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BASEL, SWITZERLAND

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Novartis Campus, Fabrikstrasse 15, 4056 Basel, Switzerland

From Programmer to AI-Enabled Clinical Data Scientist:

Accelerating Clinical Development with Trusted Copilots

Daniel Christen – Advisory Solutions Engineer – HLS Solutions at SAS

Reimagining the Clinical Data Scientist Role:

Future-Proofing Skills and Partnerships

PhUSE SDE Focus

Reimagining the clinical data scientist role means embracing a future where technical excellence, strategic thinking and cross-functional collaboration converge to create greater scientific and operational impact. As technological acceleration reshapes the clinical development landscape, our role evolves from traditional programming to orchestrating intelligent, end-to-end data ecosystems. Future-proofing our skills requires combining expertise in analytics, data standards and quality with new capabilities offered by state-of-the-art technologies.

1. How our role may evolve and future skills in demand

2. Tool transformation – practical examples of AI-assisted programming

.

3. Closer integration with statisticians and clinical, regulatory and technology teams in more agile and digital environments

1. How our role may evolve and future skills in demand

How much intelligence is in AI ?

1. AI is "just retrieval"

- AI does not understand information the way humans do.
- It has no consciousness, self-awareness, desires, or intentions.
- Everything it produces is ultimately derived from patterns found in training data.
- When connected to RAG* systems, it is effectively a very sophisticated search-and-summarization engine.

2. AI shows genuine intelligence

- Intelligence does not necessarily require consciousness.
- Humans are also heavily pattern learners.
- Modern AI can perform tasks it was never explicitly programmed to do.
- It can reason across multiple sources, write software, solve novel problems, and explain concepts in ways that look remarkably similar to human reasoning.

3. The middle ground

- Current AI exhibits some components of intelligence, but not human-like understanding.
- A modern LLM is **like an extremely well-read assistant that has absorbed patterns from vast amounts of text and can synthesize them into new responses**
- The validity of any AI-generated conclusion **must be reviewed and confirmed by a qualified human** subject matter expert with full knowledge of the relevant context and data.

The conversation is shifting from "Can AI find an answer?" to “Can we trust, validate, and trace how the answer was produced?"

*RAG (Retrieval-Augmented Generation) combines a large language model (LLM) with external knowledge sources, retrieving relevant information at query time to generate more accurate, contextual, and traceable responses.

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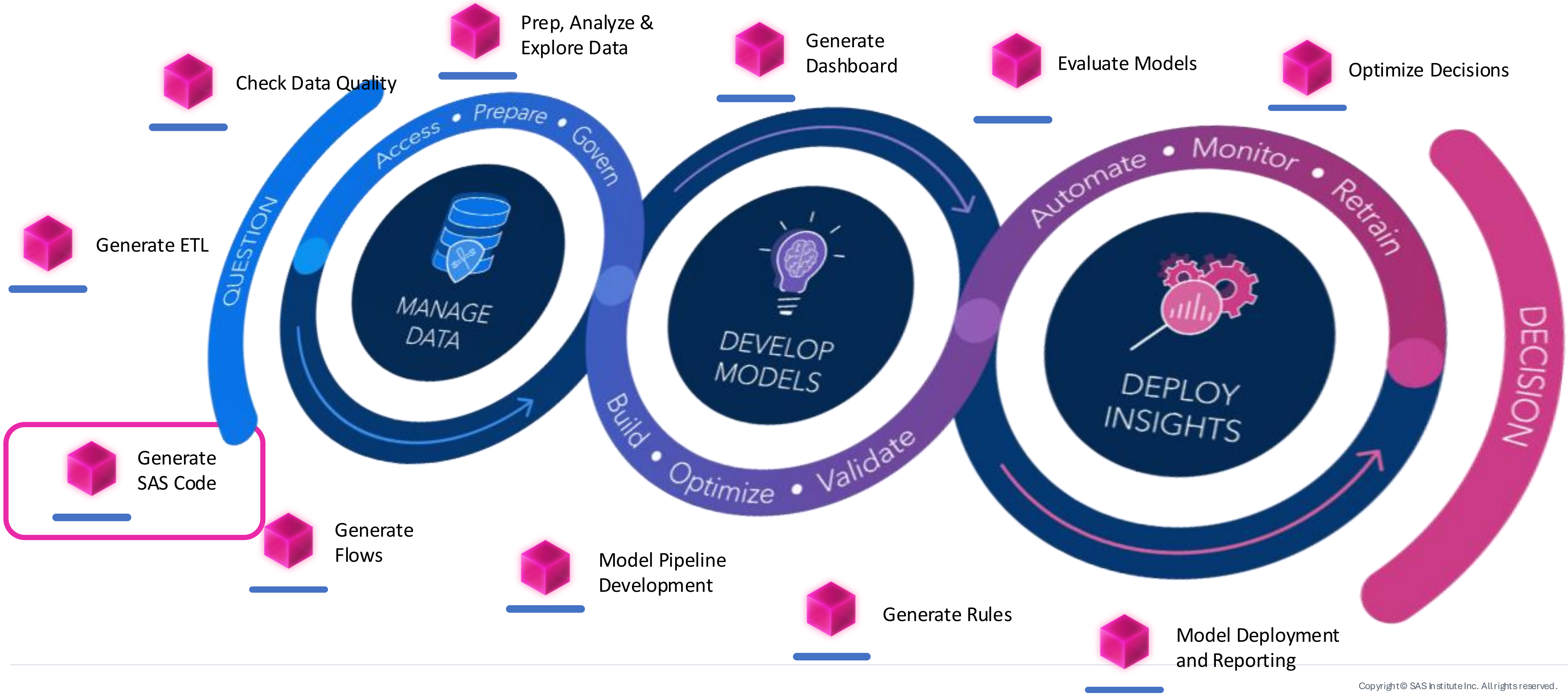
SAS Co-Pilot for Code Generation

Generate	Document	Explain

2. Tool transformation – practical examples of AI-assisted programming

Your AI assistant for the Data and AI Lifecycle



Generate SAS Code

From RAW data to final TFLs

1. RAW to SDTM

- Implementation Guide (Previous CDISC Mappings)

2. SDTM to ADaM

- Implementation Guide
- Study Design Documents

3. ADaM to TFL

- Implementation Guide
- Study Design Documents
- Mock-up TFL

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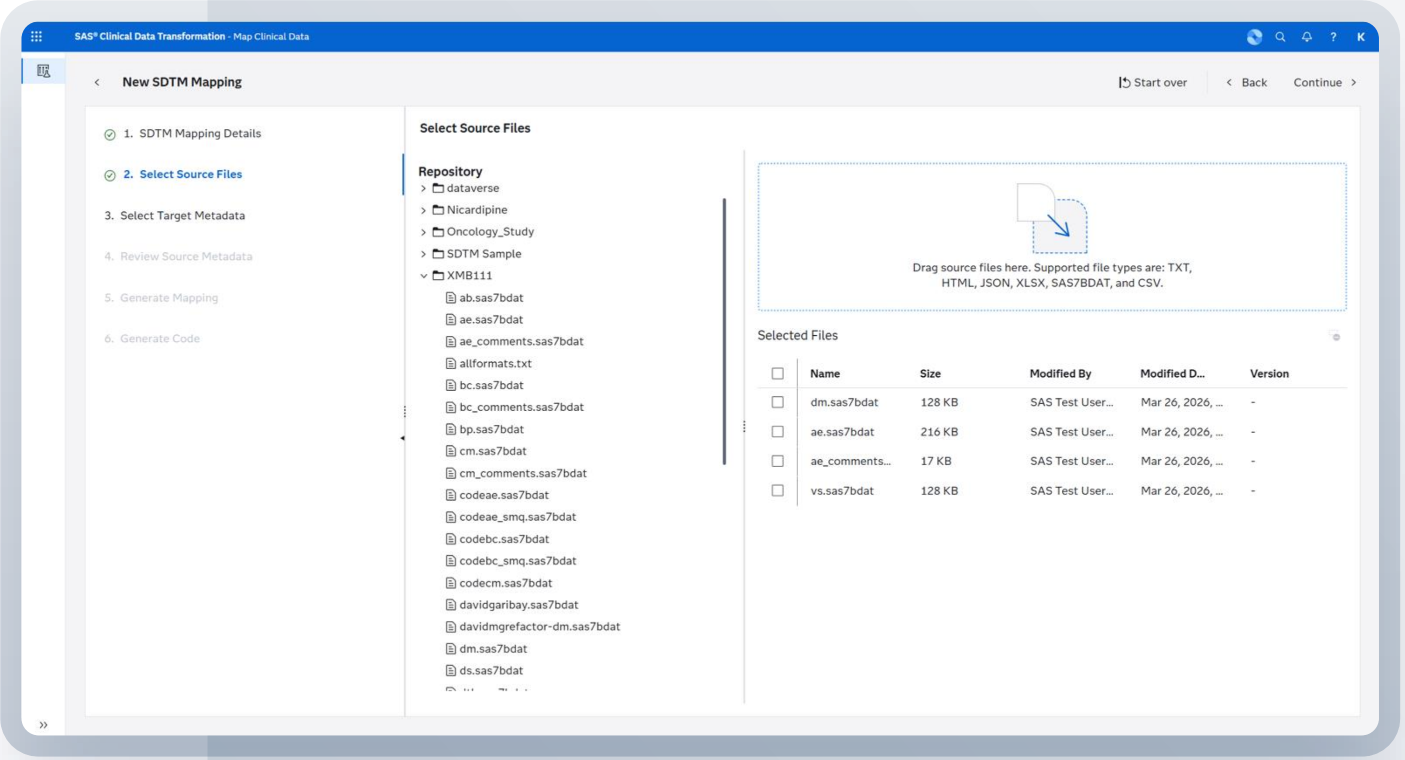
Clinical Data Transformation

Raw to SDTM

01

Select source data from Clinical Acceleration Repository select the dataset(s) you’d like to map

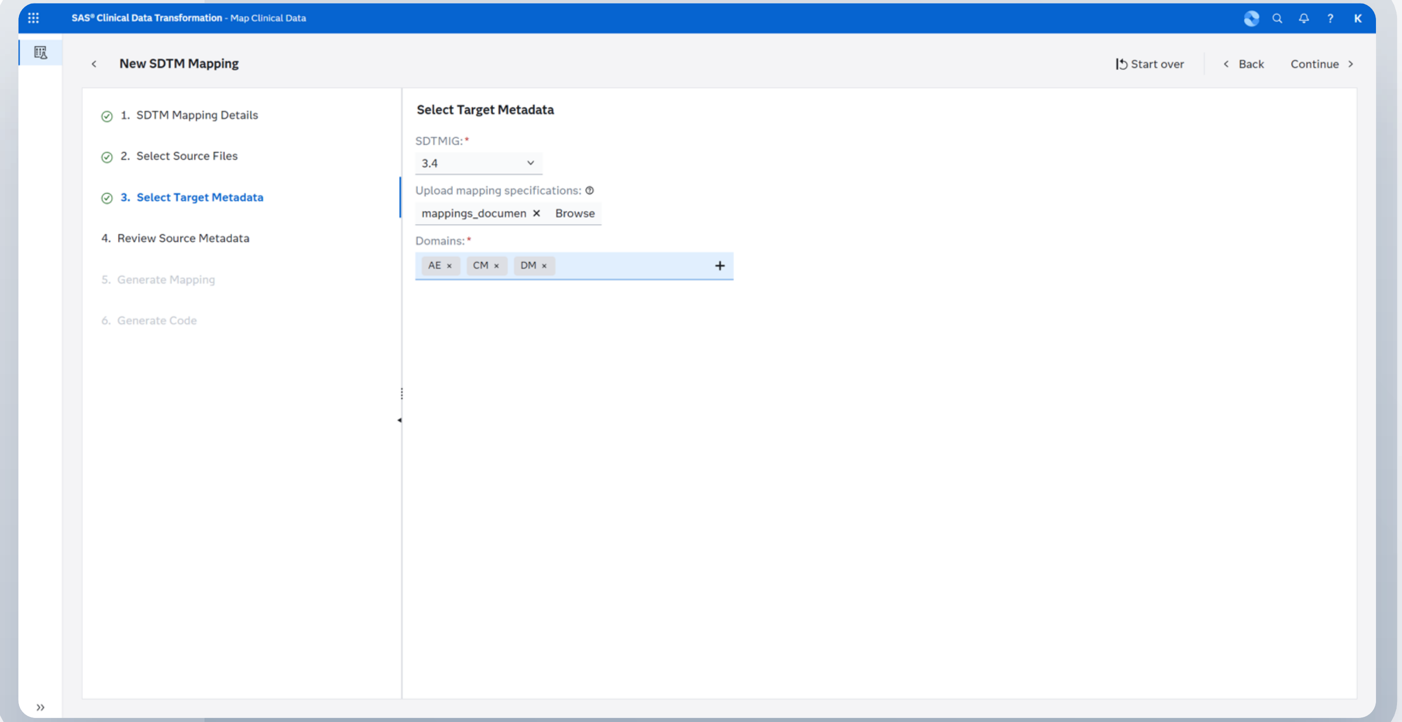


Clinical Data Transformation

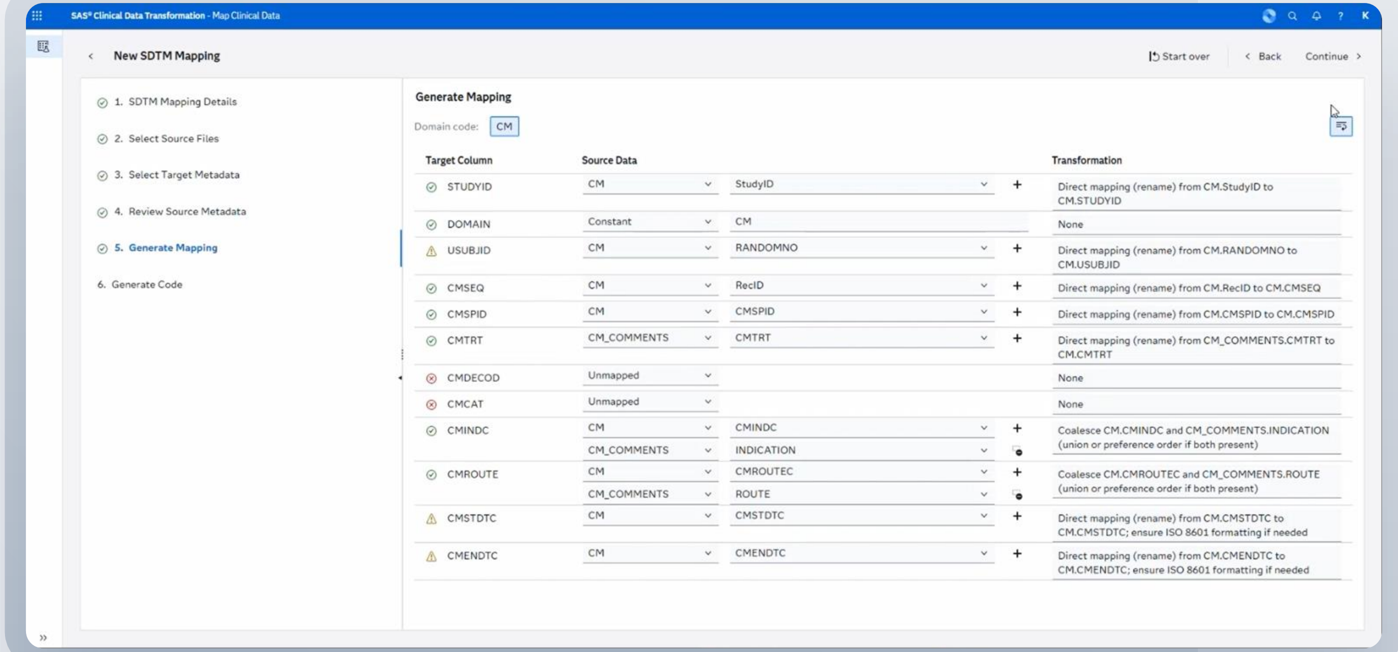
Raw to SDTM

02

Select target data structure
by selecting implementation guide from CDISC importing previous mapping specifications or specific target structure



Raw to SDTM



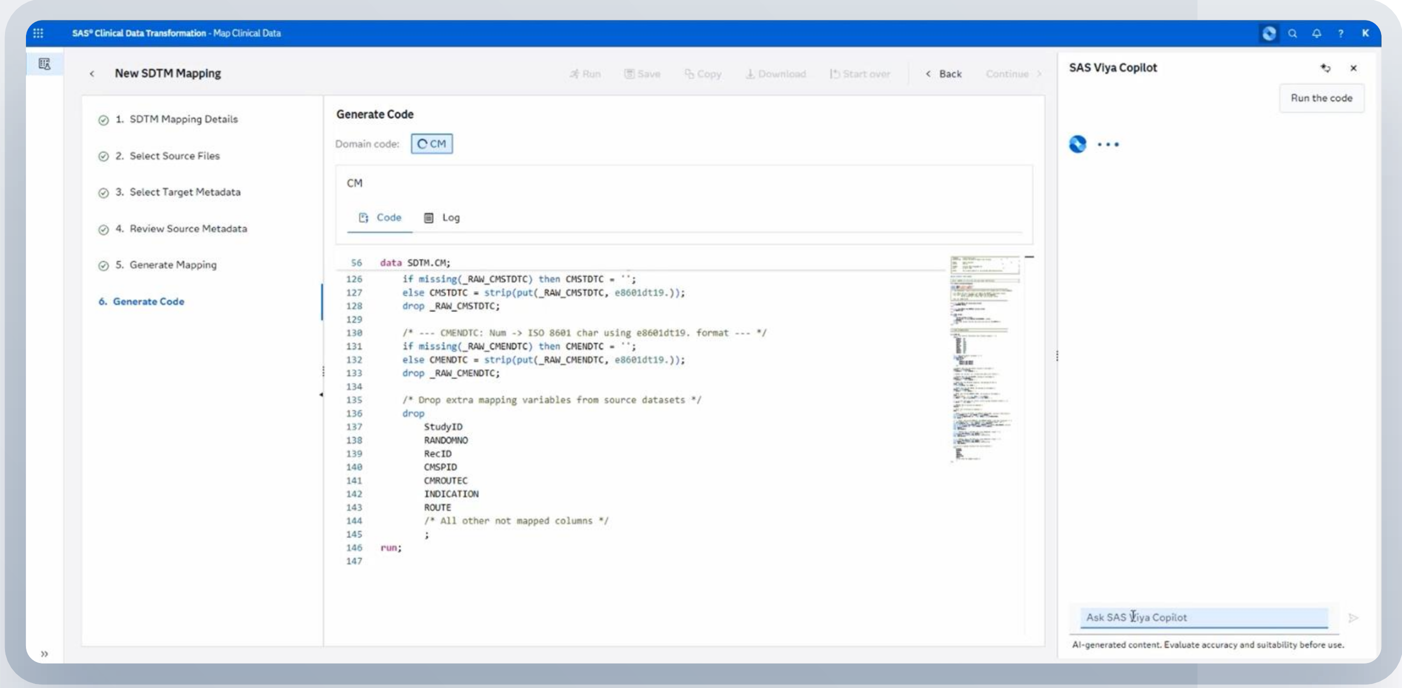
Clinical Data Transformation

03

Run Agent

to map from source to target with access to edit mapping and transformation directly via the UI

Raw to SDTM



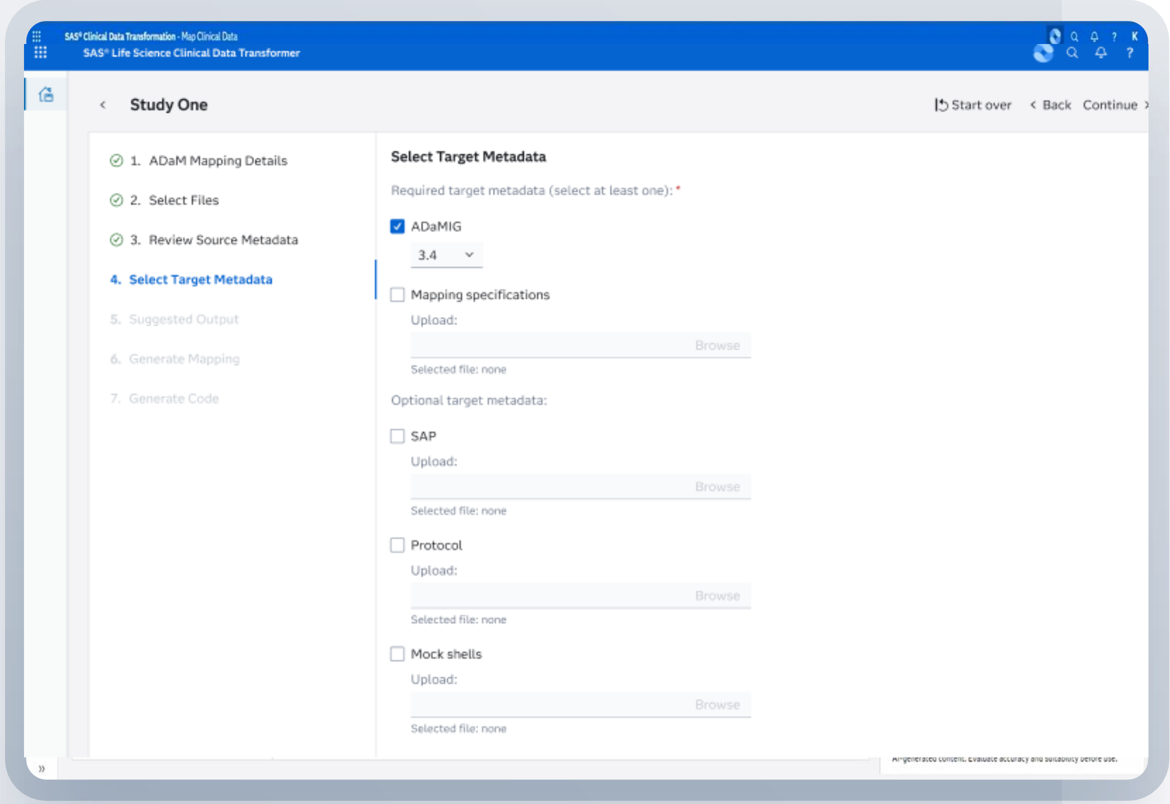
Clinical Data Transformation

04

Produce your code

and run it directly within Clinical Data Transformation, engage with Code Assist or Co-Pilot or save to your workspace to begin work

SDTM to ADaM

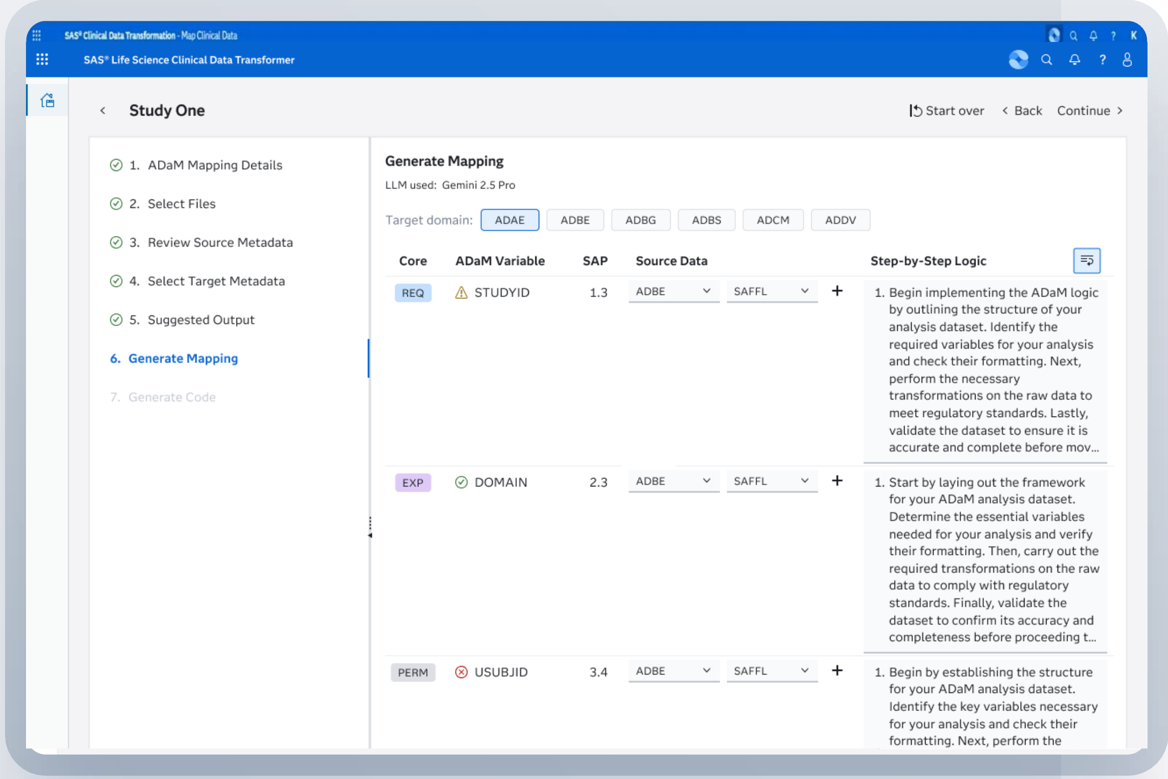


Clinical Data Transformation

05

Select target data structure by selecting implementation Guide from CDISC and importing study design documents.

SDTM to ADaM

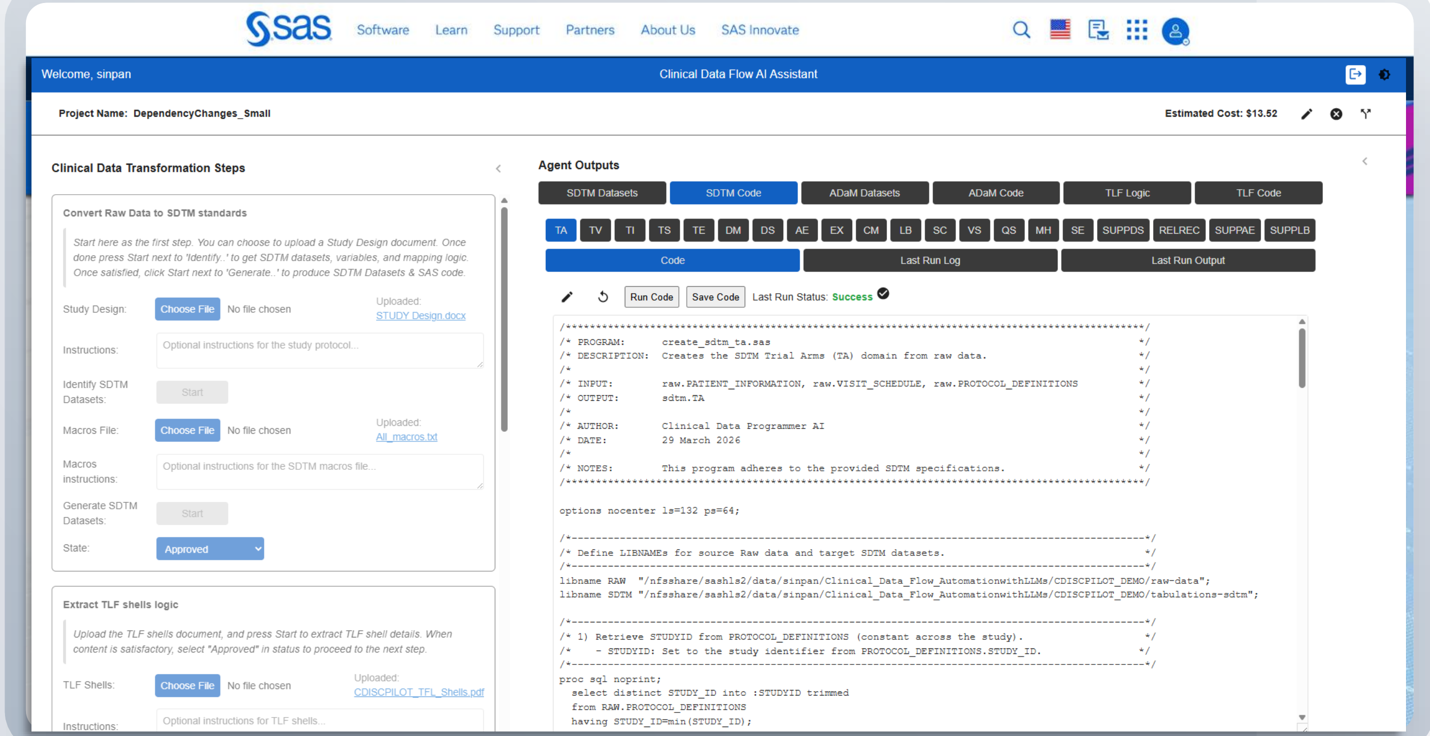


Clinical Data Transformation

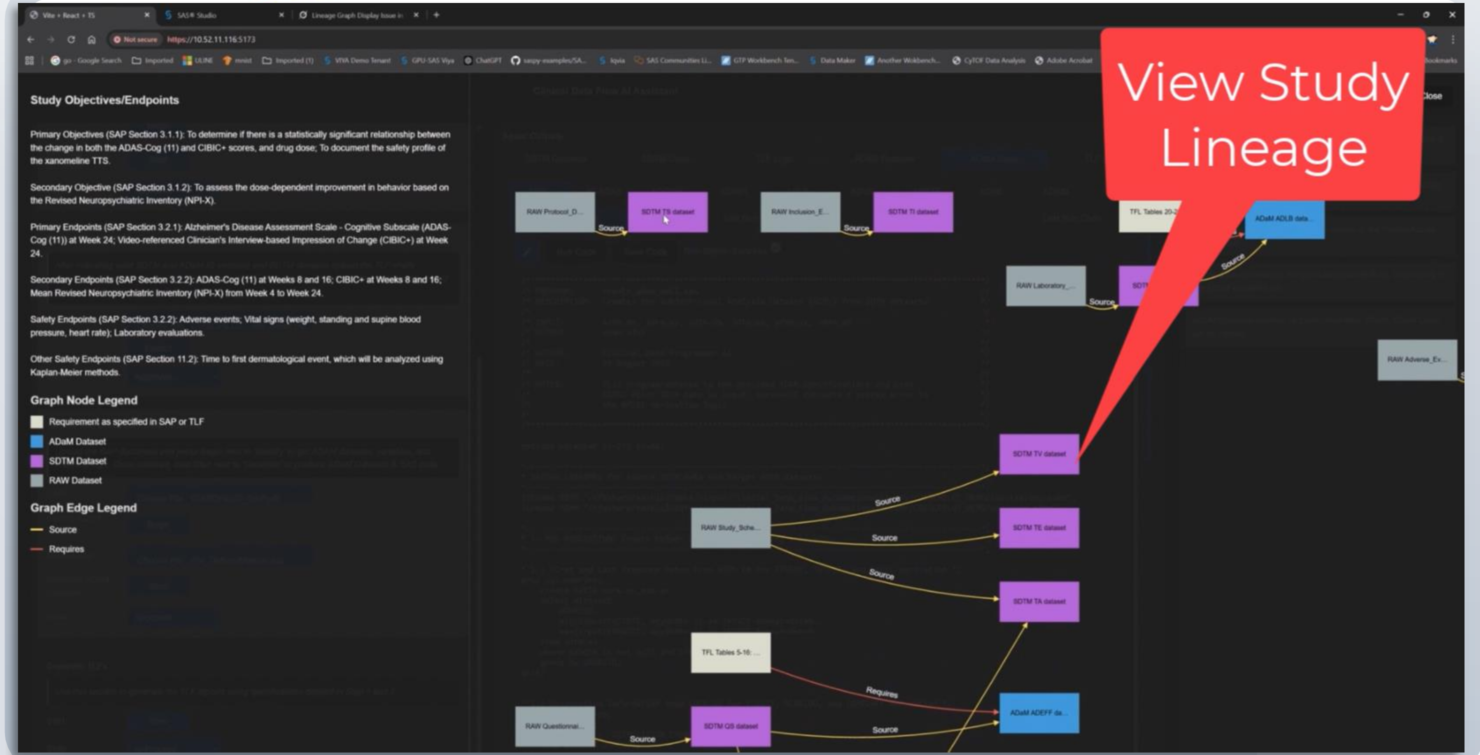
06

Run Agent

to map from source to target with access to edit mapping and transformation directly via the UI



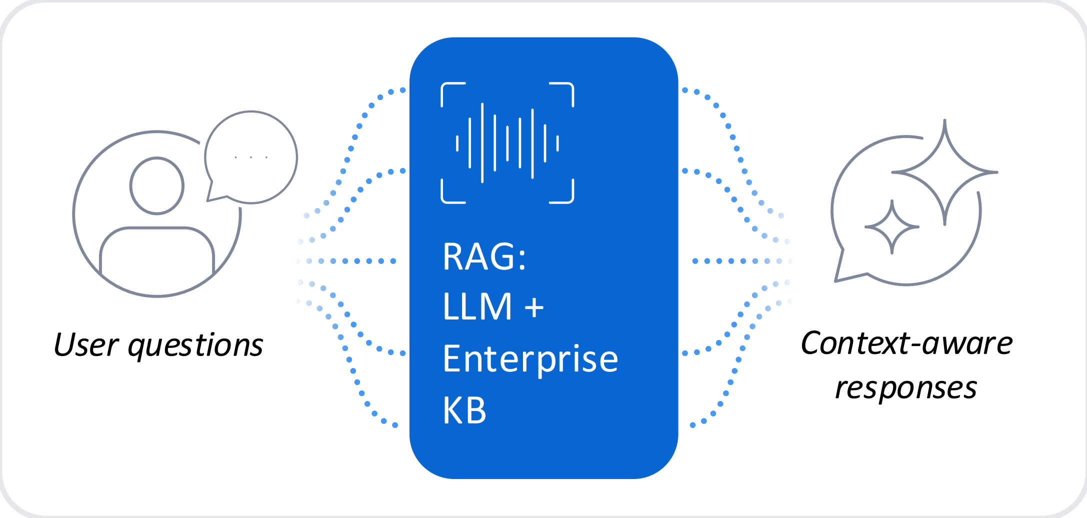
Continue with your standard operating process to validate code and data



View complete Study Lineage

RAG:
The Enterprise Game-Changer

Retrieval-Augmented Generation
= search + generate
so outputs are **grounded** in your enterprise knowledge base



Why RAG matters to users:

Factuality & Trust
Model cites the source; reduces hallucinations

Freshness
Pulls latest policies/specs at answer time—no retraining

Governance
Keeps enterprise access controls & auditing in the loop

Flexible
Not locked to a specific AI model

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SAS approaches tool transformation **by embedding Generative AI and Retrieval-Augmented Generation (RAG) directly into the analytics lifecycle**, enabling users to generate code, access contextual knowledge, automate complex programming tasks, and accelerate the path from data to insight while maintaining transparency and governance.

3. Closer integration with statisticians and clinical, regulatory and technology teams in more agile and digital environments

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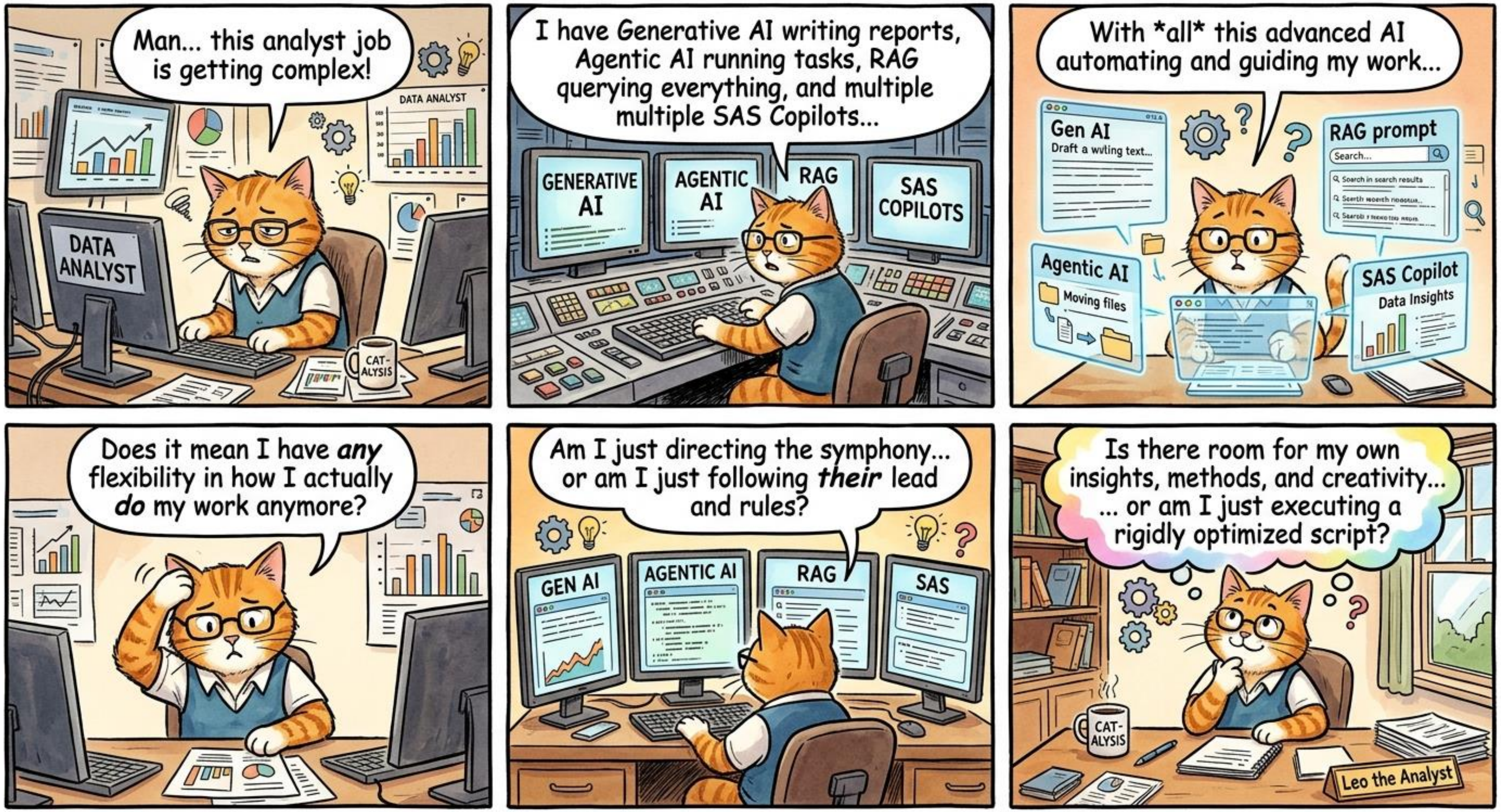
Future-Proofing Skills and Partnerships



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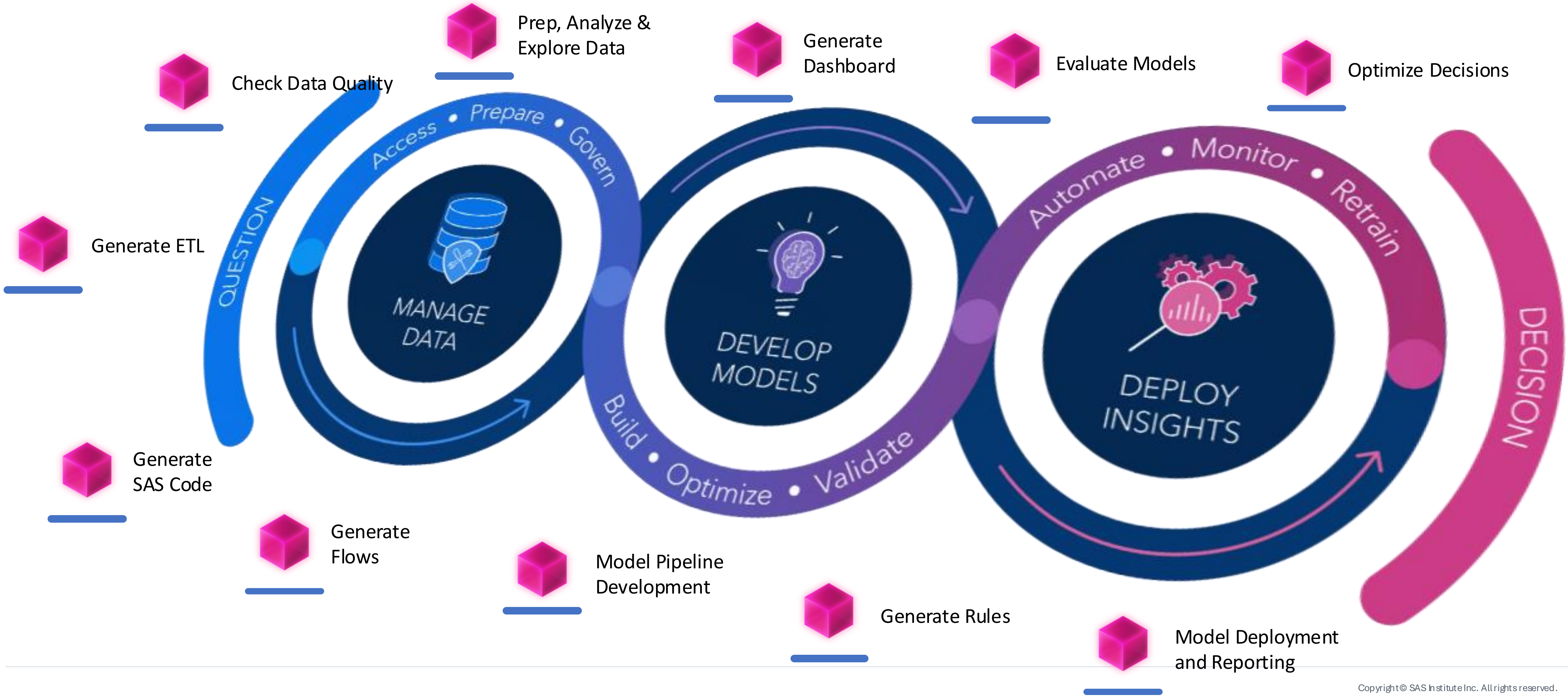


Agents:
The Enterprise Game-Changer

AI Agents = reason + act

so systems don't just answer – they can decide and act

Why Agents matter:

Autonomy & Action
Move from answering to acting — trigger workflows, updates, or decisions automatically

Personalization
Tailor responses as per Organizational context

Adaptability
Evaluate results, adjust strategies and improve in dynamic environments

Governance
Keeps enterprise access controls & auditing in the loop

SAS Viya MCP* Server

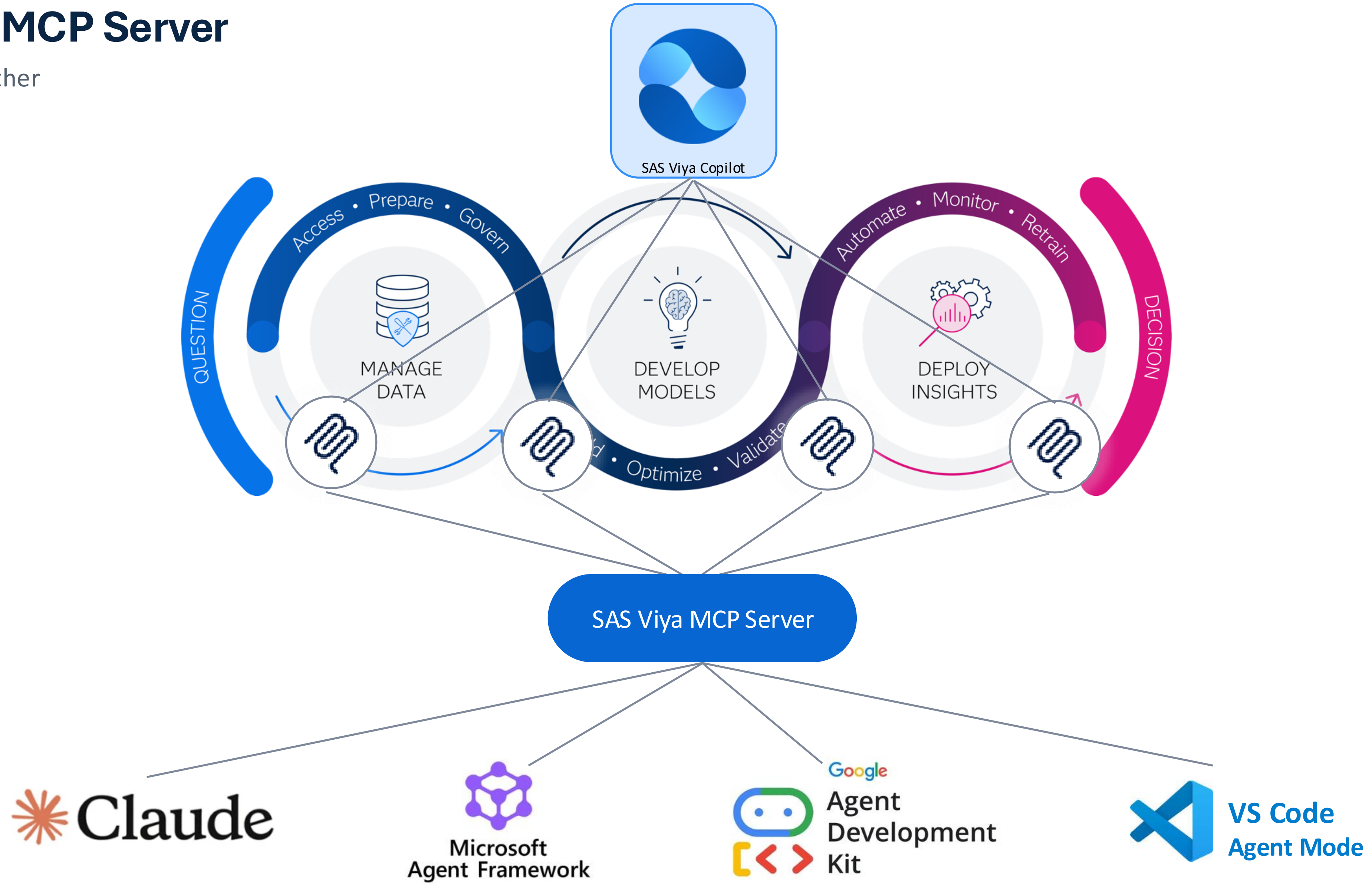
Tying it all together

- **Connect any AI assistant to SAS** by enabling tools such as Microsoft Copilot, Claude, and custom agents to securely access SAS analytics and decisioning capabilities.
- **Expose SAS as a trusted set of AI tools**, allowing agents to prepare data, execute SAS code, run models, score data, and trigger business decisions within governed workflows.
- **Bridge external LLMs with enterprise analytics**, combining conversational AI with SAS' trusted, explainable, and validated analytical engines.
- **Maintain governance and control through security**, auditability, transparency, and human oversight while AI agents interact with enterprise data and processes.
- **Enable interoperable agentic AI architectures, allowing organizations to use their preferred AI models** while leveraging SAS for analytics, decisioning, and operational execution.
- Accelerate the path from insight to action by allowing AI agents to move beyond conversation and **directly interact with SAS data, reports, models, and decision services**.

*MCP stands for Model Context Protocol. This is the open standard introduced by Anthropic for connecting AI assistants and agents to external tools, data sources, and systems.

SAS Viya MCP Server

Tying it all together



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SAS views Agentic AI in Life Sciences as a trusted, governed digital collaborator that augments scientific and clinical experts **by automating complex analytical workflows while ensuring transparency, traceability, and regulatory compliance.**

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Thank You