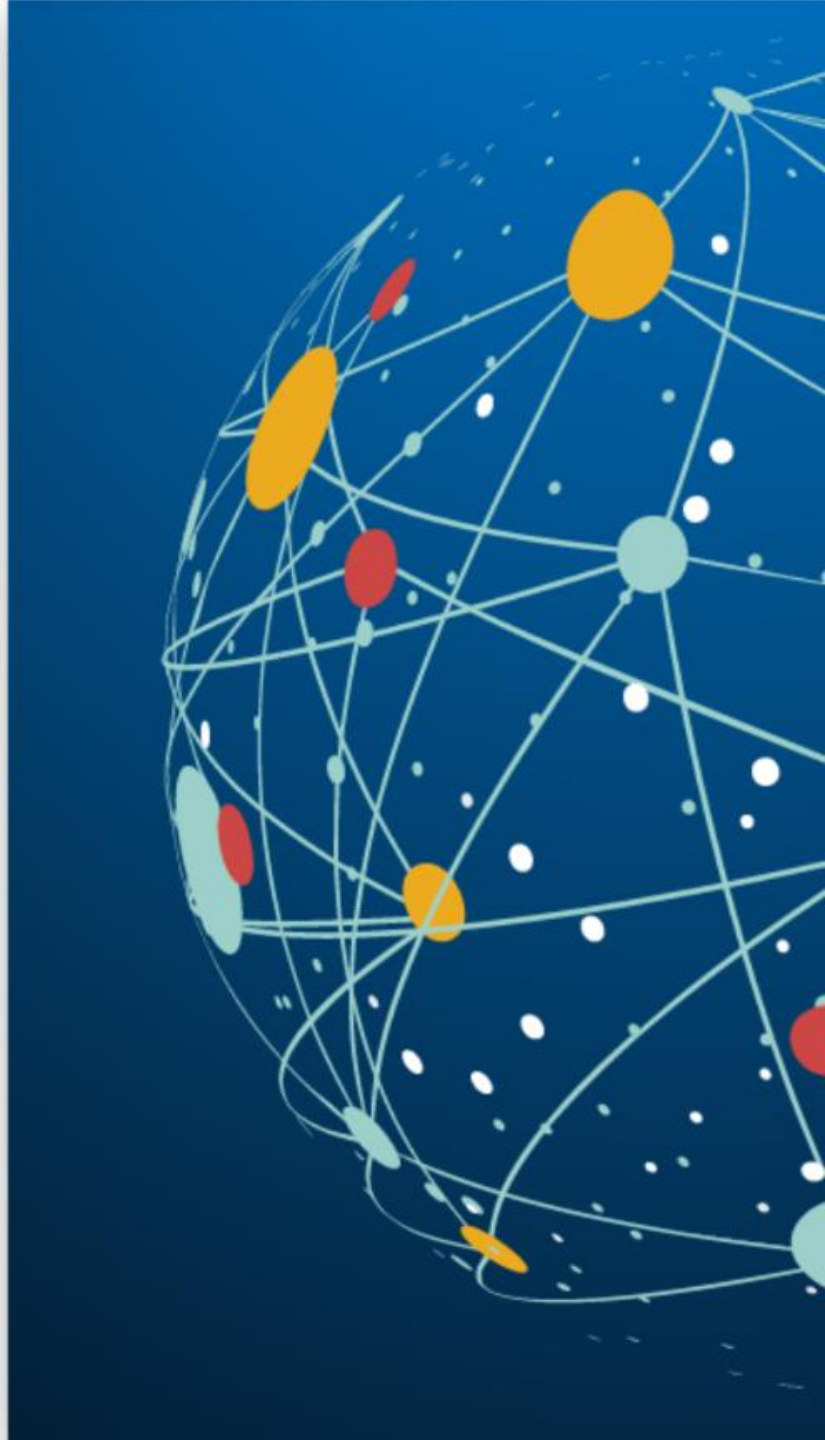
Session Roadmap

1. Understanding AI tools and language
2. Evaluating the shift in modern AI
3. Utilizing AI Workflows in the TMF
4. Envisioning the future eTMF landscape

Real-World TMF Demands

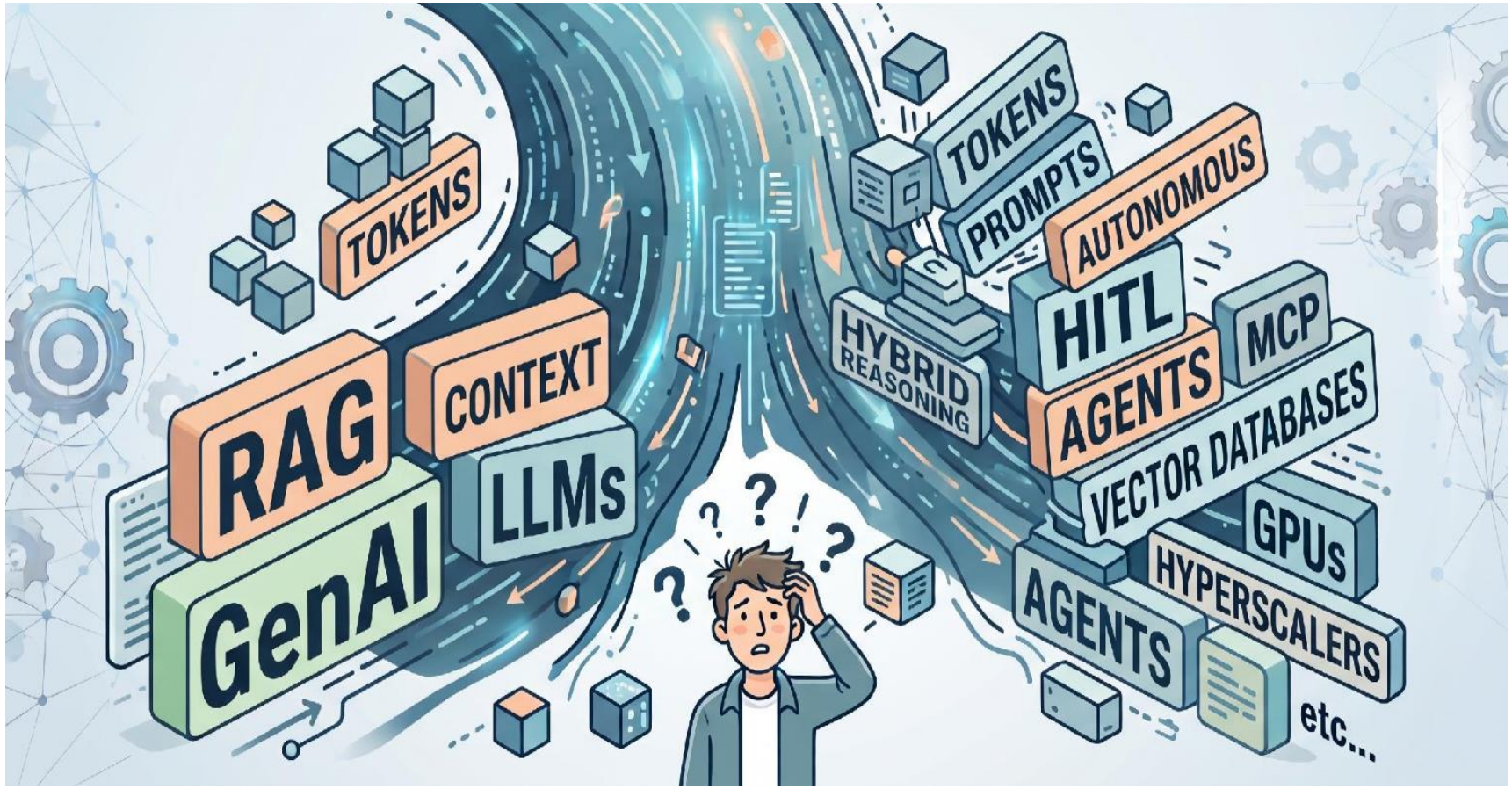
? Is Study XYZ inspection ready?

? Show me risks in Study XYZ.

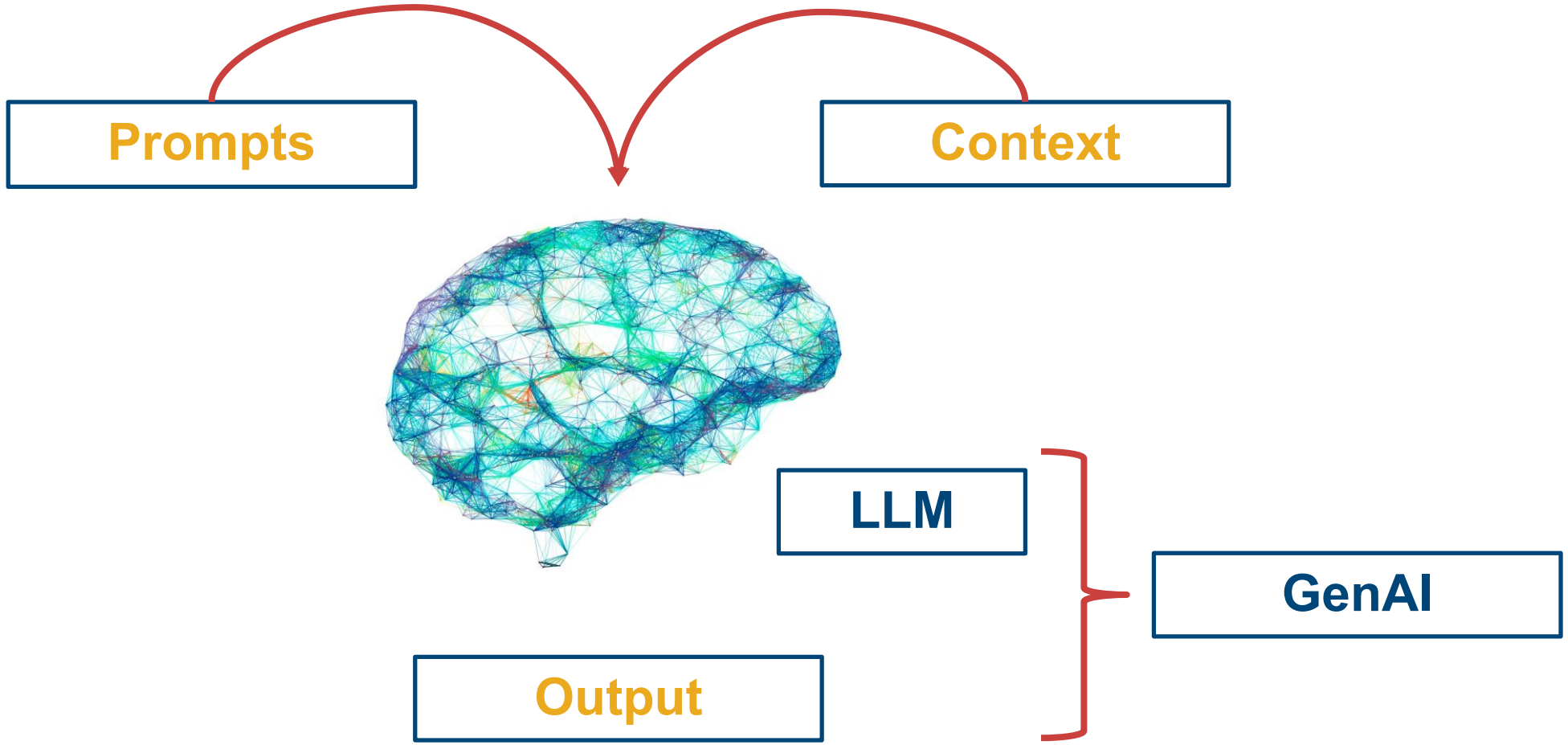


Understanding AI tools and language

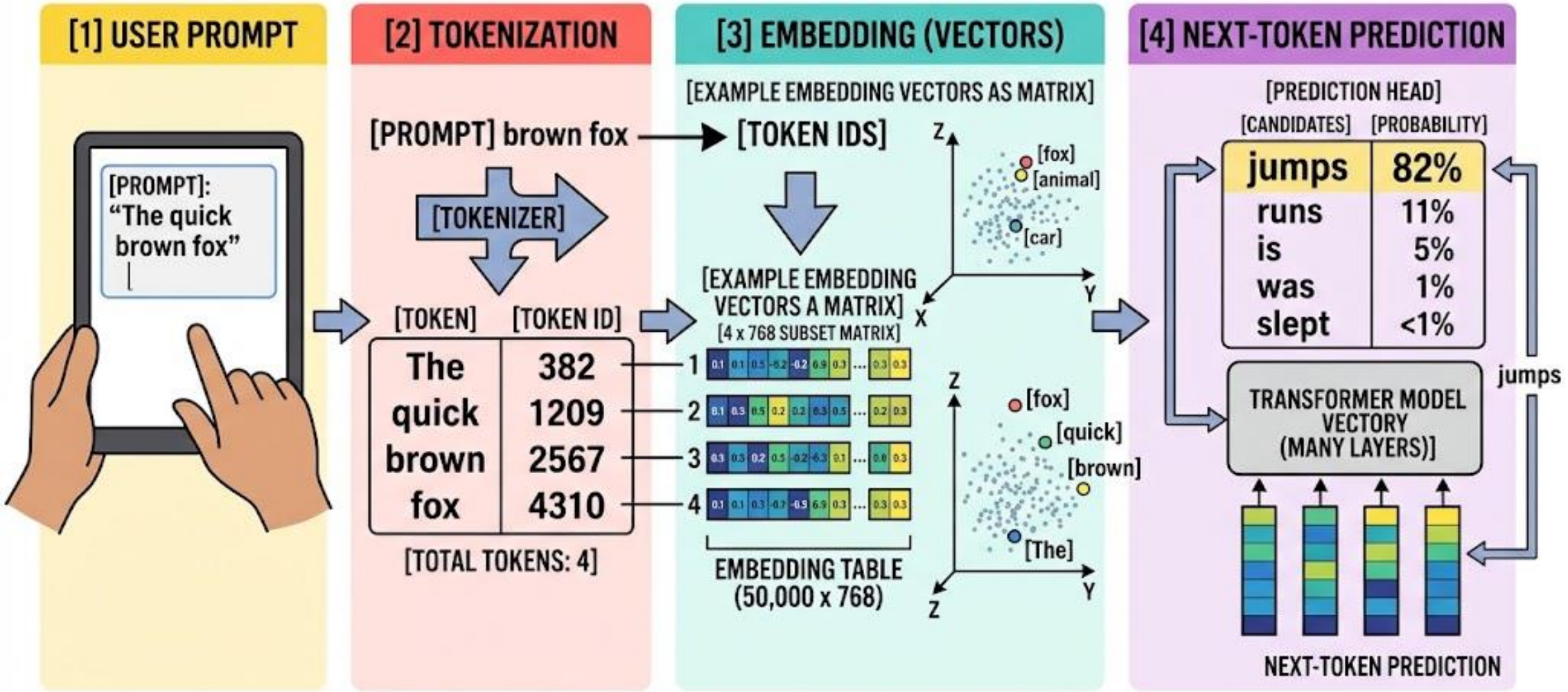
AI Brings a New Vocabulary



Building AI Literacy: Core Engine



FROM PROMPT TO OUTPUT: HOW AN LLM WORKS



Building AI Literacy: Smart Architecture

RAG (Retrieval Augmented Generation)	Agents	MCP (Model Context Protocol)	Hybrid Reasoning
• Supplements LLM with external data • Reduces model "hallucinations" • Improves factual accuracy and relevance	• Performs autonomous task execution • Completes multi-step, complex tasks • Processes at high-level and is goal-oriented	• Manages context flow between users, applications, and models	• Combines rule-based systems and learning models • Leverages best of deterministic rules and machine learning

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Building AI Literacy: Oversight and Governance

HITL (Human in the Loop)	Human by Exception	Autonomous
• Human verifies every critical decision • Active monitoring of all system actions • Decisions require human approval	• System processes routine data autonomously • Human is called only when outliers or anomalies occur • Optimizes efficiency for standard tasks	• Full system independence in designated tasks • End-to-end completion without human interaction • Self-contained system for decision and execution

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Evaluating the Shift in Modern AI Implementing Agentic AI Workflows

AI Models

Machine Learning	Large Language Models
• Focuses on specific functionality • Requires large amounts of data for training • Incurs cost to develop and upgrade • Experiences challenges with “unknown data”	• Specializes in natural language communication • Comes ready for use • Imitates human thought patterns and reason • Updates continuously by large AI companies

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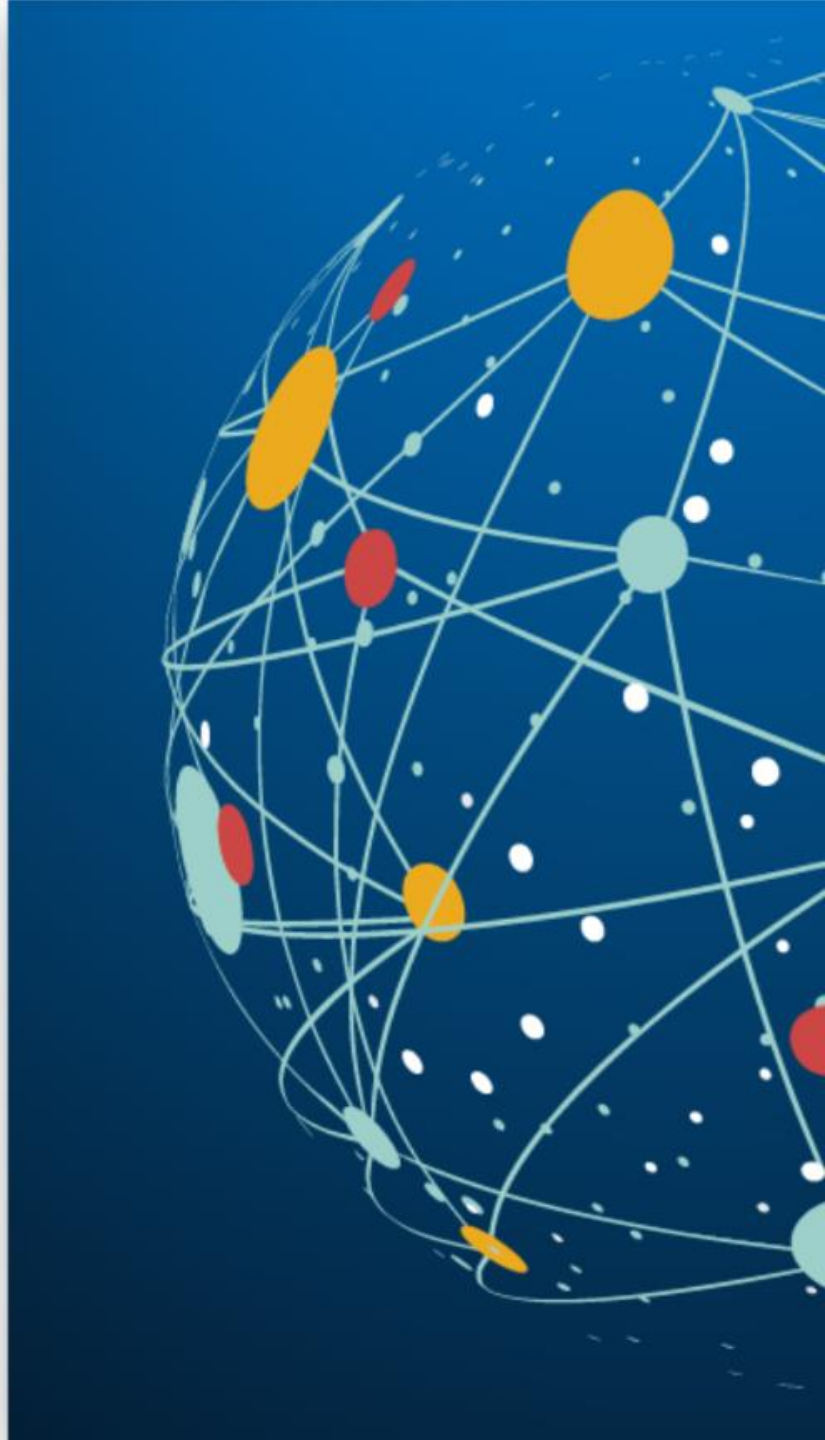
Understanding Model Boundaries

Training	Interaction	Tokens
• Only trained on publicly available data • Not continuously trained on new data • LLMs have no native knowledge of proprietary data	• Input: Prompts + Context (tokens) • Output: It depends (but also tokens!) • LLMs are stateless	• Unit of measurement for models • Used to quantify input context and output generation • Dictate overall cost

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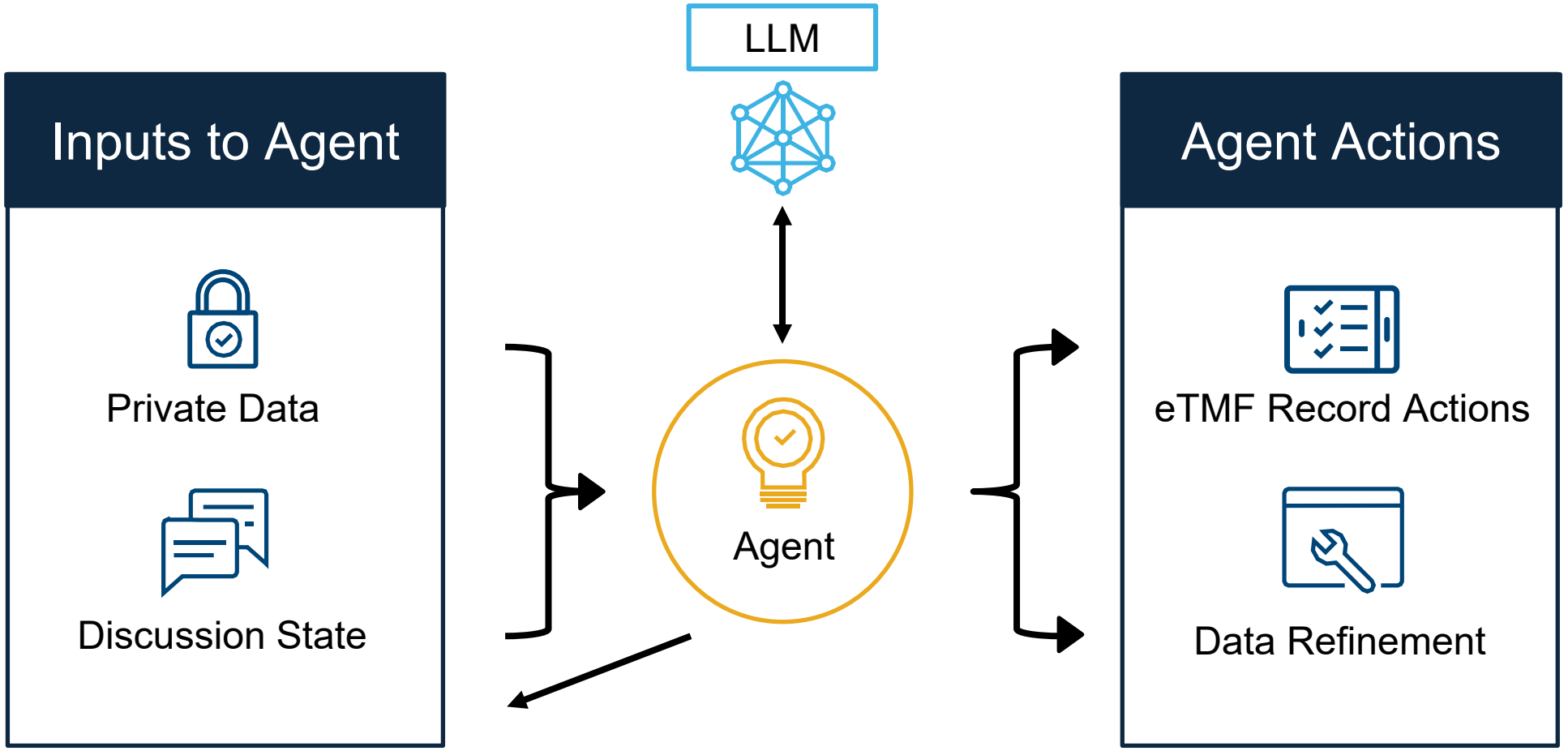
Using LLMs in eTMF Workflows

- TMFs contain natural language data that is difficult to harness at scale.
- The volume of data in the TMF is often a limiting factor to TMF Operations.
- LLMs specialize in Natural Language Processing (NLP) and reasoning.
- LLMs analyze data at scale with speed and depth.



Utilizing AI Workflows in the TMF

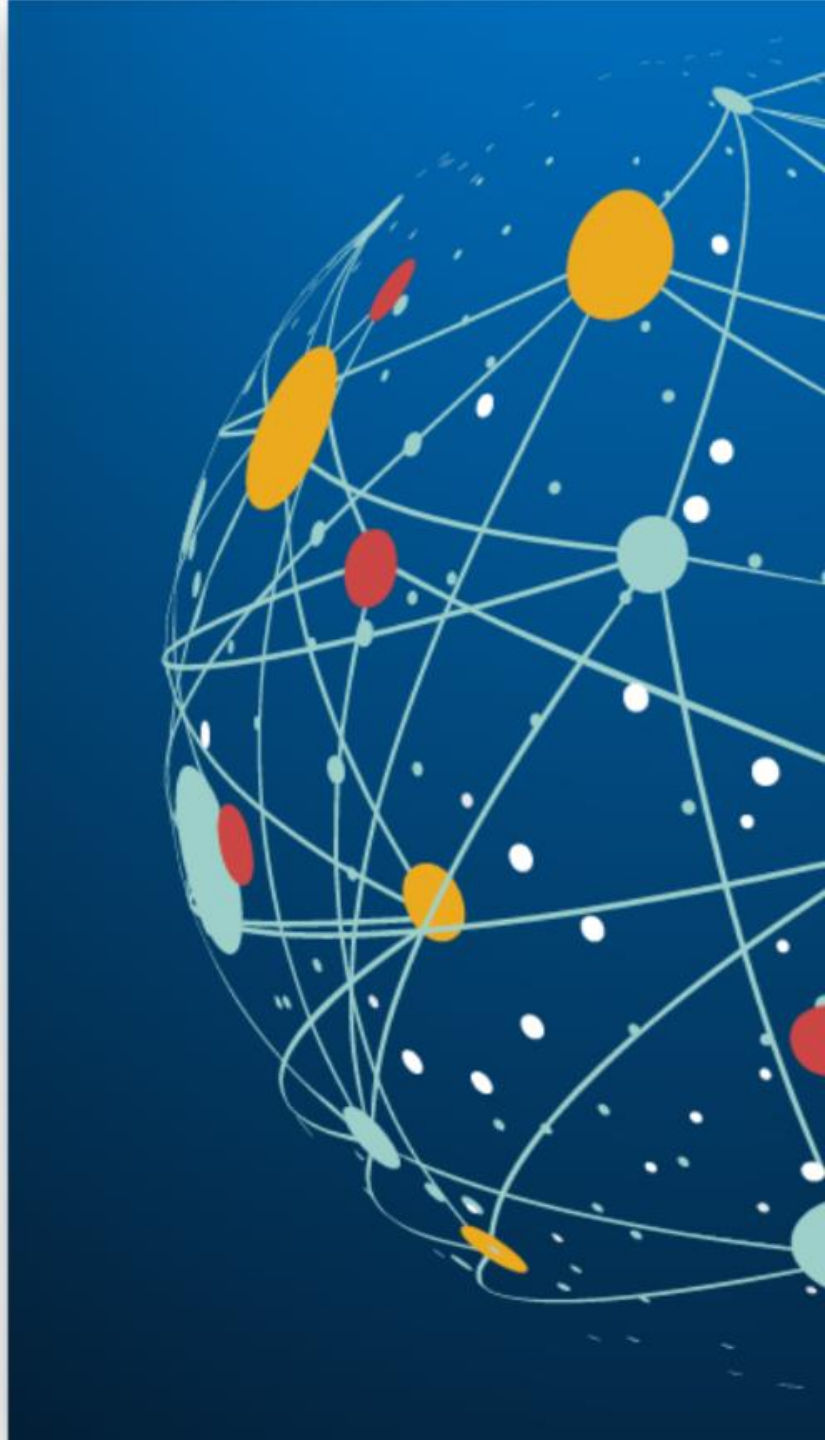
How Agents Harness the Power of the LLM



Envisioning the future eTMF landscape

Revisit initial question, how would this work?

- [x] Is Study XYZ inspection ready?
- [x] Show me risks in Study XYZ.



Questions?



Thank you!

