



Problem-First Agentic AI- Transforming Statistical Computing with Purposeful Automation

*Transforming Clinical Trials through Purposeful
Automation, Orchestration and Governance*

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Session Objectives

Opening & Introduction

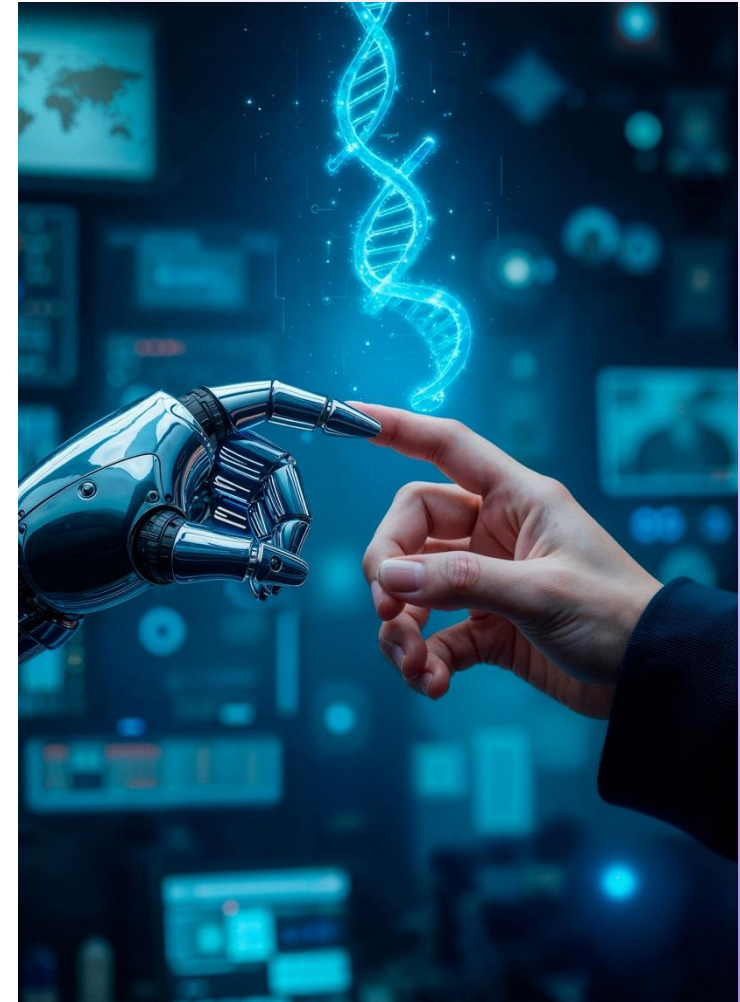
What is Agentic AI

The Mindset Shift
Innovation Landscape

Problem-First Agentic AI Transformation

- Architecture and Implementation
- Assess governance, validation, and compliance
- Analyze operational impact and ROI

Pathway to
Innovation in
Clinical Data
Science



MAXIS What Is Agentic AI?

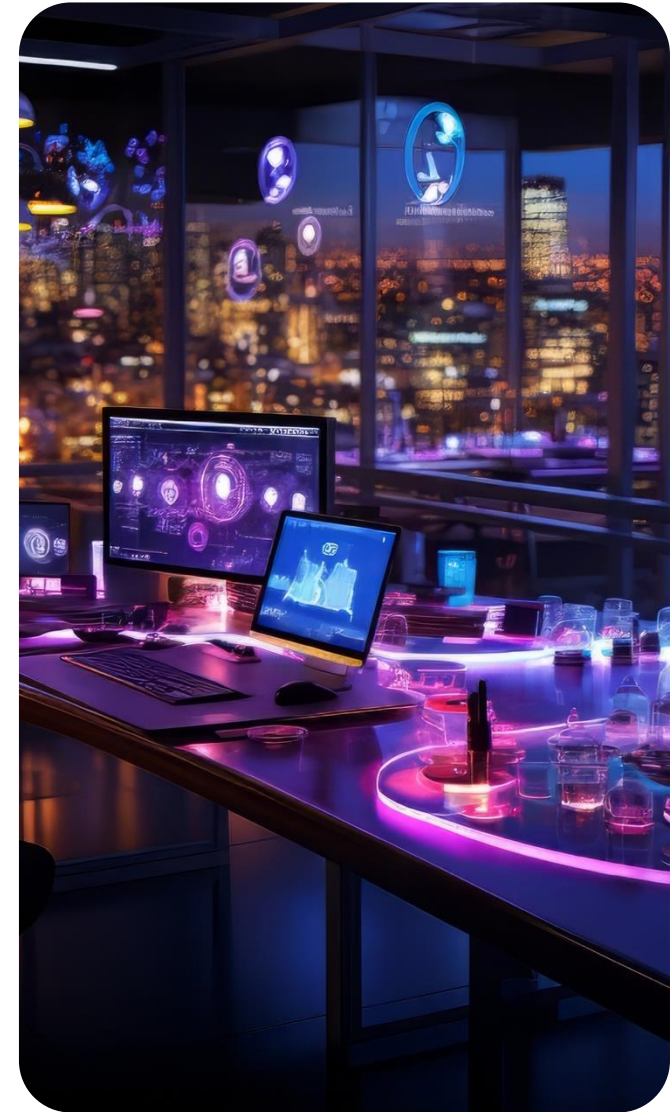
Agentic AI = AI systems capable of autonomous planning, context reasoning, and multi-step tool use toward a goal.

Four Types of Agentic Systems:

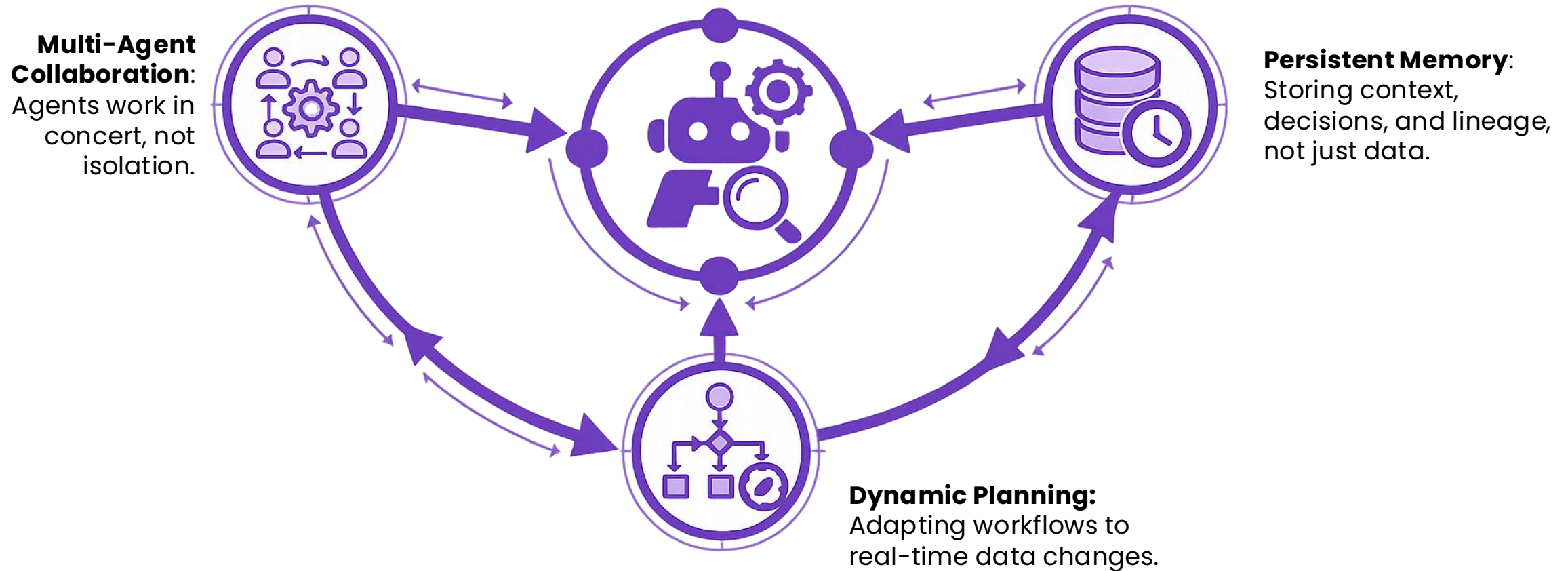
1. **Workflow Agents** – Rule-based orchestrators with Limited Autonomy.
2. **Semi-Autonomous Agents** – Context-aware but Human-in-Loop.
3. **Reasoning Agents** – can Evaluate, Plan & Adapt to Environment Feedback.
4. **Fully Autonomous Agents** – possess Episodic, Semantic, & Procedural Memory with Dynamic Tool use.

Not every business use case needs autonomy level 4.

The right agent type depends on operational risk, cost, and compliance constraints.



Defining **Agentic AI** in Clinical Data Science



Definition: Systems capable of autonomous goal-directed behavior, planning, and reasoning, designed to interact seamlessly with human experts.

Moving from **Model-Driven Hype** to **Problem-Driven Orchestration**

THE CHALLENGE:

Traditional Statistical Computing Environments (SCEs) are constrained by fragmented tooling, manual orchestration, & reproducibility gaps. This slows down the generation of SDTM, ADaM, TLFs, & CSRs, delaying regulatory submissions.



THE MINDSET SHIFT:

Pivoting from “Technology-First” solutions (AI for AI’s sake) to “Problem-First Agentic AI”—an architectural paradigm where autonomous agents solve specific workflow bottlenecks.



THE OUTCOME:

A multi-agent ecosystem balancing autonomy with strict Human-in-the-Loop (HITL) oversight.

Key Benefits: Reduced cycle times, full reproducibility, and audit-ready compliance for 21 CFR Part 11, EU Annex 11, and broader GxP requirements.



Innovation Meets Regulation: 2025–2026 Landscape

2024:

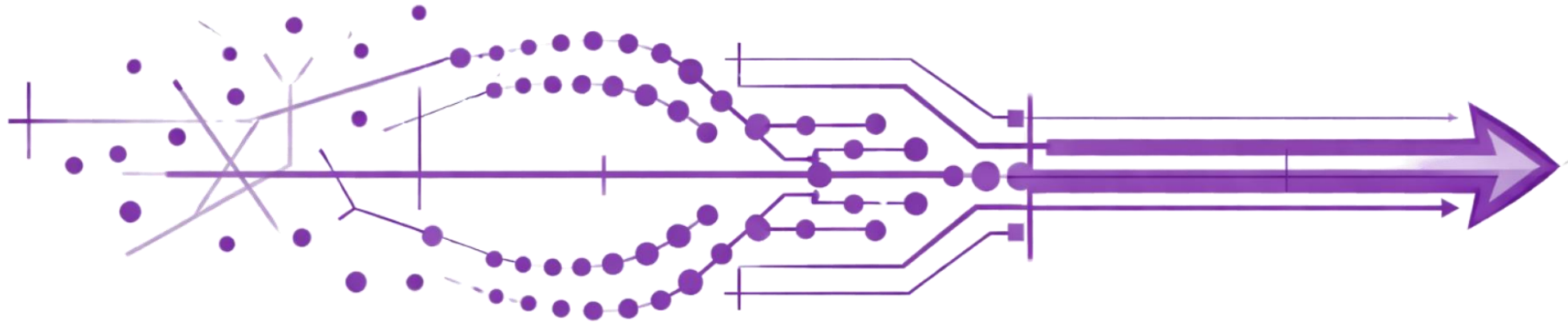
Isolated AI Pilots

2025–2026:

Integrated Workflow.

Future:

Agentic Orchestration.

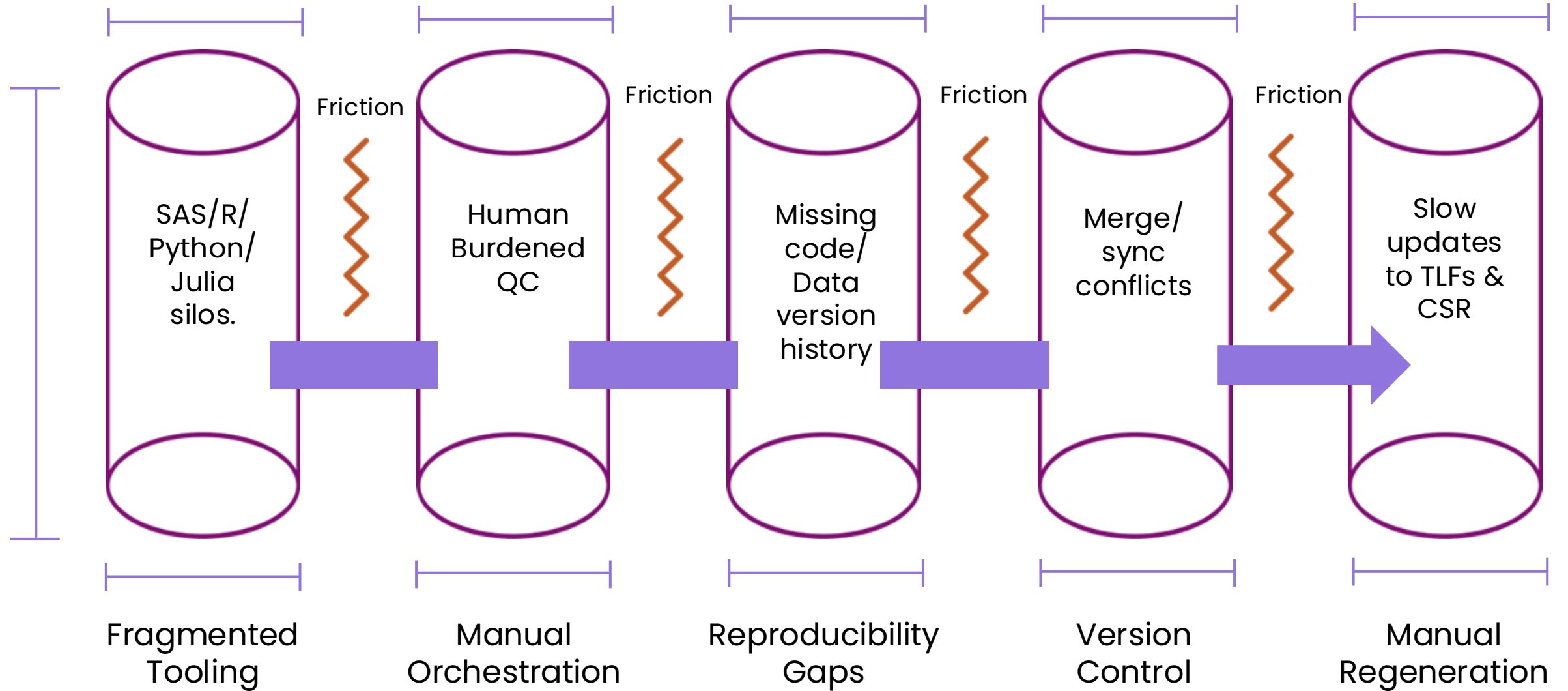


Regulatory Driver: FDA and EMA joint framework emphasizes traceability, lifecycle monitoring, and human oversight.

The Goal: Moving beyond Generative AI novelties toward purposeful systems that execute multi-step tasks.

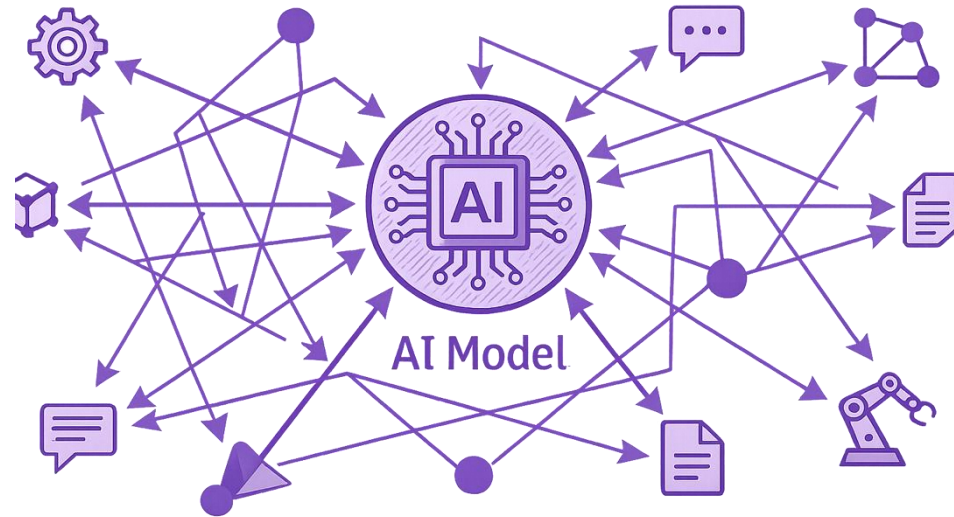
The focus has moved beyond isolated AI pilots to integrated , workflow-oriented agentic AI systems.

Friction in Traditional Statistical Computing Environments



Philosophy: Problem-First vs. Technology-First

Technology-First Approach: Question:
"What can this GenAI model do?"



(Leads to uncontrolled complexity and tool fatigue).

Problem-First Approach: Question:
"Why is our data cut turnaround slow?"



(Leads to specialized agent design).

Defined Pain Point + Purposeful Agent = Tangible Value.

Ecosystem Architecture

GOVERNANCE & GUARDRAILS:

Policy Enforcement, Risk Management, Privacy, Transparency.

ORCHESTRATION LAYER (Brain):

Workflow Management, Task Assignment, Error Handling.

Ingestion
Agent

Transformation
Agent

Analysis
Agent

Validation
Agent

Reporting
Agent

MEMORY & LINEAGE LAYER (Foundation):

Persistent Memory, End-to-End Lineage Tracking, Audit Logs.

MAXIS Cloud-Native Infrastructure & Implementation

Built for scalability, elasticity and cost efficiency

Integration Layer:

API Gateways

Event Buses
(Message queues)



Microservices: Agents deployed via containers for portability.

Compute Layer:

Docker Containers

Serverless



Serverless: Event-driven tasks optimise operational overhead.

Data Layer:

Data Lake Houses

Warehouses

Security Layer:

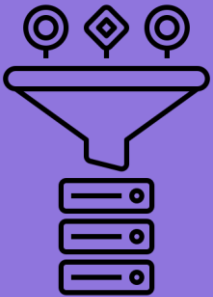
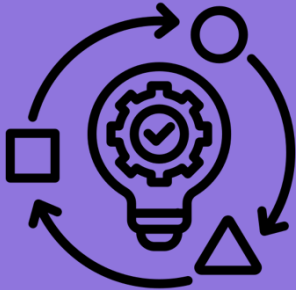
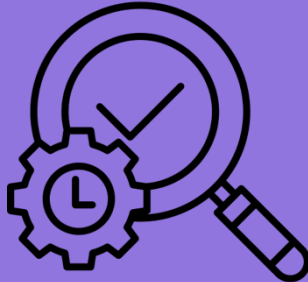
IAM policies

VPCs, and encryption

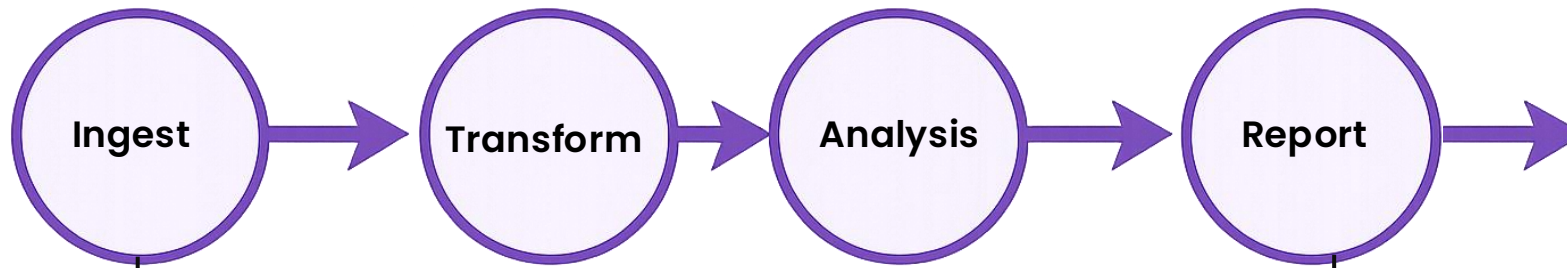


Integration: Loose coupling with existing Inbound & Outbound sources

Specialized Agents: Roles and Responsibilities

Data Ingestion Agent	Transformation Agent	Analysis Agent	Validation Agent	Reporting Agent
 Secure acquisition and standardization of raw clinical trial data.	 Processing raw data into submission-ready formats (SDTM /CDM).	 Executing Statistical Analysis plans ,shells to generate Analysis-ready & results. (ADaM, TLF's)	 Automated checks against business rules and regulatory guidelines.(Custom, P21 integration)	 Assembling final deliverables (CSRs, submission documents).

Orchestration & Persistent Memory: The Central Nervous System



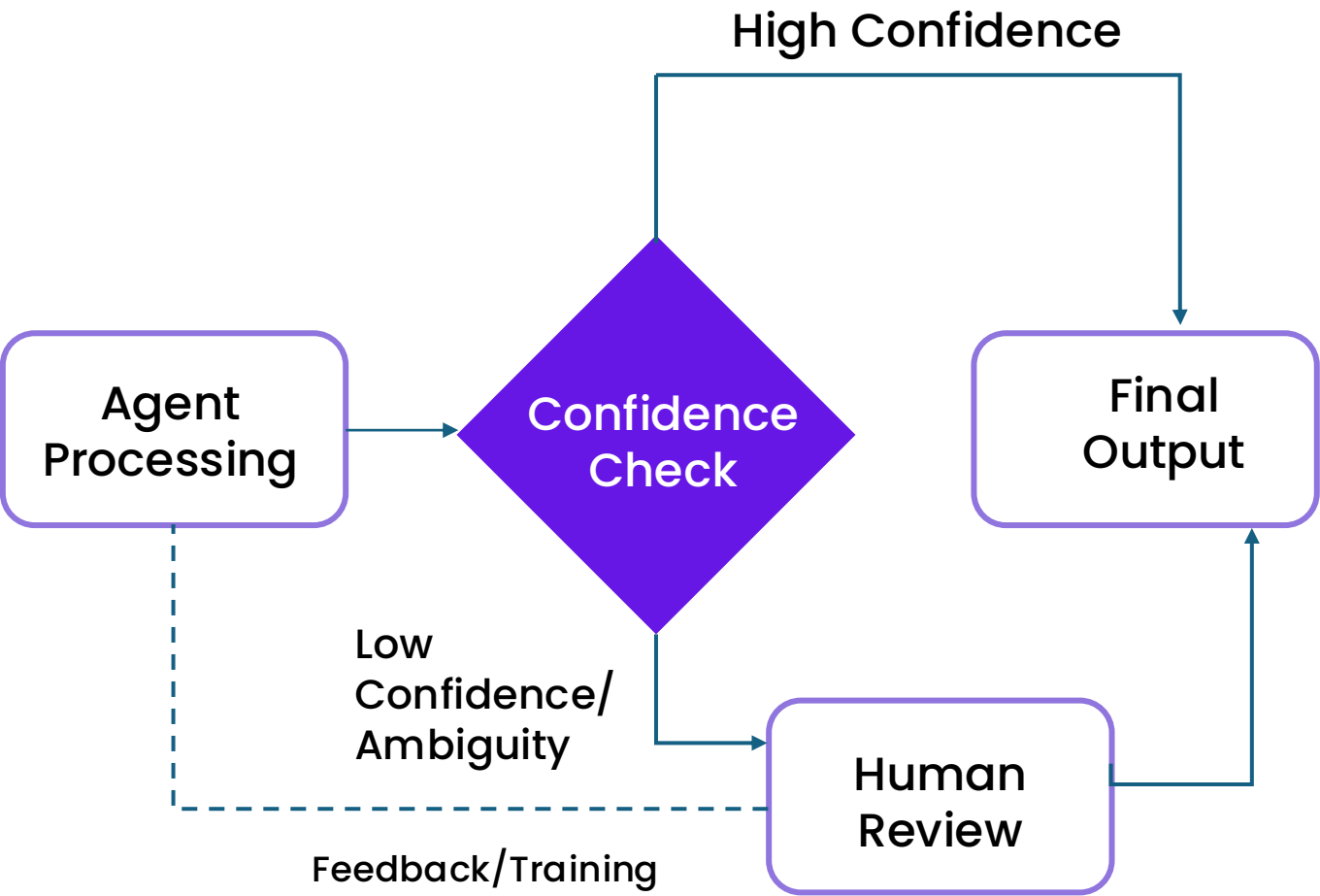
Dynamic Adaptation: Workflow adjusts dependencies automatically.

Chain of Custody: Unbroken audit trail from ingestion to reporting.

GxP Compliance:
Reconstruct any output from the stored context and decisions.

Governance, Compliance, and the Human-in-the-Loop

Built for scalability elasticity and cost efficiency



Escalation Paths:
Orchestrator routes low-confidence results to experts.



Review & Feedback: Expert decisions improve future agent performance.



Guardrails: Humans define operational boundaries.

MAXIS Privacy by Design & Regulatory Compliance.

Anonymisation



De-identification: This process occurs at the earliest stage of data handling.

Anonymisation Agent: This specific agent performs the de-identification to ensure all downstream data remains privacy-safe.

Access Control



Granular Access: The system uses role-based access (IAM).

Selective Access: This ensures that both AI agents and human users can only access the specific data subsets necessary for their tasks.

Immutable Audit Trails

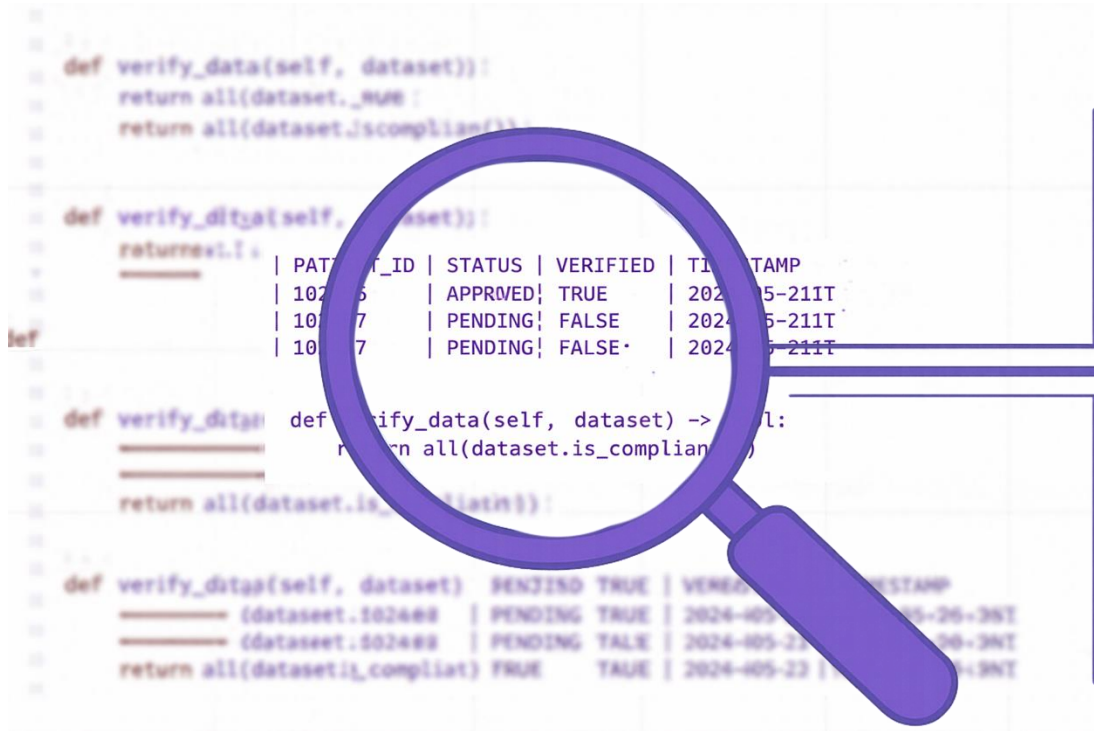


Audit Agent: This component is responsible for recording every instance of data access, modification, and decision.

Accountability: These records create a permanent, unchangeable trail for compliance purposes.

Goal: Full audit readiness for HIPAA, GDPR, and regulatory inspections.

Validation, Verification, and Trust



Automated Cross-Checks: Verifying derived datasets align with raw specs.



Hallucination Mitigation: Factual grounding and confidence scoring.

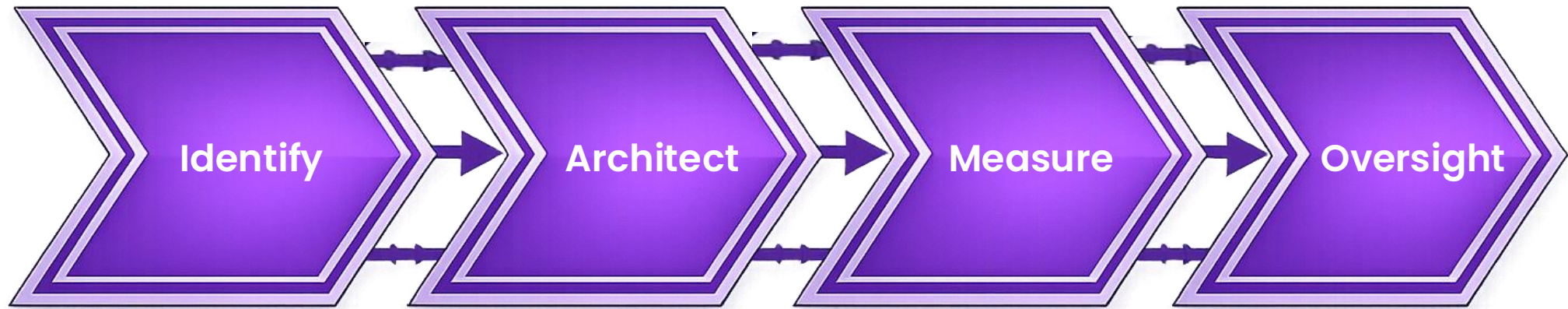


Compliance Monitoring: Real-time checks against SOPs 21 CFR Part 11, Annex 11, GxP requirements.



Explainability: Agents provide justifications for every action.

Implementation Model: From Concept to Reality



Map workflows to find manual bottlenecks. Start with the problem

Define agent roles and orchestration logic. Prototype iteratively.

Track KPIs: Cycle time, effort reduction, error reduction.

Embed human review steps and escalation paths.

Operational Impact & ROI

Manual Operations



High Effort in spec design & creation, Programming, Submission packaging



Slow Time-to-Analysis.



Risk of manual error.

Agentic Operations



High Speed (Reduced time-to-analysis).



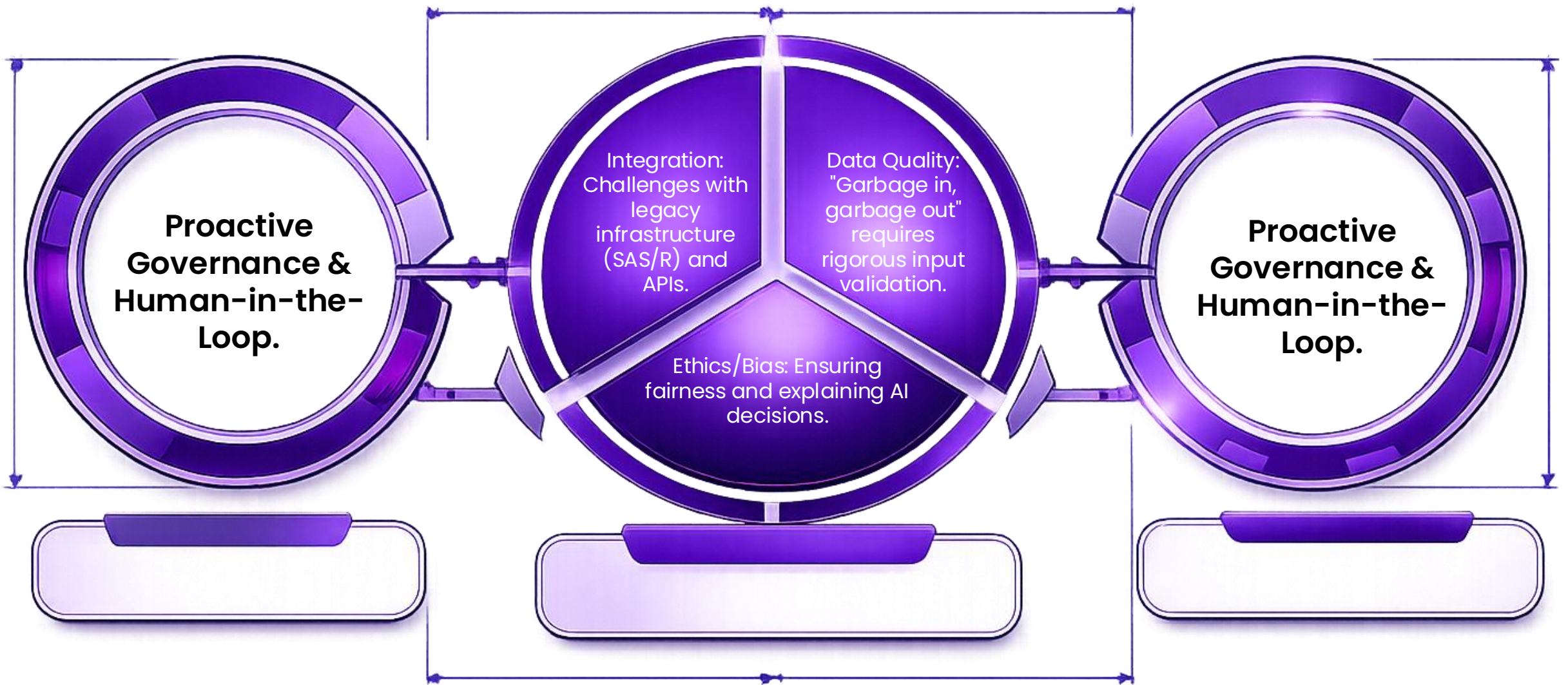
Low Effort (Decrease in programming effort).



High Quality (Enhanced reproducibility).

Strategic Shift: Focus moves from data cleaning to strategic data science.

Risk Management & Limitations



Pathway to Innovation in Clinical Data Science



Summary : Problem-First Agentic AI shifts statistical computing from fragmented automation to orchestrated, problem-driven intelligence.



**Final Thought:
Balancing autonomy
with human control for
safety.**



**Call to Action: Prioritize
problems, architect for
trust, embrace purposeful
automation.**

Conclusion: Problem-First Agentic AI offers a compliant, efficient path to modernizing clinical trials.

Q&A

Thank you for your time!
Open to questions &
discussion.

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