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Single Day Event

Get It Done: Accelerating Clinical Trial Submissions with SAS Agents

Streamlining the path to regulatory submission with SAS Viya

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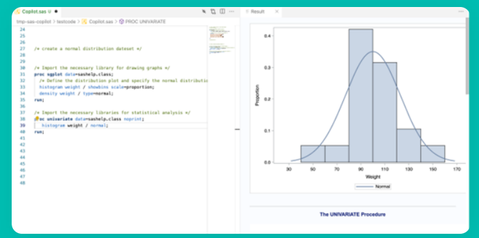
Global Health and Life Sciences Practice
SAS Institute

phuse.global

SAS and Generative AI (GenAI)

SAS Viya Copilot
to accelerate user productivity

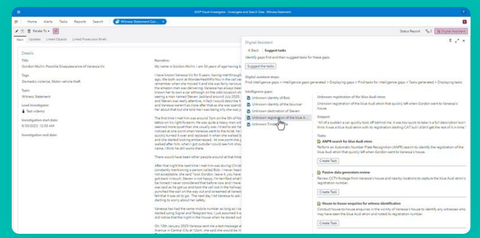
Conversationally query SAS Viya to increase user productivity, further democratizing analytics



example: SAS Code Generation

Specialized SAS Viya Copilots
to accelerate industry workflows and processes

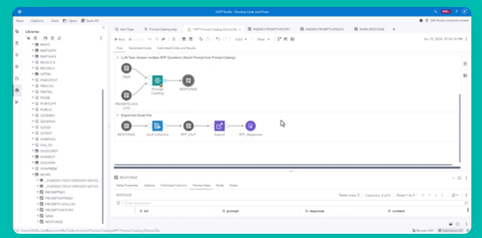
GenAI driven assistants to accelerate domain-specific workflows



example. Clinical Data Lifecycle

SAS Viya to help build your LLM-based applications to unlock value in your proprietary business assets

Flexible SAS Viya GenAI building blocks to help with development and orchestration of your LLM application stack



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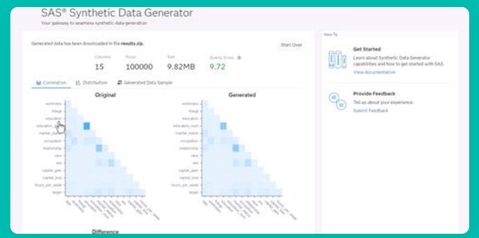
Standalone GenAI services
to enable your toolchains, like a synthetic data generation service

API-first low-code/no-code synthetic data generation and validation experience

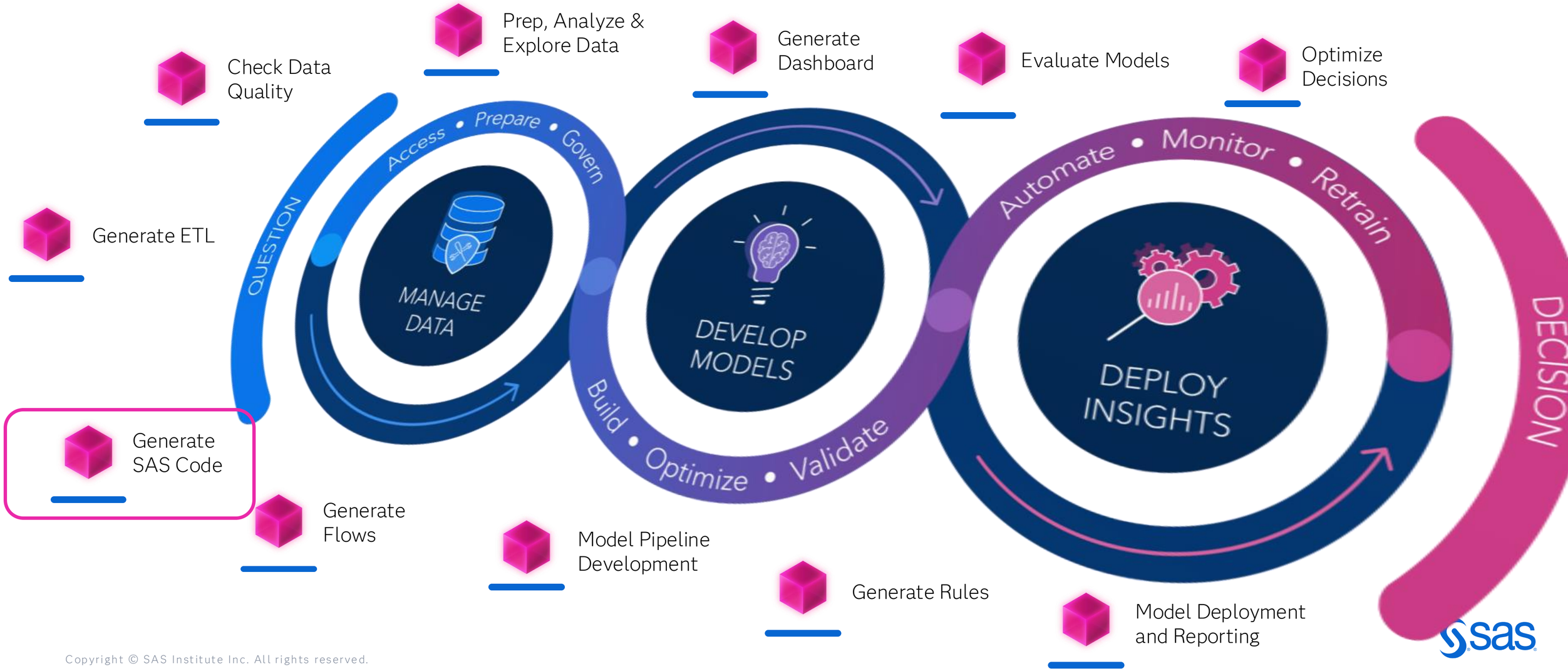


example. Synthetic data generation API

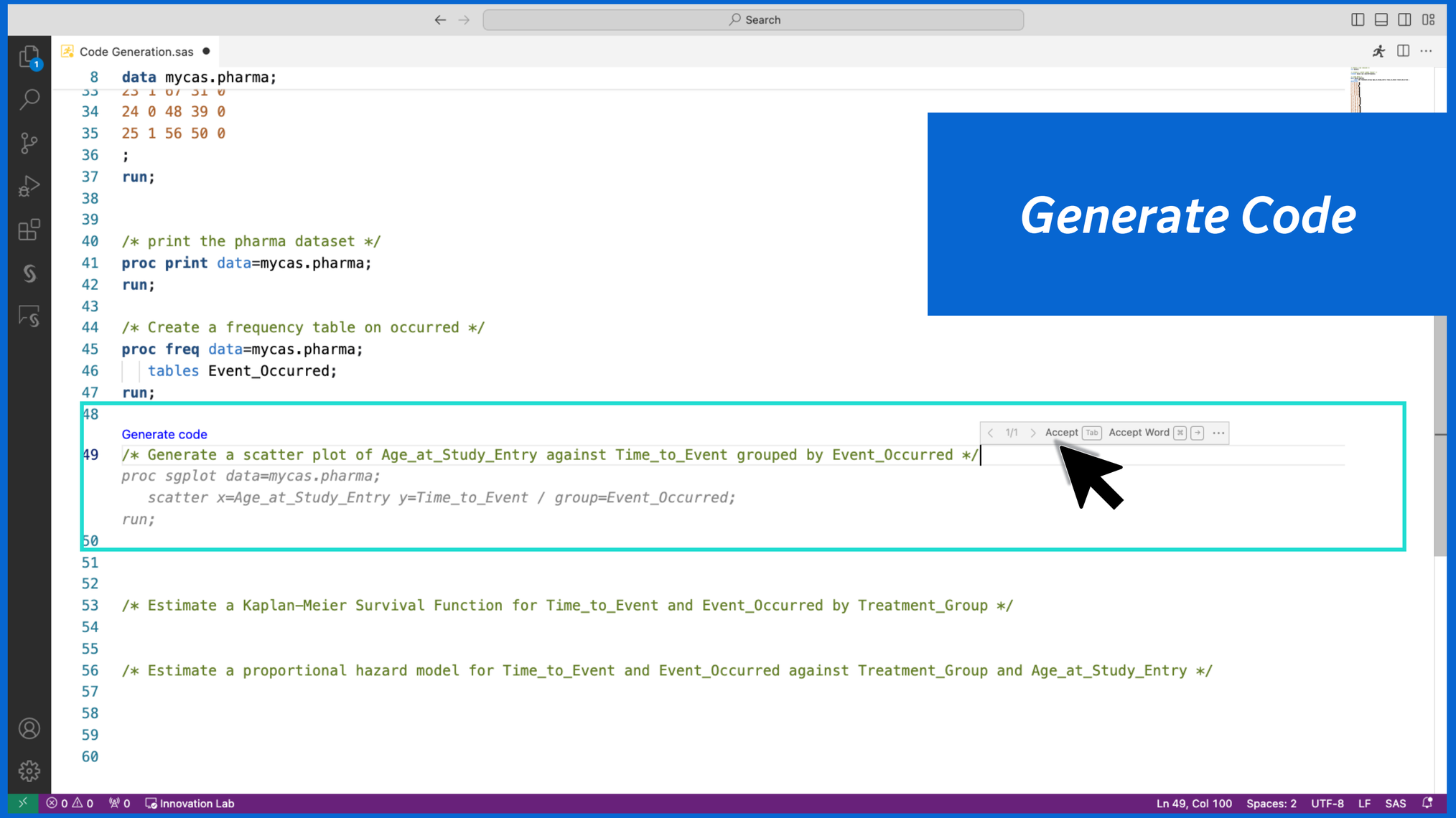
sas.com/generative-ai

Your AI assistant for the Data and AI Lifecycle

Ease the barrier to data analysis and AI development

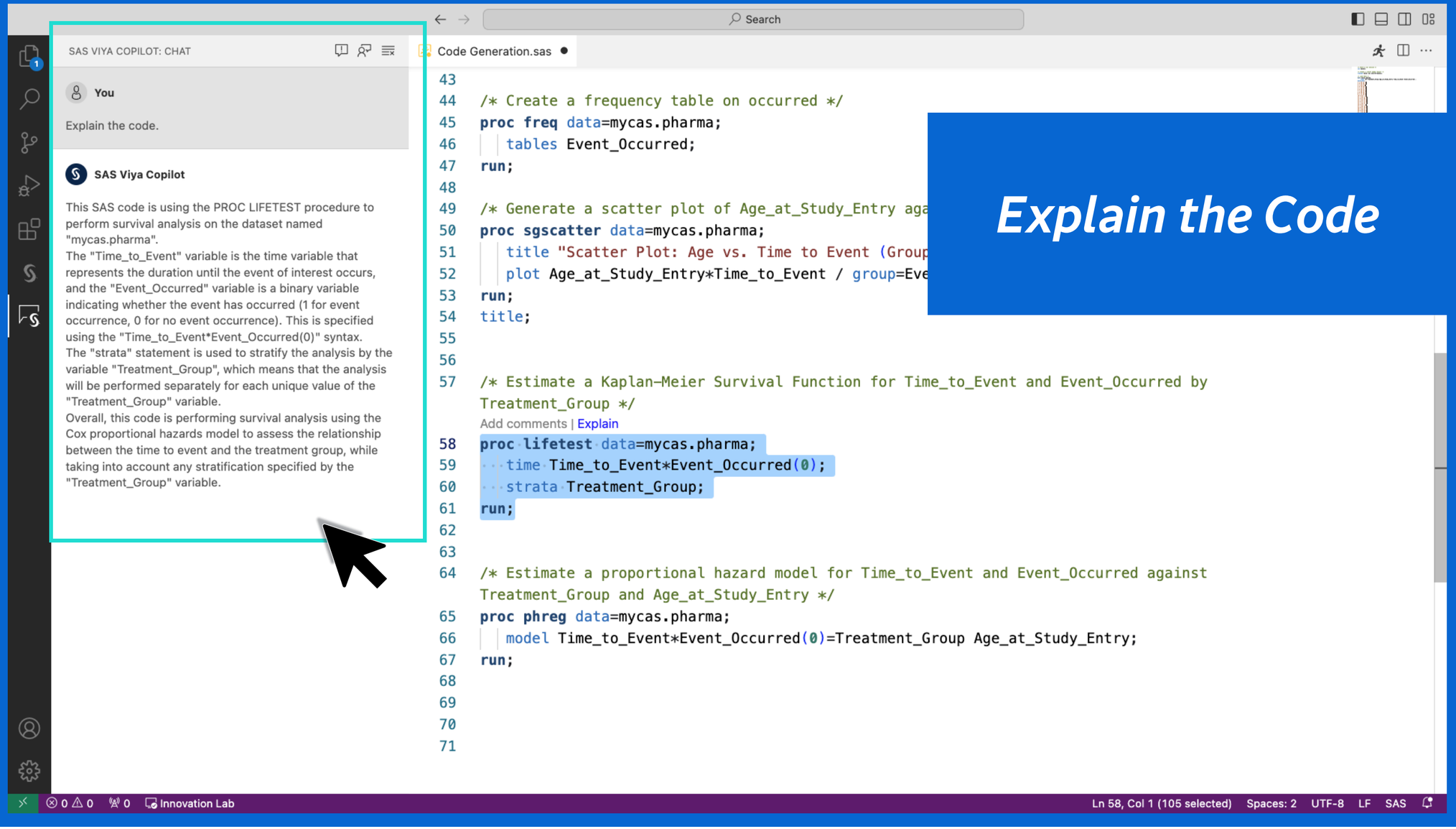


SAS Code Generation



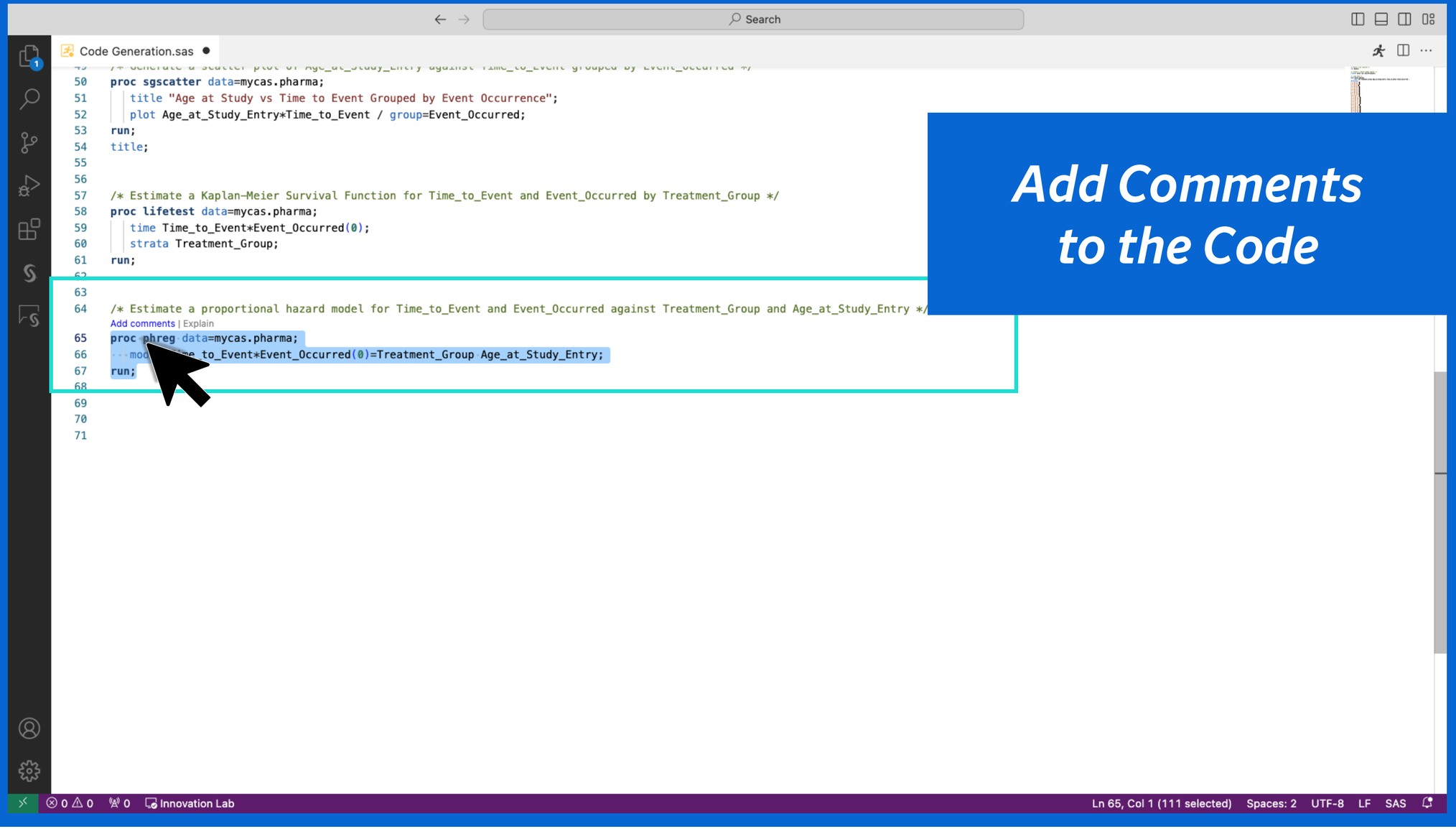
Generate Code

SAS Code Generation



Explain the Code

SAS Code Generation



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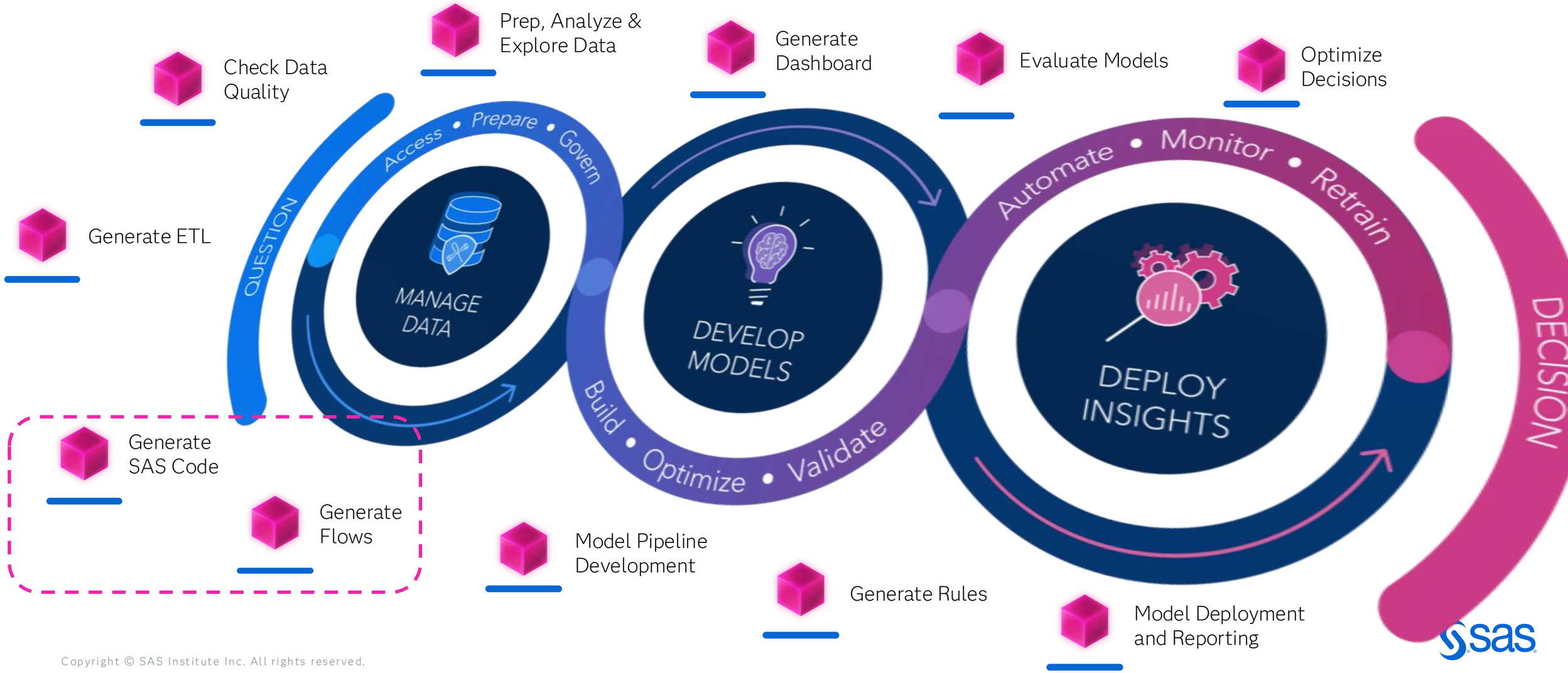
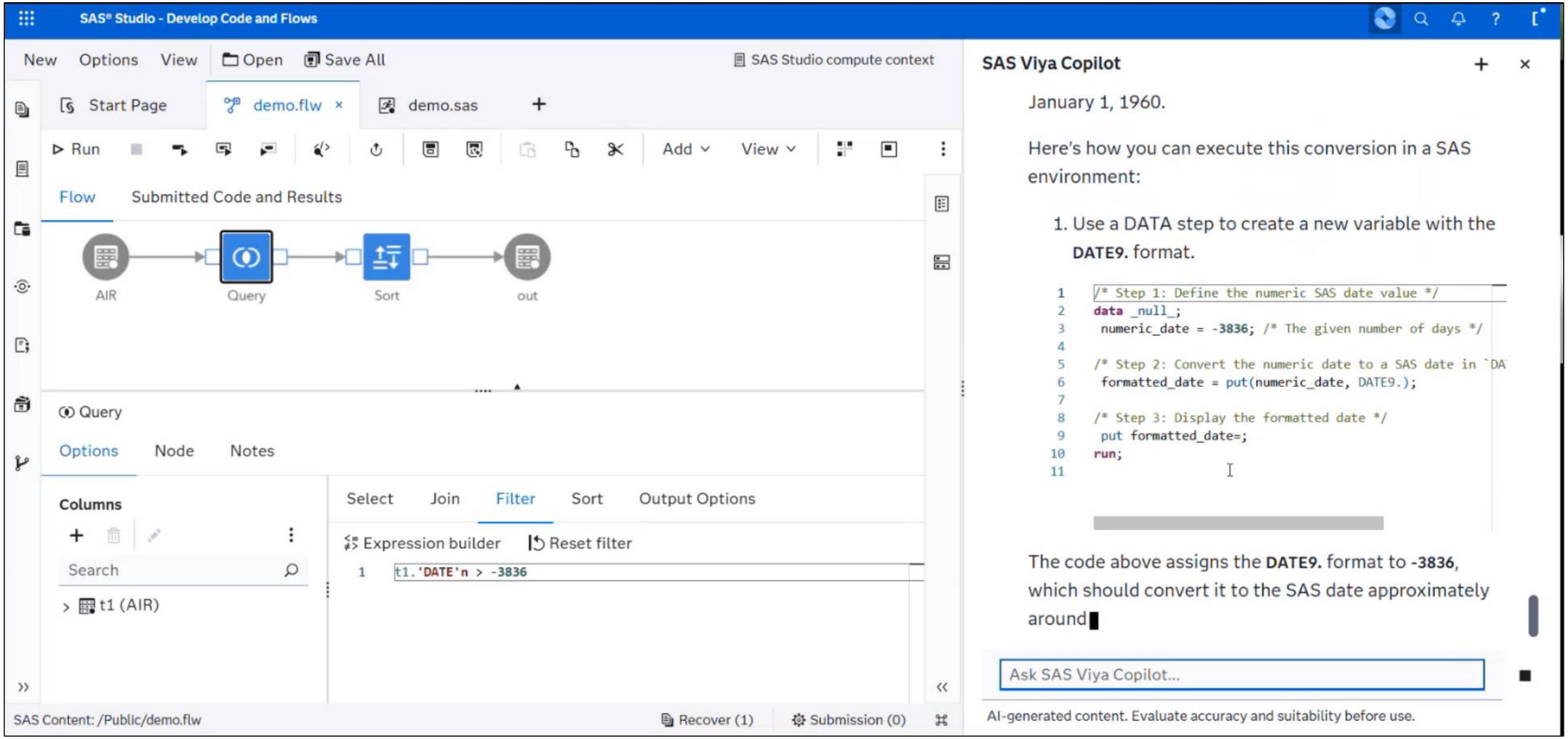
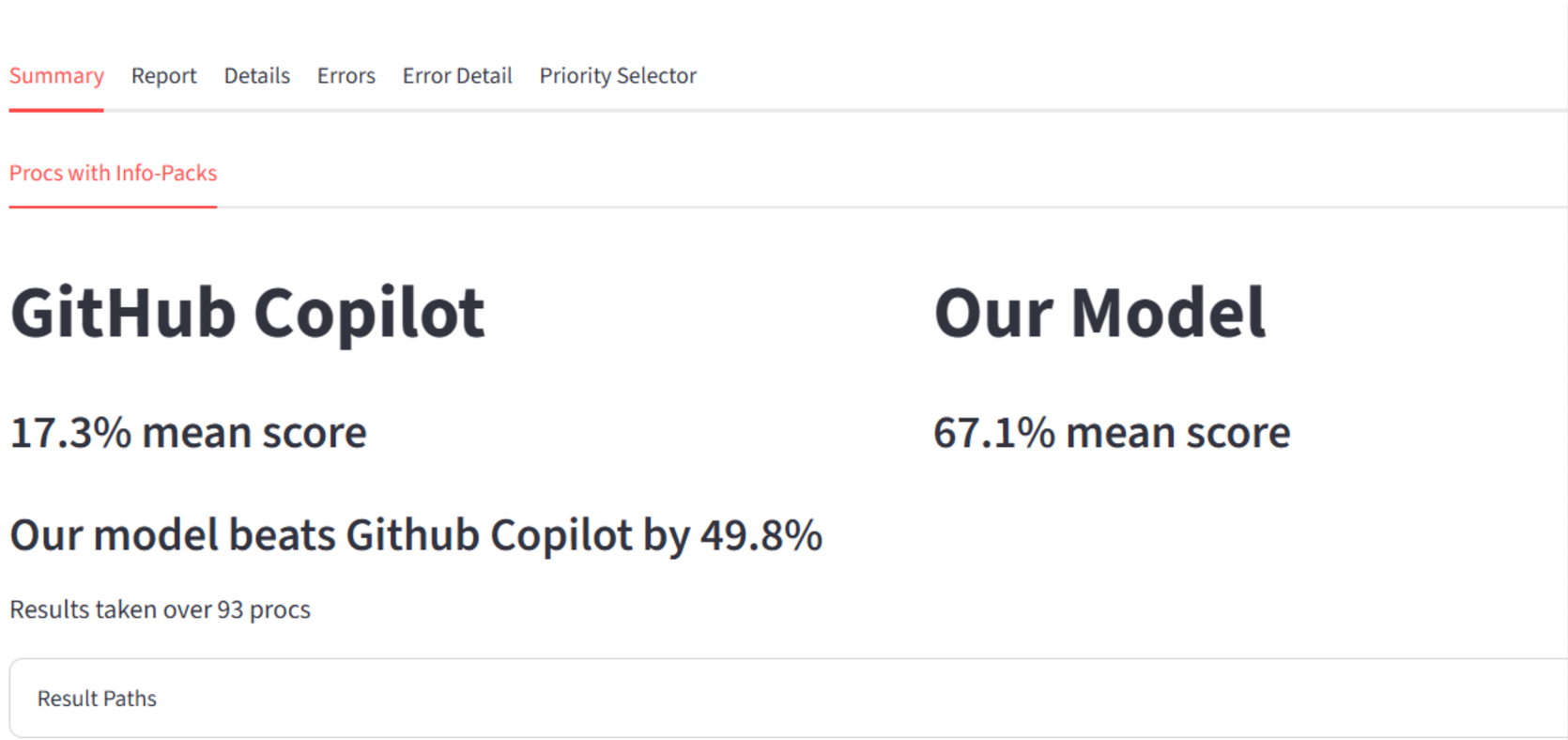


SAS Viya Copilot for Data Processing Code Flows



Benefits of SAS Viya Copilot



proc	GitHub Copilot	Phi-3-mini2025.6.0
anova	0	0
assess	0	0.736
assessbias	0	0.928
astore	0.125	0.861
bchoice	0	0.938
binning	0	0.6
bnet	0	0.658
cancorr	0	1
cardinality	0.288	0.915
catmod	0	0
cattransform	0	0.54
correlation	0	0.593
cspade	0	1
datastep	0.79	0.822
dynbnet	0	0.837
export	0.978	0.889
factmac	0	0.947
fastclus	0.2	0.853
fastknn	0	0.701
fism	0	0.667
fittedqnet	0	0
flattenimages	0	0.88
forest	0	0.914
freq	0.753	0.982
gee	0.2	0.6
genmod	0.2	0.775
glimmix	0.217	0.535
glm	0.58	0.75
glmmod	0	0.8
glmselect	0.775	0.114

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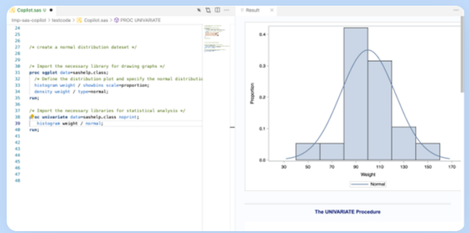

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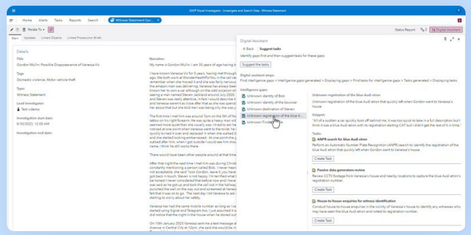

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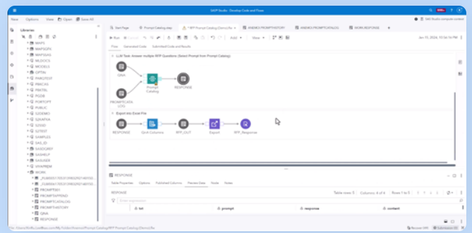

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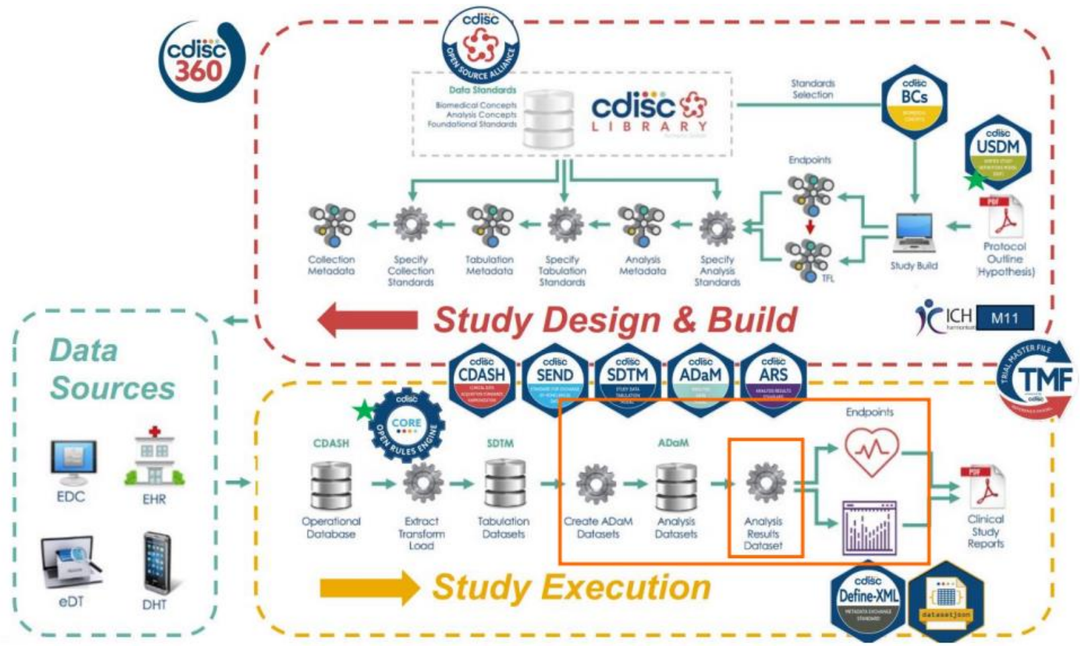
example. Synthetic data generation API

Automation of the Drug Submission Process using a Multi agent framework



Raw data to SDTM format
SDTM Validation
SDTM to ADaM
ADaM Validation ★
Creation of define.xml
Creation of TLFs

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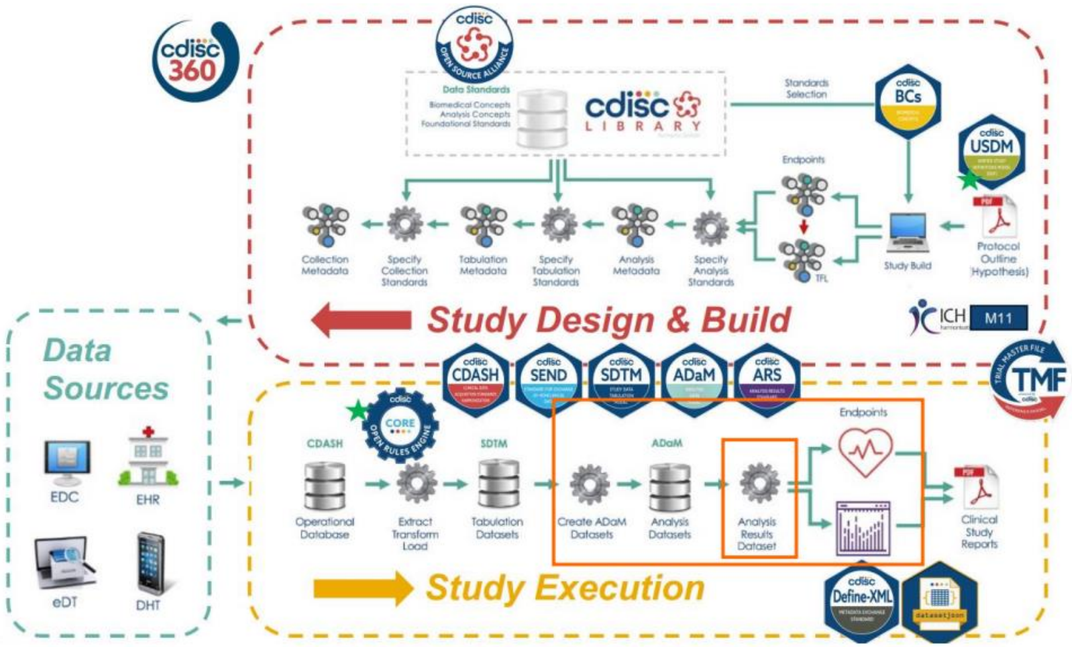

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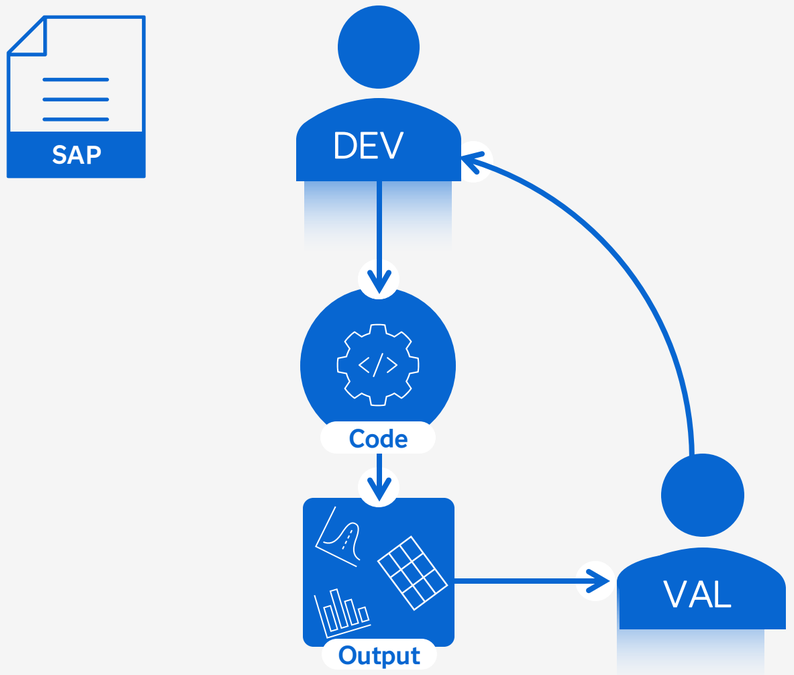
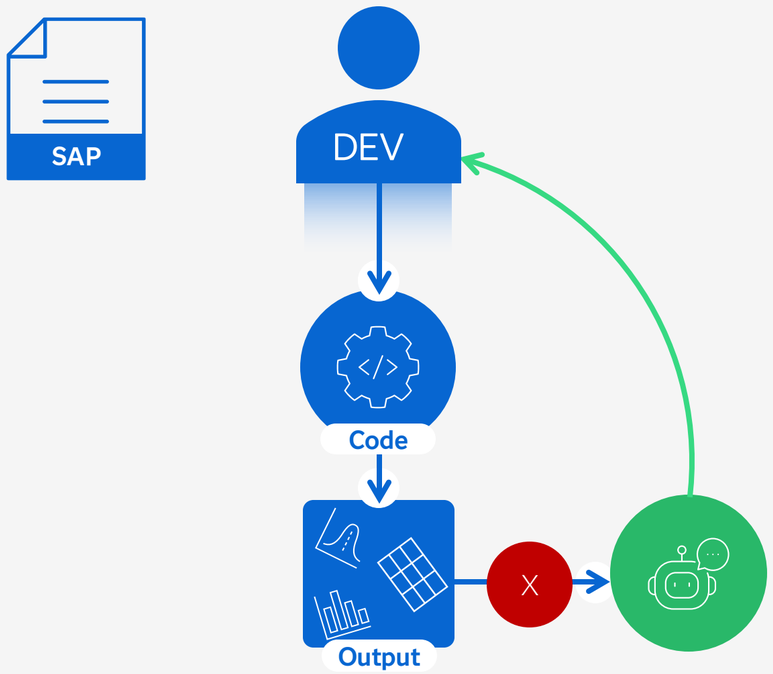
Validation of Statistical Output



VALIDATION OF RESULTS

TIME CONSUMING

AI Validation Challenges



LEGAL QUESTIONS

- Ethics
- Confidentiality

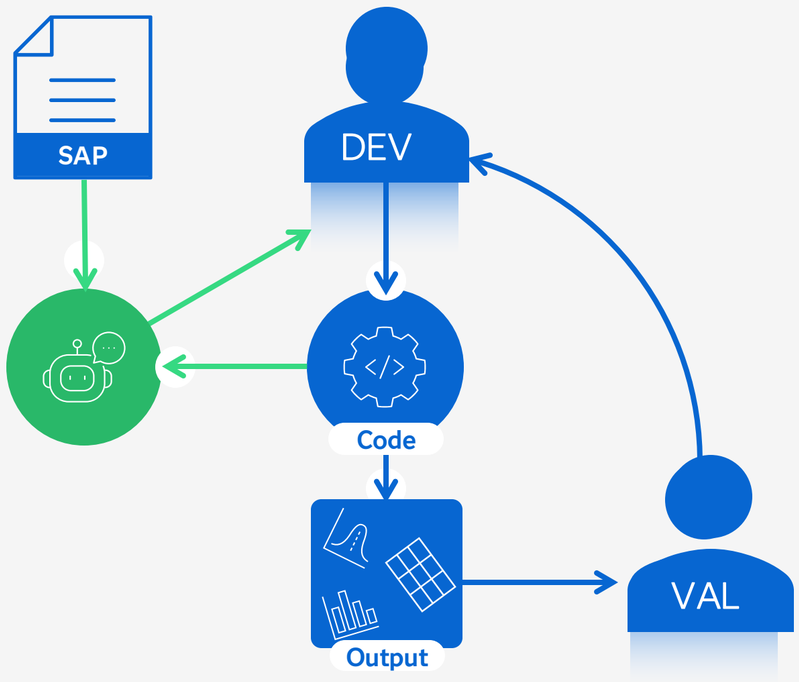
TECHNICAL ISSUES

- Hallucinations
- Version control

FINANCIAL IMPACT

- Data limits
- Token usage

Validation of Statistical Output



INPUT

- SAP + Code
- Confidentiality

INSTRUCTIONS

- By section
- Incremental

Select a task to perform on the **ADSL** program (adsl.sas):

- (None)
- Validate Presentation of Treatments
- Validate Rounding of Derived Variables
- Validate Analysis Sets
- Mark Validation as Finished

Select a task to perform on the **ADaPer** program (adaper.sas):

- (None)
- Validate Consistency Between adaper.sas and adsl.sas
- Mark Validation as Finished

Select a task to perform on the **24_advs.sas**:

- (None)
- Normal Range
- Include All Parameters?
- Check ANL01FL
- Mark Validation as Finished

ADaM Code Validation using LLM

Step 1: Get SAP.

Drag and drop the SAP here, or click to browse

Drag and drop file here

Limit 200MB per file • DOCX

Browse files

No SAP file uploaded yet.

Step 2: Get SAS Code.

Step 2.1 : Please enter the folder path containing the SAS code files for ADaM data creation.

\STAT\Analyses\Programs\AI\02_testrun02\repository\1.ADAI

Example:

```
\STAT\Analyses\Programs\AI\02_testrun02\repository\1.ADAM\\
```

Step 2.2: Please select the SAS files that you would like to check from the `.sas` files found in **/STAT/Analyses/Programs/AI/02_testrun02/repository/1.ADAM**:

- [x] Select All SAS files

Selected SAS files:

```
[
  0 : "01_adsl.sas"
  1 : "02_adaper.sas"
  2 : "24_advs.sas"
```

Example: Validate Normal Range in advs.sas

Results

Original


```
else if kupcase(vstestcd) eq 'DIABP' then do;
   ATOXGRHN = 0 + (aval ge 141) + (aval ge 151) + (aval gt 155);
   if not missing(atoxgrhn) then ATOXDSCH = 'HYPERTENSION (DIASTOLIC)';
end;
```

LLM Update

```
else if kupcase(vstestcd) eq 'DIABP' then do;
   /* Corrected the ranges for Hypertension (Diastolic Blood Pressure) */
   ATOXGRHN = 0 + (aval ge 91) + (aval ge 96) + (aval gt 100);
   if not missing(atoxgrhn) then ATOXDSCH = 'HYPERTENSION (DIASTOLIC)';
end;
```

AI annotates any changes

Code structure is kept

Agentic Workflow for ADaM Validation

Leveraging Multi-Agent system to Ensure Data Integrity and Compliance

Input Data

SAP
Code
CDiSC-API: ADaM Specs,
SDTM etc.

Data Processing

Data Cleansing
Chunking
ETL - Database

Context Engineering

Programming Instructions
Code Generation

Hierarchical Multi-Agent validation system

Response evaluation

Scoring Metrics: Evaluation Score

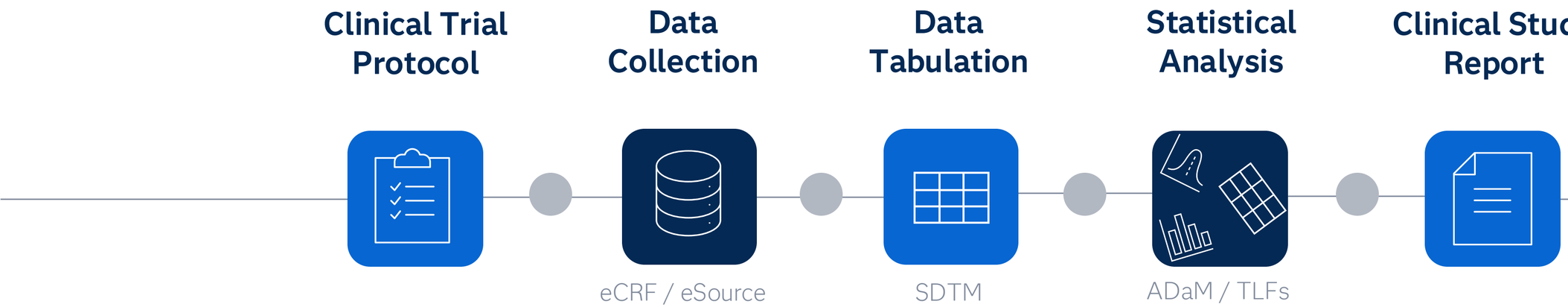
Guardian Agent

CDISC Standards
Safety Checks
Toxicity
Ethical-AI

Output

Issue
Resolution
Description
Score
Source

Clinical Trials Workflow Vision



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Thank you !

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