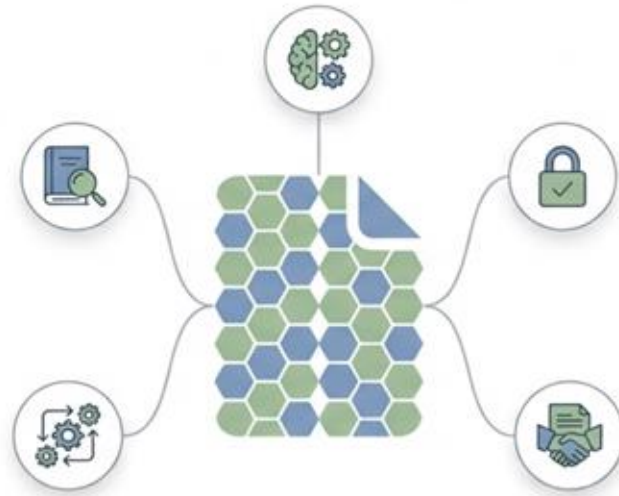




 **saama**

# ML06: The AI-Powered Scribe: An Agentic Framework for Automated for CSR Generation





# The Challenge: CSR Generation as a Systemic Bottleneck





# The False Start: Why Standard GenAI Fails

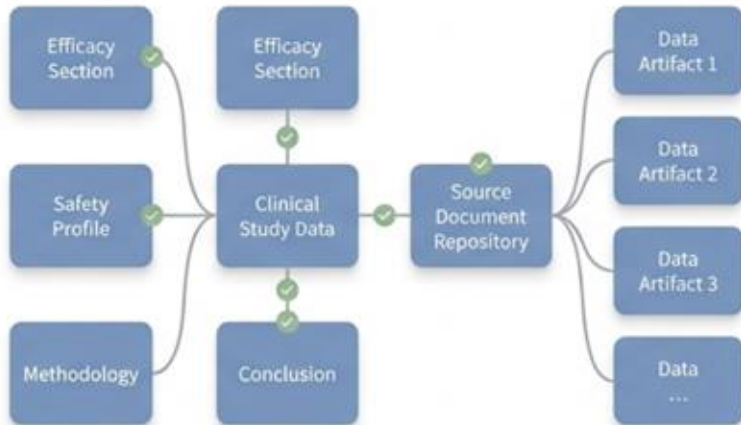
## Standard LLM Approach



- **Amnesia:** Lacks persistent memory across sections.
- **Inconsistency:** Numbers drift between Efficacy and Safety.
- **Black Box:** No audit trail for derivation.

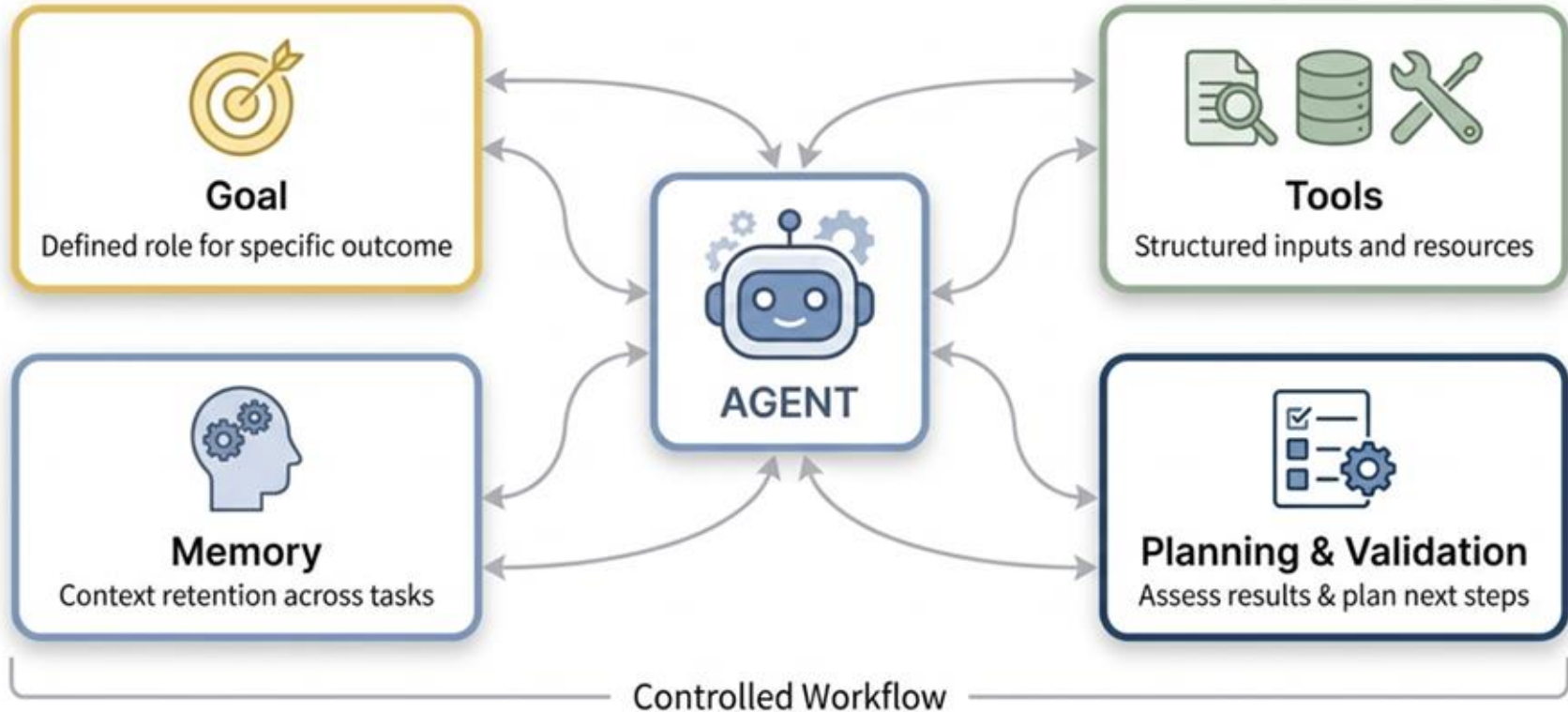
VS

## Agentic Approach



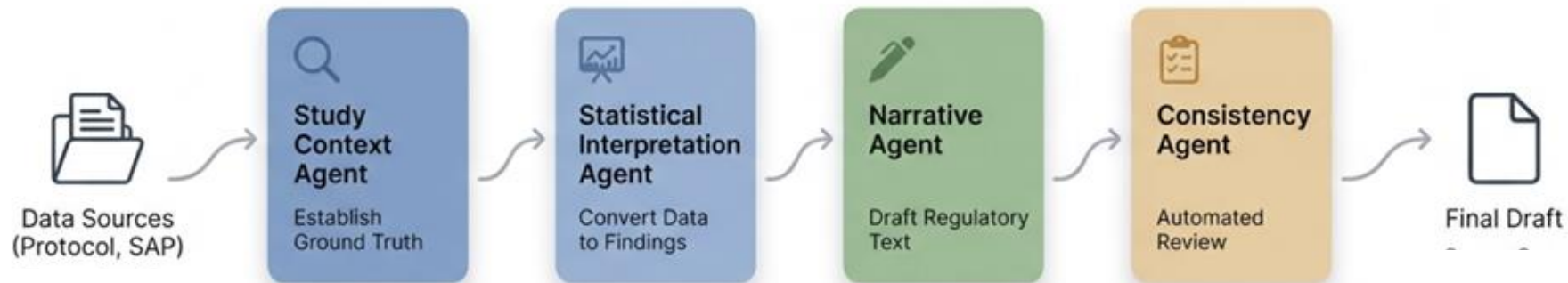
- **Contextual Memory:** Retains facts across the document.
- **Single Source of Truth:** Data is linked, not hallucinated.
- **Traceability:** Every sentence links to a source.

# The Solution: What Constitutes an Agent?





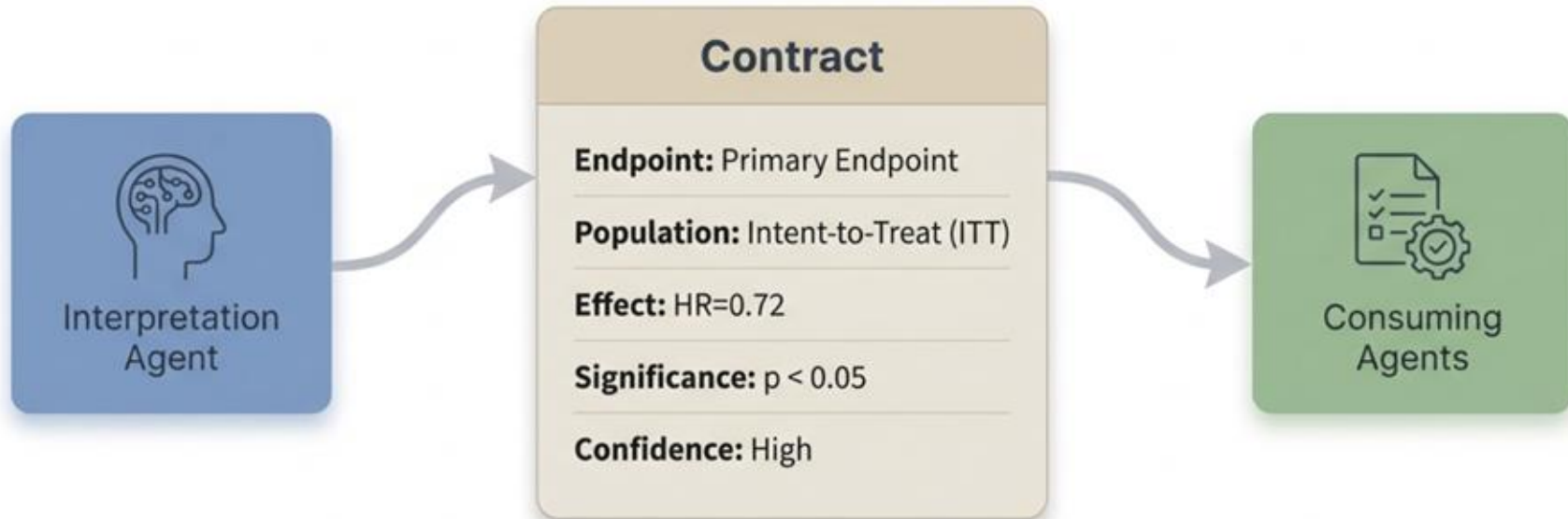
# The Architecture: A Multi-Agent Workforce



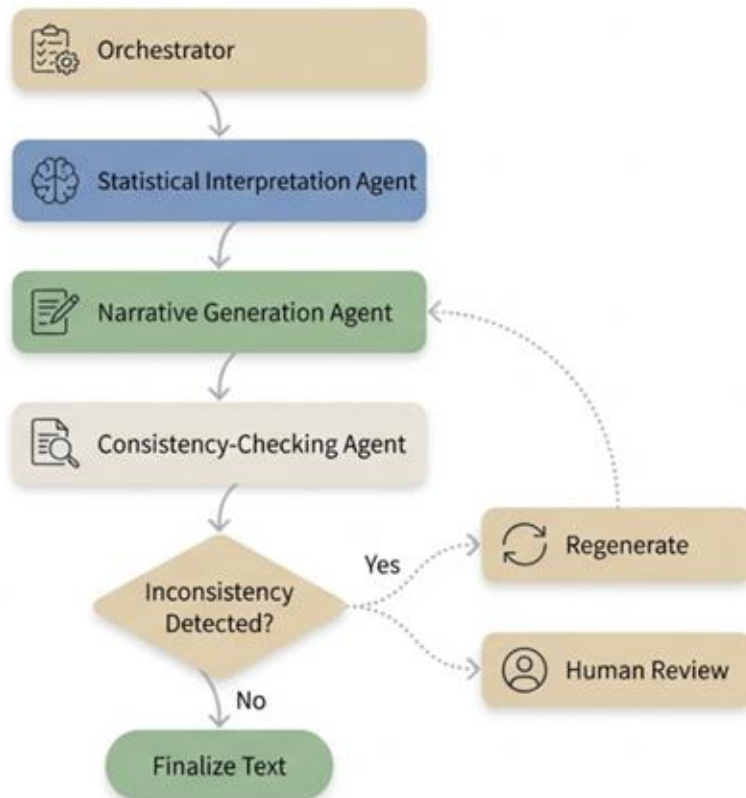


# Contract-Based Communication

Agents exchange structured data objects, not free-form chat.



# Orchestration & Control Logic

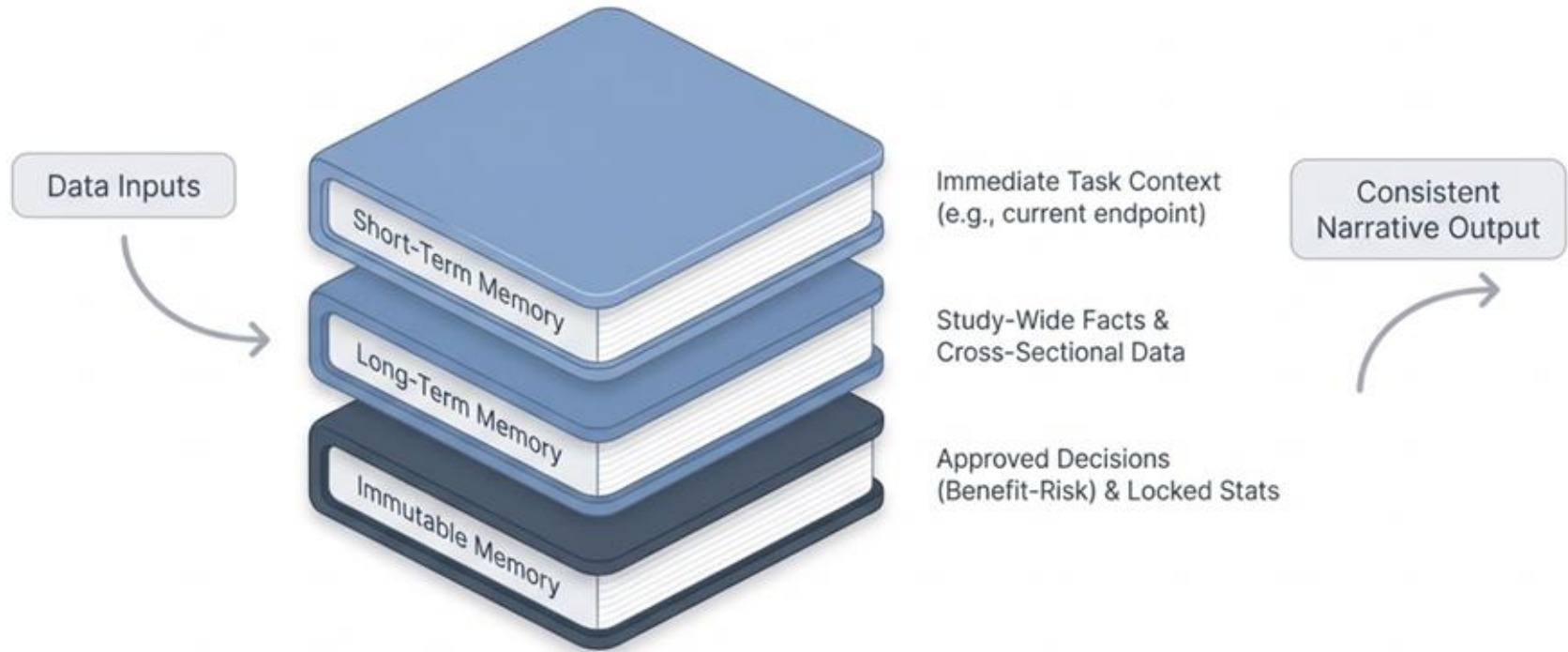


# Multi-Agent System Architecture

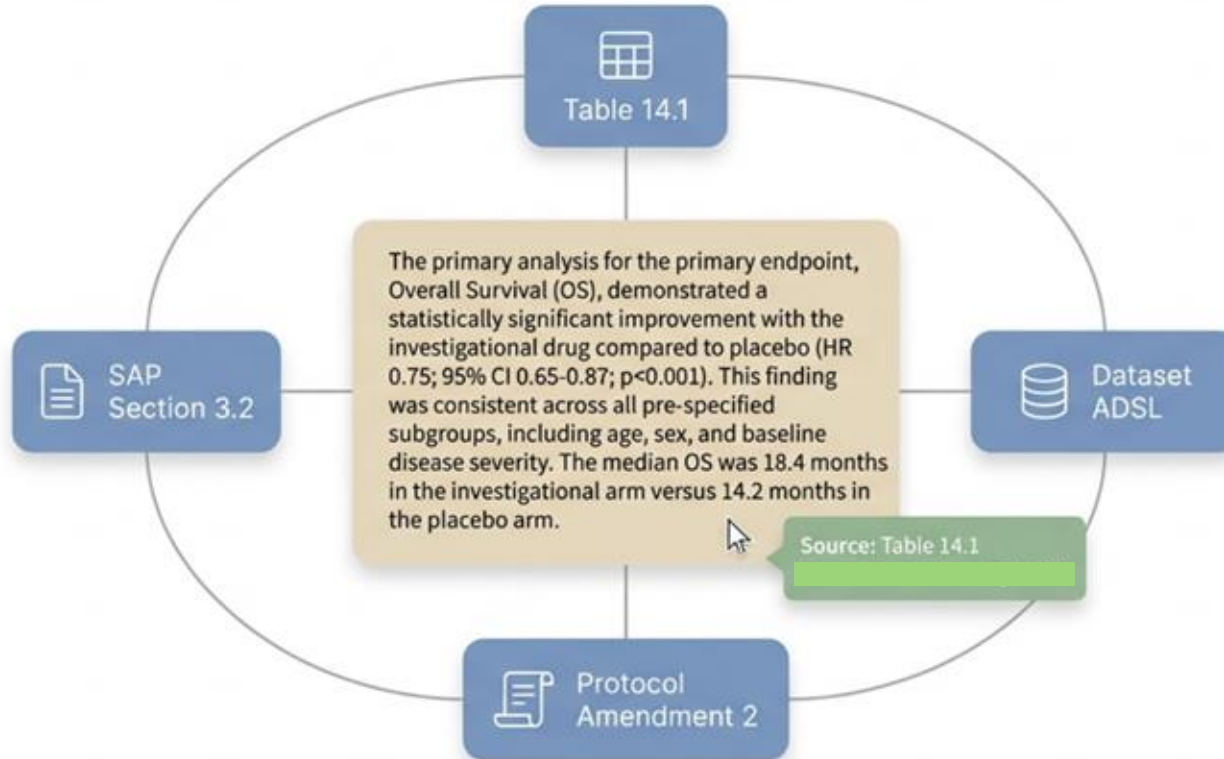
Four-layer design enabling scalability, parallel processing, and maintainability



# Layered Memory Prevents Hallucinations



# Traceability as a Living Graph



# Operational Opportunities



## Decoupled Drafting

Draft narratives using interim data before DB lock. Auto-update when final data arrives.



## Early Detection

Identify inconsistencies between SAP and Tables weeks before the deadline.



## Audience Views

Tailor outputs for Statisticians (Technical) vs. Clinicians (Outcome-focused) from one source.

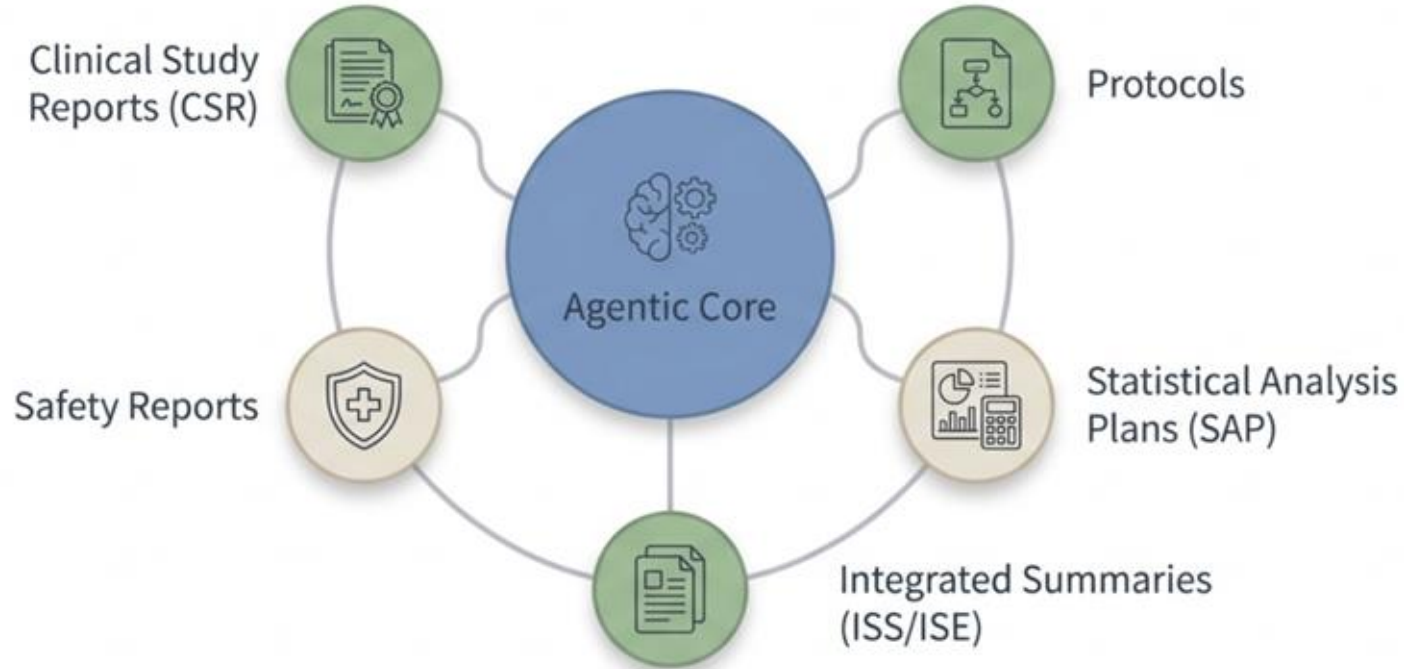
# Governance & GxP Compliance

## Transparency Over Autonomy



No content is finalized without explicit expert approval.

# Future Outlook: Scientific Coordination



Shift from 'Writing Text' to 'Engineering Reasoning'.

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**Thank you**

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