Beyond Manual Programming: LLM Automation in Clinical Data Workflows

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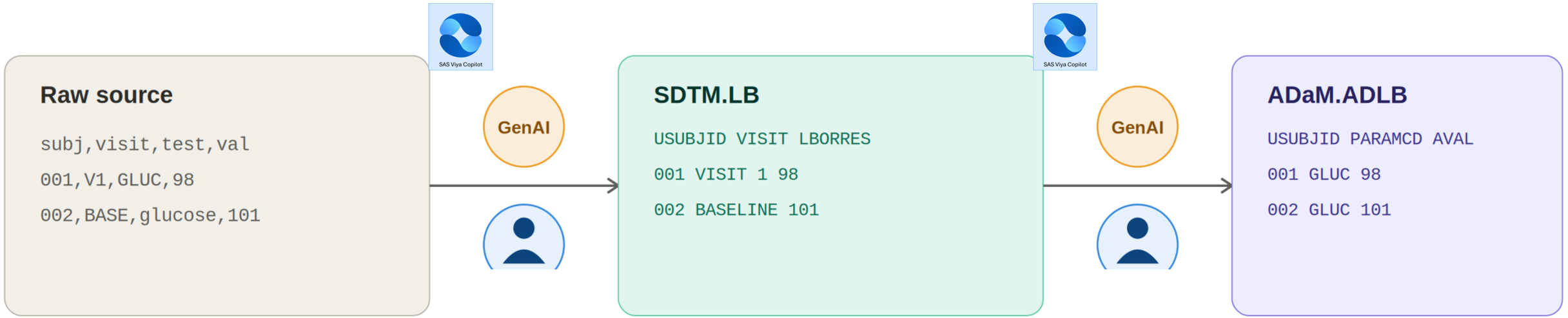
Single Day Events

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COPENHAGEN, DENMARK

Thursday 22 October 2026
Ferring Pharmaceuticals A/S
Amager Strandvej 405 2770 Kastrup

This presentation is focused on how Generative AI transforms the day-day tasks of the Statistical Programmer



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AI Pulse 2026 at US Connect: 37% are applying or exploring AI in SDTM & ADaM automation

Where AI is applied or explored today

28 SDTM & ADaM automation

26 TFL automation

23 Data review & QC

21 Metadata & standards

20 Clinical doc generation

4 Not using AI

Where organisations stand today

22 Piloting / proof of concept

14 Evaluating

11 In production

2 Not started

The biggest barrier to scaling

28 Data privacy & security

19 Trust / validation of outputs

17 Regulatory & compliance

14 Workflow integration

12 Skills & expertise gap

10 Organizational resistance

1 Lack of standards

Sources: AI Pulse: Taking the Industry's Temperature on GenAI in Statistical Programming, PHUSE US Connect 2026,

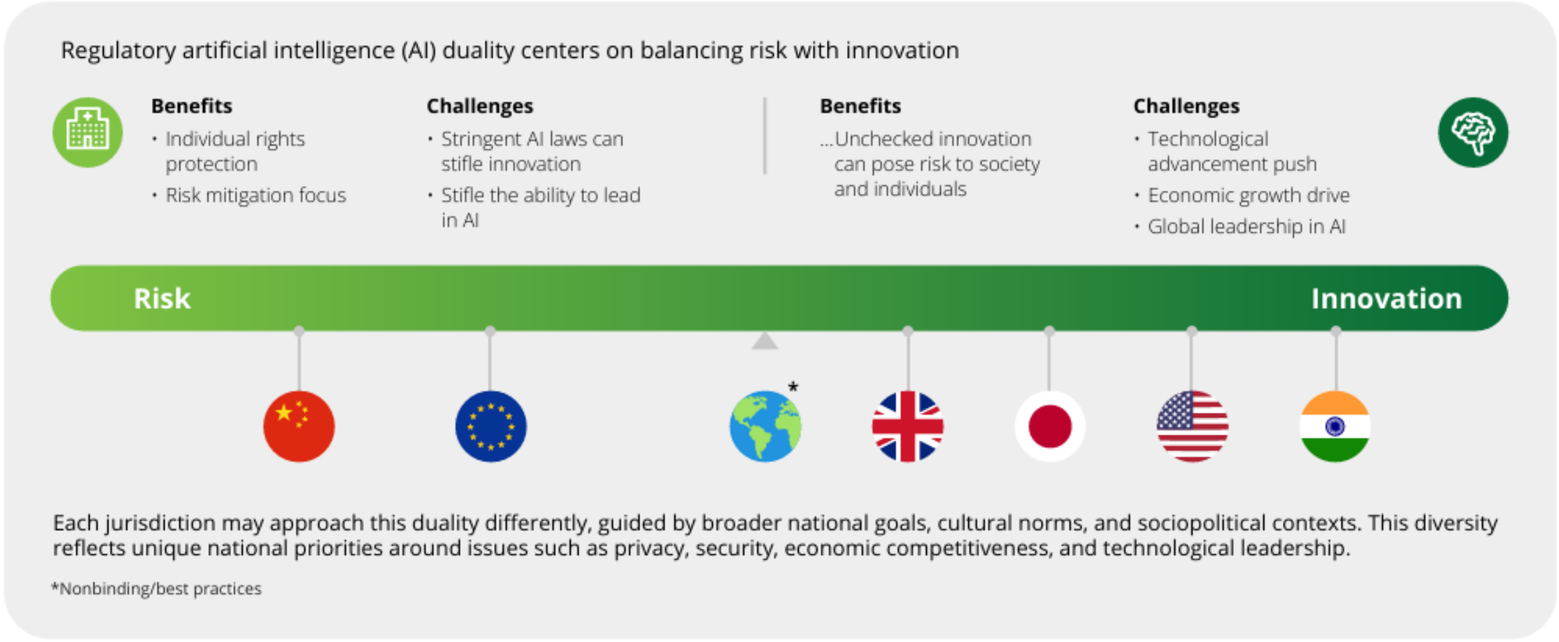
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Need for a unified global approach to AI regulation

Different regions are approaching AI regulations differently

Figure 1: The AI duality

The duality between risk and innovation



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Source: Deloitte (2025), "The AI duality", Figure 1. GenAI regulations in life sciences.

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FDA and EMA on AI in drug development

FDA

- January 2025 **draft guidance** on AI to Support Regulatory Decision-Making for Drugs and Biologics
- CDER : A marked increase in submissions containing AI components

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

- September 2024 **Reflection paper** on AI in the medicinal product lifecycle

What they ask of sponsors

- Assess the model risk
- Own the accountability —keep humans in the loop
- Validate and monitor across the life cycle, and engage regulators **early**

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The 10 joint FDA–EMA **guiding principles** of good AI practice in drug development, January 2026

1 Human-centric by design	2 Risk-based approach	3 Adherence to standards	4 Clear context of use	5 Multidisciplinary expertise
6 Data governance and documentation	7 Model design and development practices	8 Risk-based performance assessment	9 Life cycle management	10 Clear, essential information

Sources: FDA, Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products, draft guidance, January 2025 (FDA-2024-D-4689) · FDA (CDER/CBER) and EMA, Guiding Principles of Good AI Practice in Drug Development, January 2026 (fda.gov/media/189581) · EMA, Reflection Paper on the use of Artificial Intelligence in the medicinal product lifecycle, EMA/CHMP/CVMP/83833/2023, September 2024 ·

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Generative AI compresses raw-to-SDTM mapping from days to hours

Current state

Statistical programming today



Highly repetitive



Time consuming



Inconsistency and rework

Generative AI + human oversight



AI drafts the mappings, transformation logic, code and documentation



The human reviews, refines, tests and approves

Future state



AI proposes the raw-to-SDTM mappings, with confidence indicators



Human oversight



Less time on mapping — from days to hours, freeing time for analysis

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Using Generative AI to automate Clinical Data flows

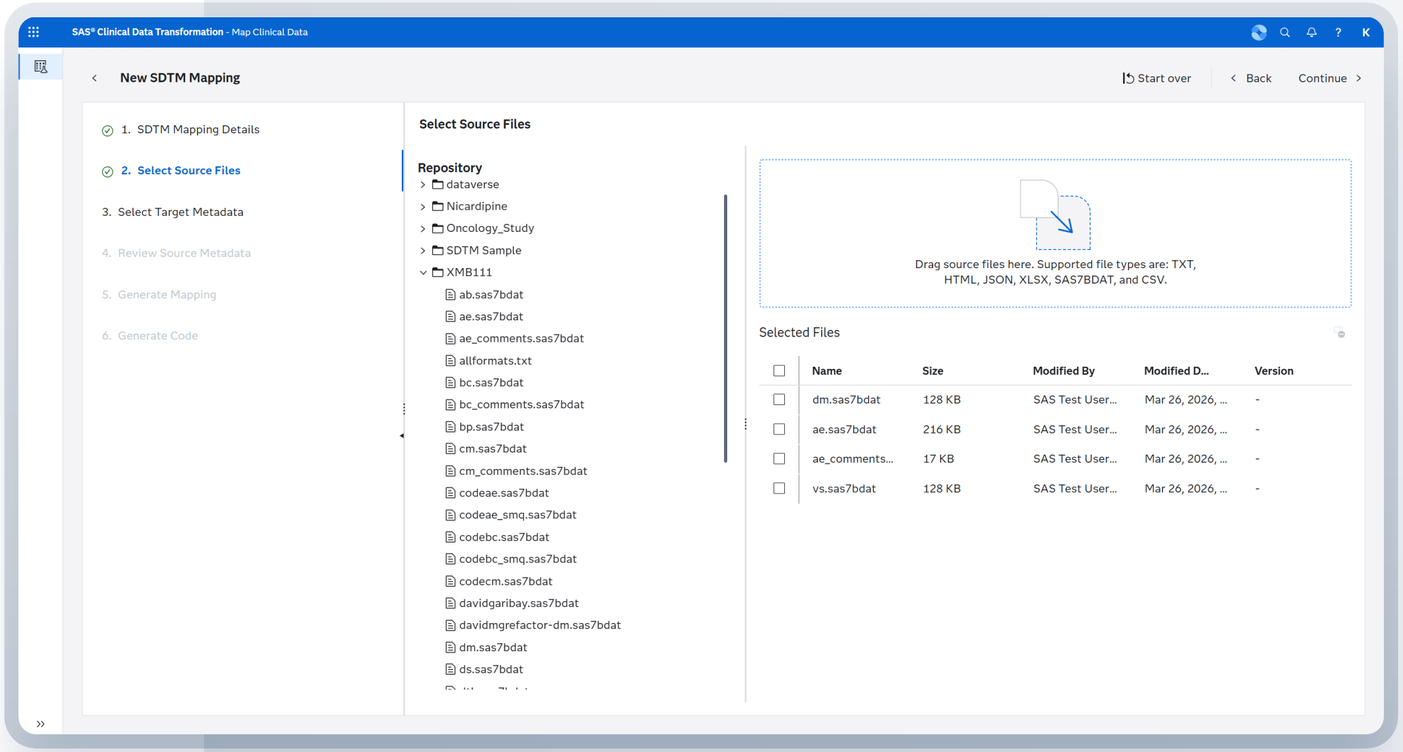
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Clinical Data Transformation

Raw to SDTM

01

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



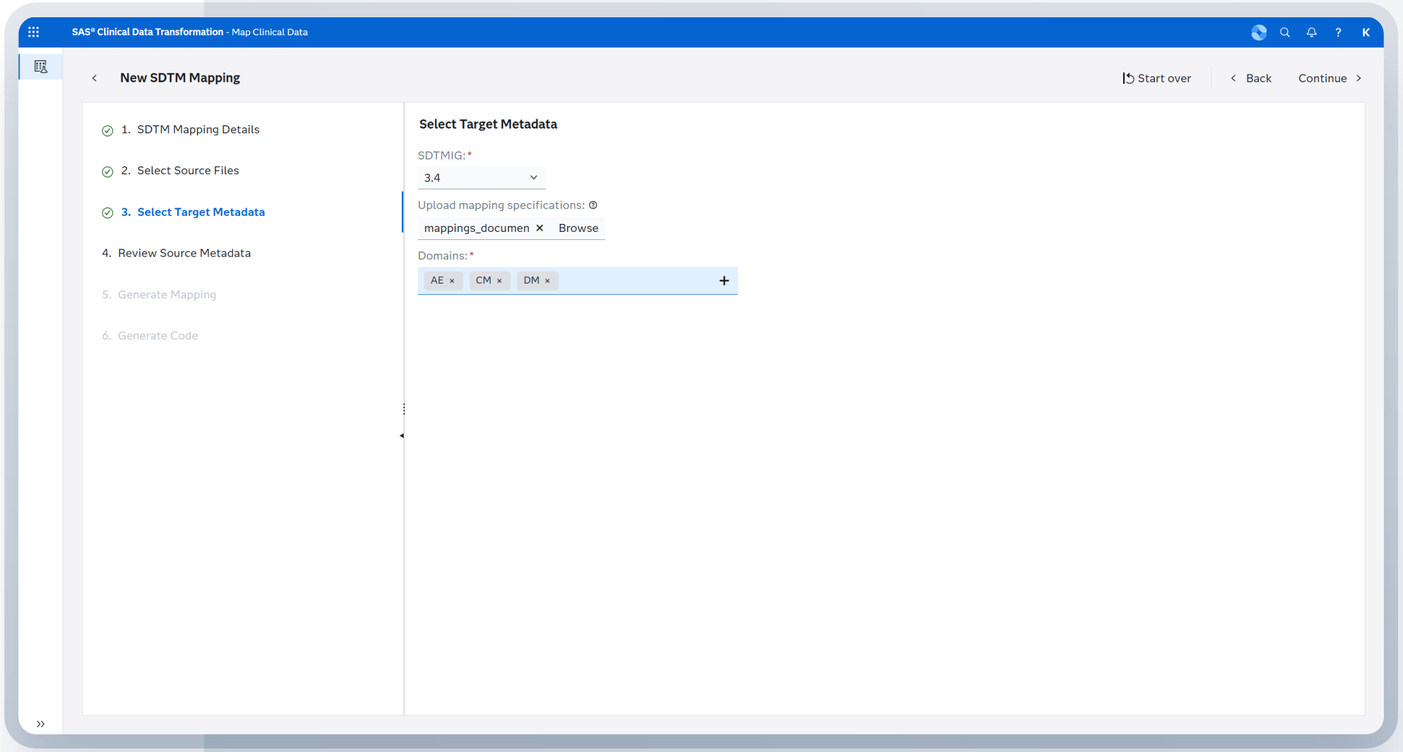
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Clinical Data Transformation

Raw to SDTM

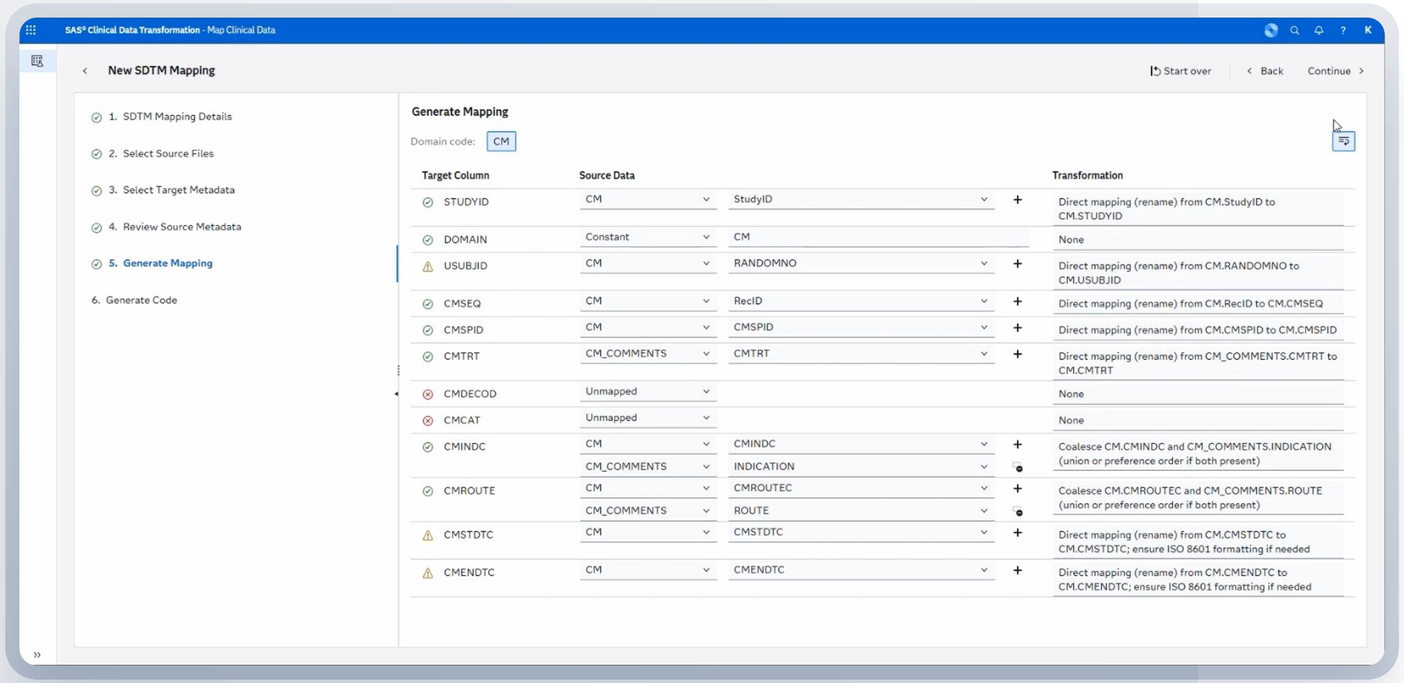
02

Select target data structure
by selecting implementation guide from CDISC and apply customer-provided standards and conventions



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Raw to SDTM



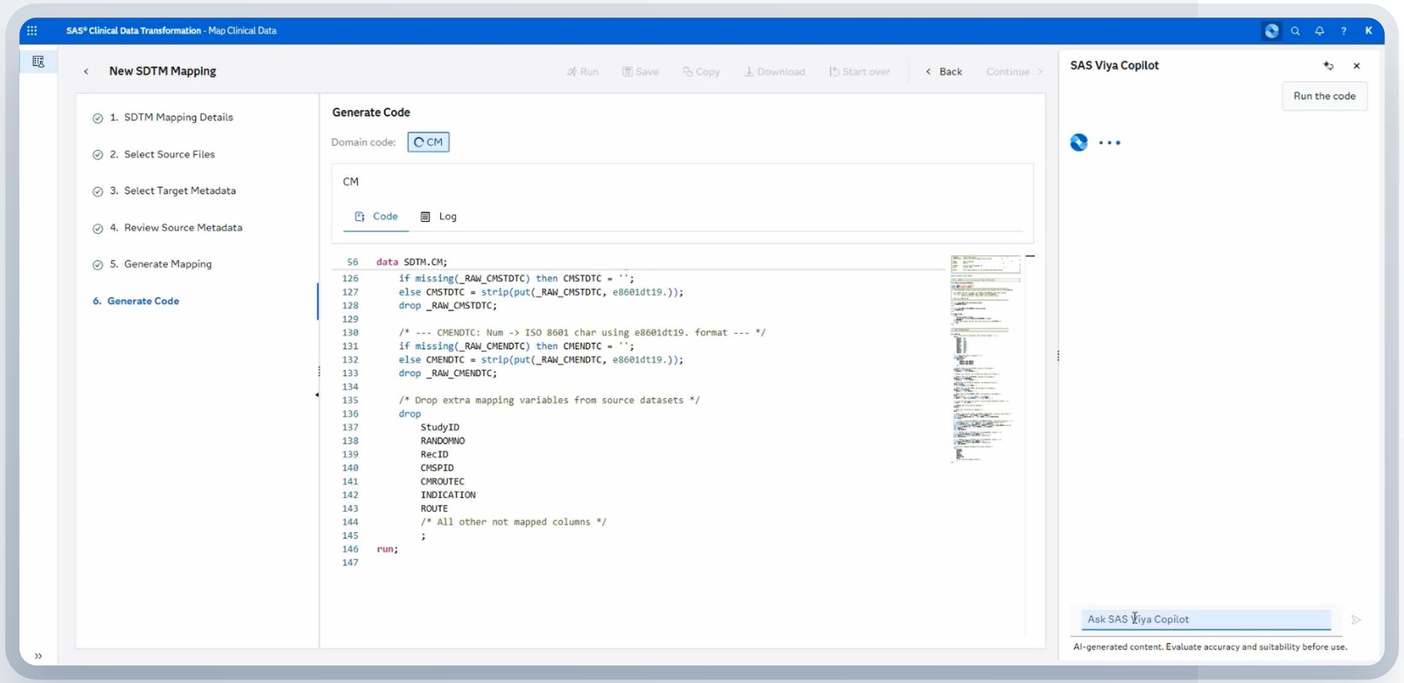
Clinical Data Transformation

03

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

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Raw to SDTM



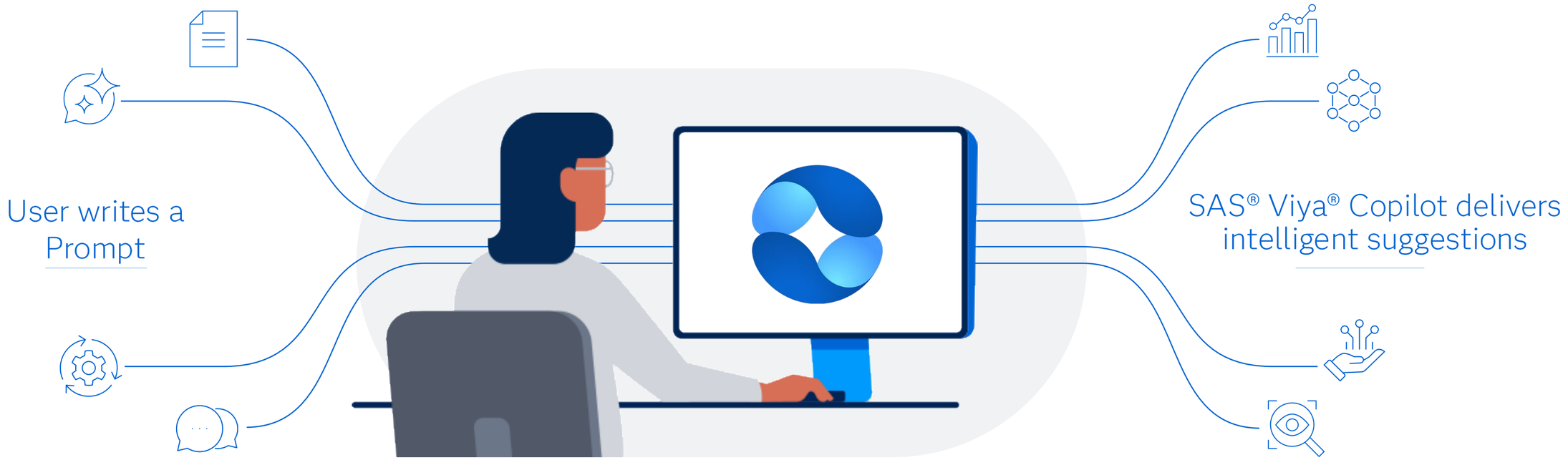
Clinical Data Transformation

04

Generate the code
and run it directly within Clinical Data Transformation, engage with Viya Co-Pilot or save code to your workspace to begin work

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SAS® Viya® Copilot



With the latest GenAI tech

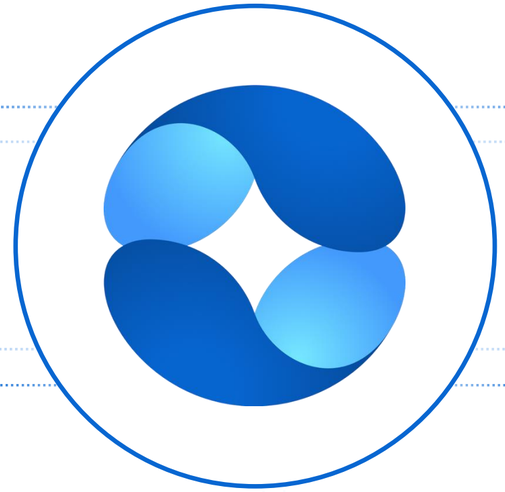
Large Language Model *Microsoft Partnership*	SAS® Viya® Knowledge Base	Trustworthy and Secure	Embedded AI Assistance in SAS Viya

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SAS Viya Copilot®

Generate, improve, explain SAS, R and Python code with AI-driven precision

Input		Output	
GENERATE CODE	**Plain English** Prompt written in plain English Inside /* */ + content code where available	**New Code**	NEW CODE
IMPROVE AND FIX CODE	**Old Code**	**Improved Code** Enhanced to your requests and requirements	BETTER CODE
EXPLAIN AND COMMENT	**Add Comments**	**Comments / Explanations** English inline comments in Editor Window	EASY TO UNDERSTAND



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Clinical Data Transformation Roadmap

01 **Clinical Trial Protocol**

02 **Data Collection**
eCRF / eSource

03 **Data Tabulation**
SDTM

04 **Statistical Analysis**
ADaM / TLFs

05 **Clinical Study Report**

Clinical Data Transformation

- Raw data to SDTM
- SDTM to ADaM
- Creation of define.xml
- Creation of Tables, Lists, Figures (TLF's)

Information is subject to change

Roadmap to broader clinical data transformation capability.

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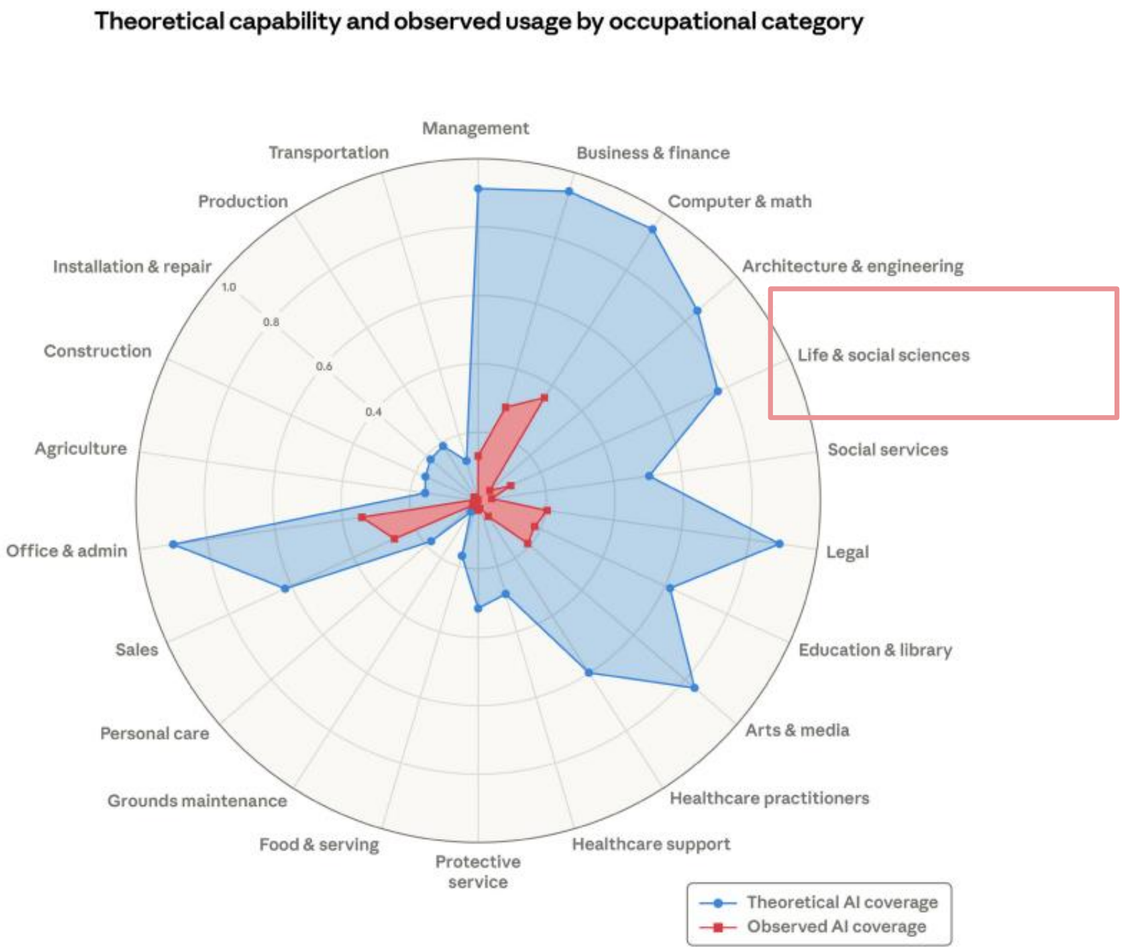


Less time on mapping — from days to hours, freeing time for analysis

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AI in Life sciences: high potential, low adoption

Labor market impacts of AI: A new measure and early evidence, Anthropic, Mar 5, 2026



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“AI will not replace statistical programmers. It will replace the ones who were already replaceable.”

Sascha Ahrweiler
VP, Global Head Statistical Programming & Analytics, Strategy & Operations, Bayer AG, *SAS Innovate on Tour, Liverpool and Frankfurt, 2026*



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THANK YOU!

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