



Human in the Middle: Accelerating with AI, Anchored in Quality

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Agenda

Context & Drivers

Human In The Middle Framework

Applications & Use Cases

Quality & Compliance

Future Outlook

Balancing innovation with quality to make AI in the GxP setting possible

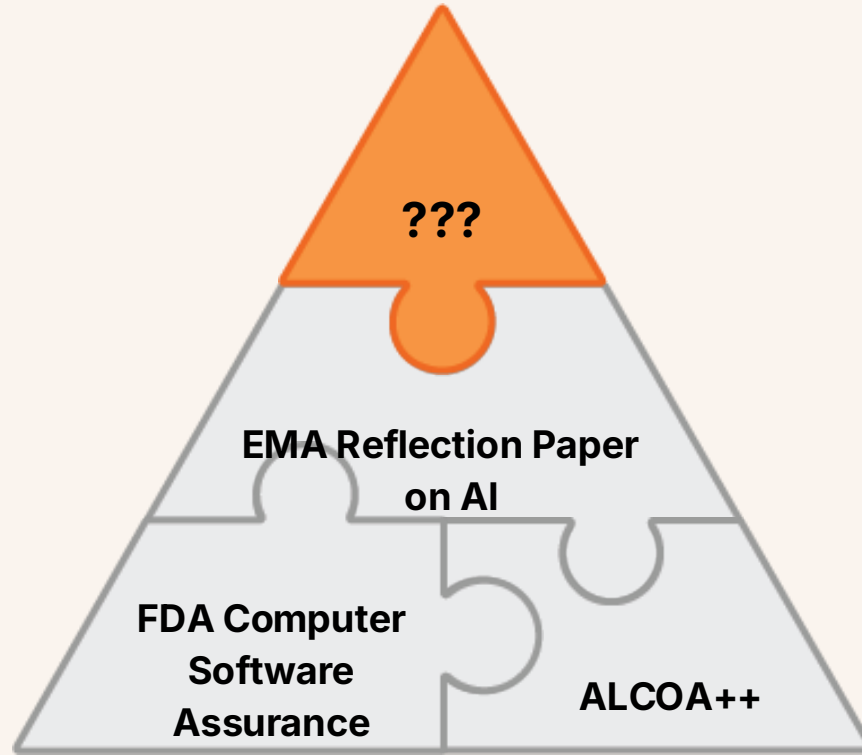
Innovation with velocity in the right direction rarely happens without a strong underlying foundation. Without quality, innovation risks collapsing under inefficiency, rework, or poor outcomes.



Quality ensures that each new idea has a reliable platform to build upon, introducing:

- **Reliability:** A strong baseline minimizes errors, allowing more time and energy to focus on creative problem-solving
- **Trust:** Teams and customers alike gain confidence in innovation when the foundation is consistent and dependable
- **Scalability:** Innovations can be scaled only if the foundation can handle increased complexity without breaking

Gaps in current AI guidance make explainability critical



References:

FDA, "Guidance on Computer Software Assurance for Production and Quality System Software," Sept 2025.

(ICH E6(R3), §5.1; FDA Data Integrity Guidance, 2018)

Ref: EMA/705725/2020.

Collaborative, risk-based methods are driving innovation

Collaborative Ecosystem Evolution

Cross-functional alignment of data, quality, and IT teams; growing use of open-source, shared frameworks.

Key Drivers:

Open innovation, governance, standardization

Risk-Based Quality & Automation

Risk-based validation models combining automation with SME oversight; AI-assisted QC and validation

Key Drivers:

Efficiency, reproducibility, risk-based assurance

Digital Transformation Across R&D

End-to-end digitalization integrating capture, analytics, and reporting; focus on real-time, interoperable data

Key Drivers:

Automation, interoperability, cloud ecosystems

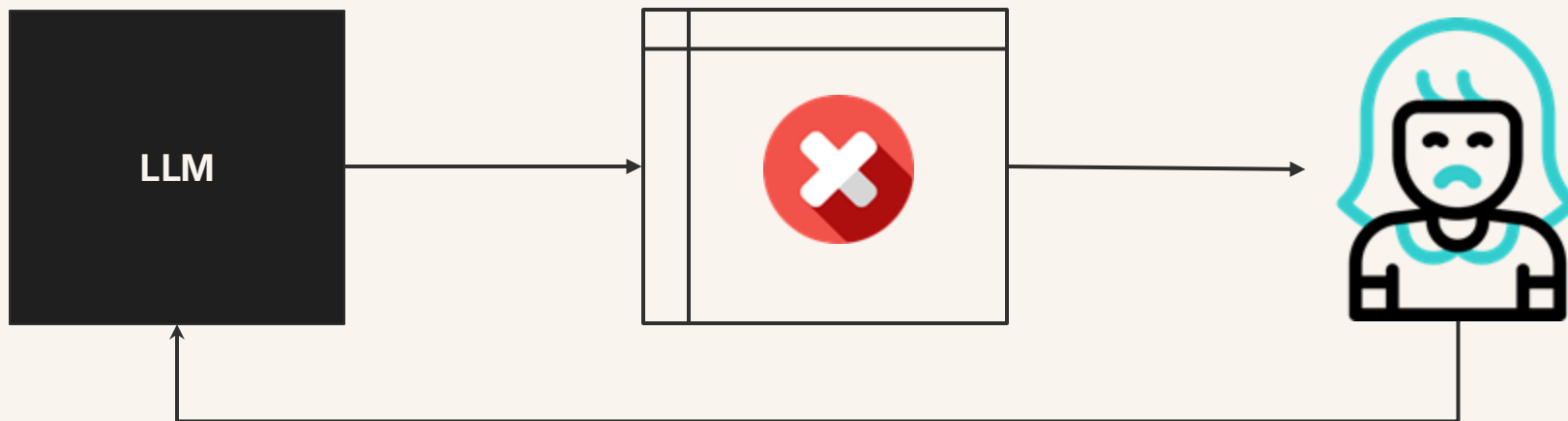
Shift Toward Trustworthy AI

Move from experimental to operational AI with focus on explainability and auditability

Key Drivers:

Ethical AI, transparency, human accountability

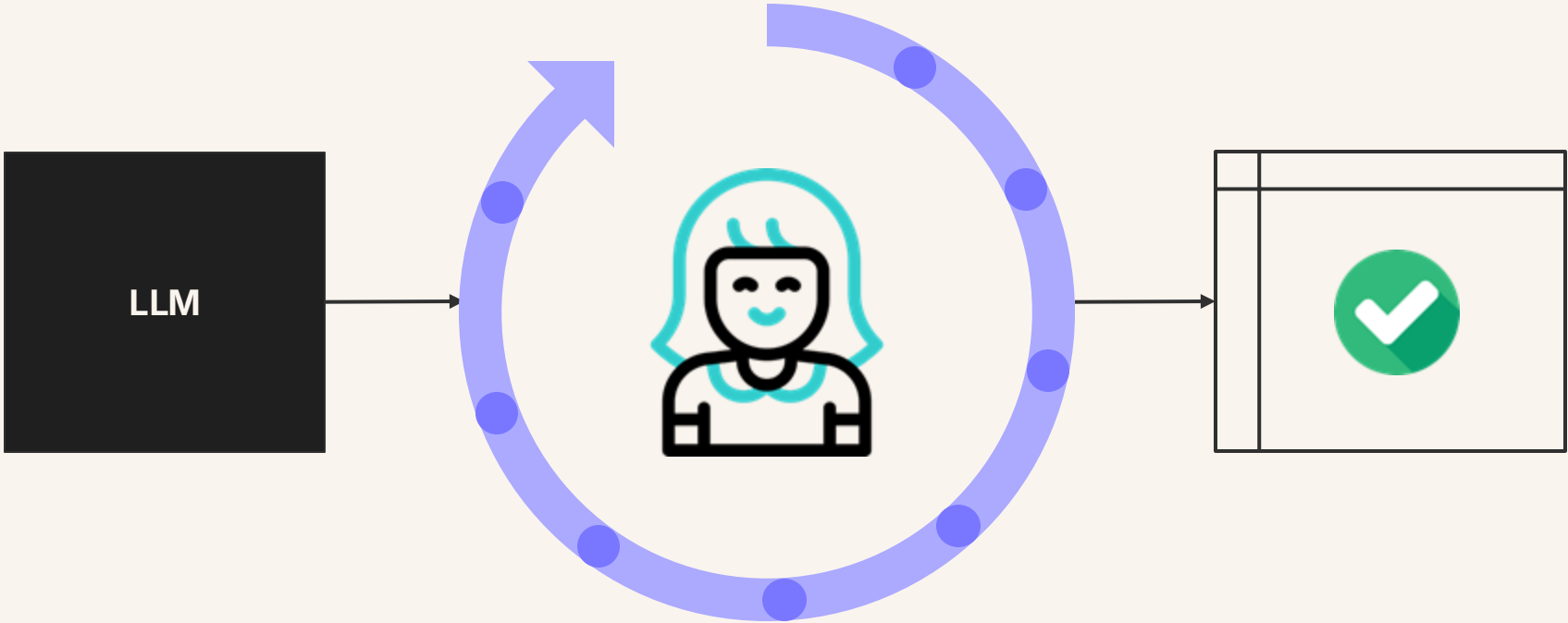
Human at the end of LLM black box doesn't work



Humans need to be in the middle of both AI development and use

Aspect	AI Model + Tool Development	AI Model + Tool Use
When	Development phase	Deployment phase
Process	Agile, iterative	Waterfall checkpoints
Human's Role	Trainer/teacher	SME gatekeeper/inspector
Goal	Improve model	Assure quality & compliance
Regulatory Lens	Design controls	GxP oversight, ALCOA++

Human in the middle of output creation delivers quality



Human in the middle process into practice

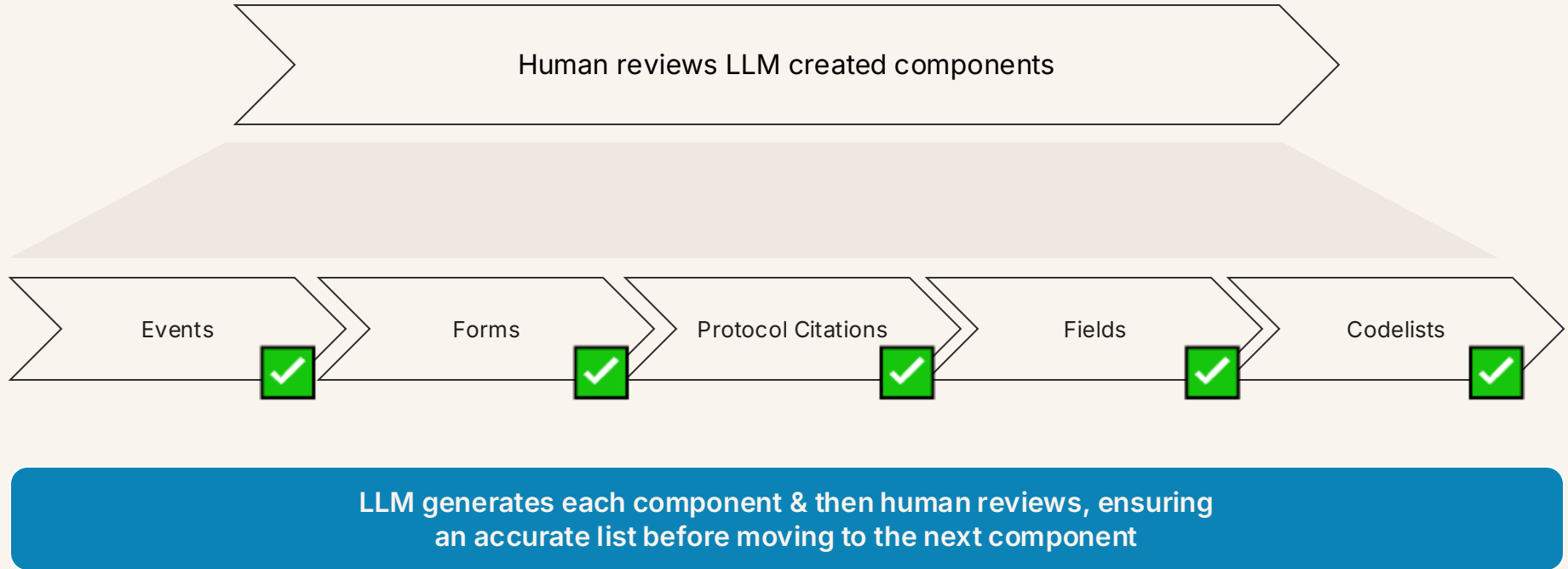
Break down AI output into smaller components that are easier for a human to review

Sequence output so humans review the most pivotal decisions first, before more output is created

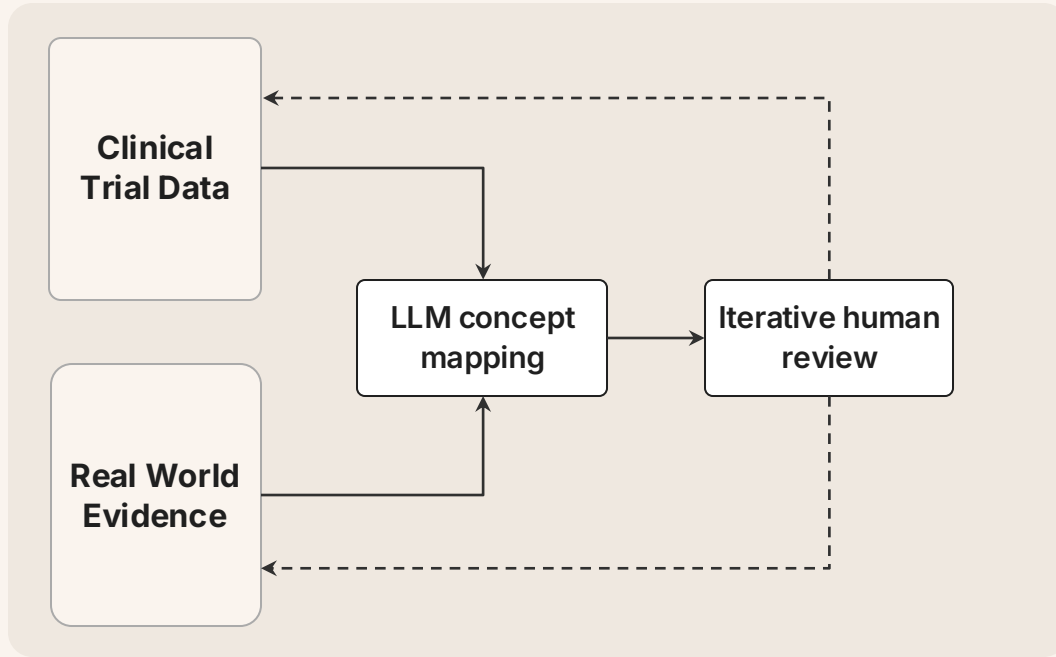
Humans iteratively review rationale for AI decisions, along with sequenced intermediate outputs

Result: Final AI output is trusted first draft

Use case #1: Data capture form design from protocol

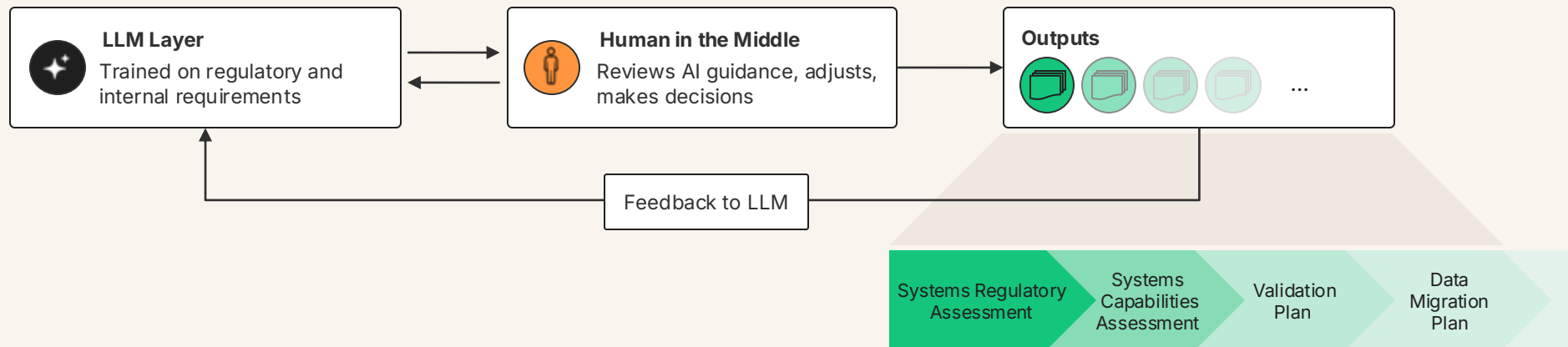


Use case #2: Data models and pipelines



LLM maps features based on concepts and then human reviews, ensuring an accurate mapping before analysis or model development

Use case #3: GxP Systems Lifecycle Documentation



LLM trained on regulatory and internal requirements guides user through reviews of each document and incorporates feedback on each step into downstream documents

Human in the middle creates built-in quality & compliance

RESULTS

Oversight

components make it easier for humans to review output

Accountability

iterative review steps ensure humans validate from high to low risk

Explainability

AI decision rationale are interpretable to SMEs and regulators

IMPACT

Trust

HITM enables confidence in AI-assisted outputs for regulated decisions

Outcome

AI becomes a *trusted co-pilot* - not an uncontrolled black box

Continued industry evolution

Human in the middle of AI tool usage will continue to enable compliance in regulated industries across **higher-risk workflows**

Collaboration in industry to harmonize expectations & practices

Expected regulatory evolution: explicit requirements & methods in FDA/EMA guidance

Next frontier: integrate human in the middle directly into complex, multi-agent AI systems to embed **governance by design**



Questions?

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