

Single Day Event

Accelerating TLF Generation in Clinical
Trials Using Domain-Tuned Generative AI

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Sycamore Informatics



Agenda

- The Problem
- The Solution
- How it works
 - Validation
- The Impact
- Conclusion

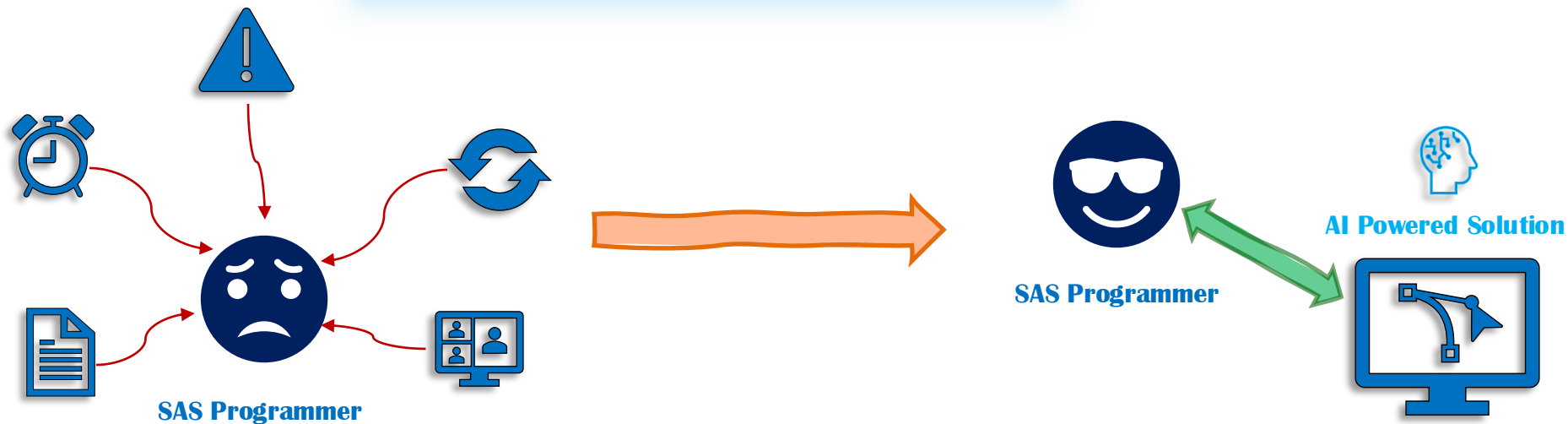


Beyond the Bottleneck:

A New Workflow for TLF Generation

From Manual Coding to AI-Assisted Review:

A "Glass Box" Approach

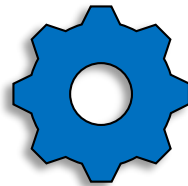




The Problem

Slow and Manual TLF Generation

**Understanding the common hurdles in our current workflow
and the opportunities they present for a new approach.**



The Problem

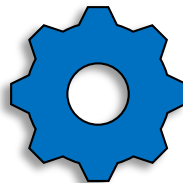
Slow and Manual TLF Generation



Time Intensive Process

A disproportionate amount of expert programmer/statistician time is spent on routine, boilerplate outputs.

May delaying high-priority analyses and slowing down the data-driven decision-making process.



The Problem

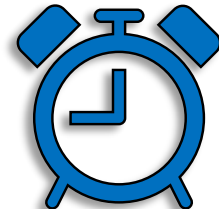
Slow and Manual TLF Generation



High Risk & Error Prone

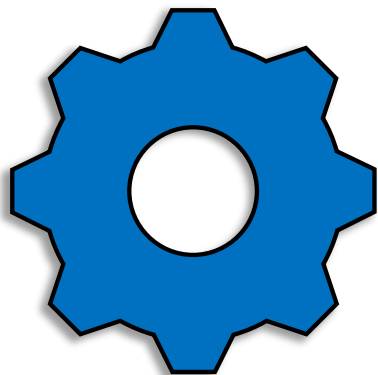
Every line of manually-written code is a new opportunity for human error.

A simple typo can have a cascading effect, jeopardizing timelines and creating a massive re-validation burden.



The Problem

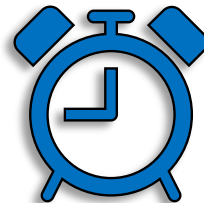
Slow and Manual TLF Generation



Gap in Standardization

In the absence of a single, enforced framework, each programmer
"style" becomes the *de facto* standard.

QC is forced into forensics of interpreting logic of each program,
not just verifying it.



The Problem

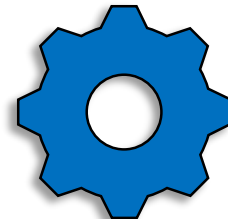
Slow and Manual TLF Generation



Repetitive & Rigid

A minor spec change often triggers a full-scale manual rework and re-validation cycle.

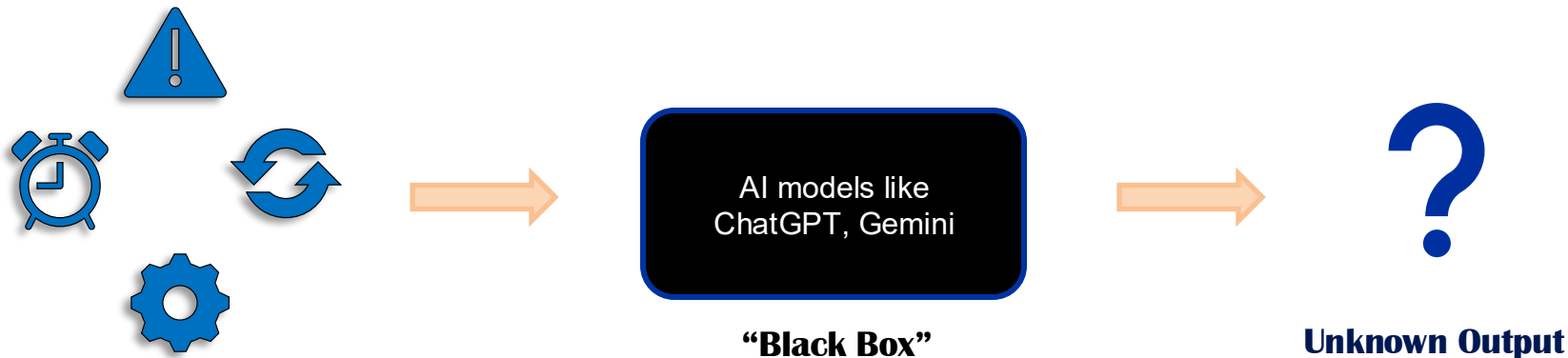
This repetitive churn is a primary source of project delays and team frustration.



The Problem

Why a General-Purpose AI is not suitable

We have these problems, and we're tempted to feed them into a "magic" AI box, but the result is a total unknown.





The Solution:

Generative AI for TLF Automation



Time Efficient



Secure env

Pick ShellEdit ShellCodeEvaluations

Generate CodeRun Code

```
```sas
options insert = (sasautos = ("../macros","../macros","../macros"));
%setup;

%listing(
 data=adam.adae,
 file=temp.html,
 title=Adverse Events,
 columns=aebodsys aeptcd,
 labels=Body System#Term Code
);
```
```

temp.htmltemp.log

Adverse Events

| Body System | Term Code |
|--|-----------|
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | . |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | . |
| GASTROINTESTINAL DISORDERS | . |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | . |
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Transparent



GxP Compliant



The Solution:

Generative AI for TLF Automation

We're introducing a framework that instantly generates high-quality SAS code -- transparent, fully editable, and immediately runnable

Pick Shell Edit Shell Code Evaluations

>

Generate Code Run Code

```
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%setup;

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Our approach is designed around a single, programmer-centric goal: to combine rapid acceleration with verifiable accuracy.



The Solution:

Generative AI for TLF Automation

SECURE

A private,
sandboxed env
for GxP
Compliance

SMART

An AI engine
with Clinical
context

SAFE

By Validation
Not “reinventing
the wheel”



How It Works: Spec-to-Code Workflow

Step 1: User picks an SAP

Pick Shell

Edit Shell

Code

Evaluations

SAP

PharmaCo_Oncology_SAP_V3.docx

1 Listing of Adverse Events

2 Demographic and Baseline Characteristics by Treatment Group (Gender)

3 Treatment History – ITT Population

4 Relapse History – ITT Population

5 Demography - ITT population

6 Exposure to study treatment - ITT population

7 Exposure to study treatment up to treatment discontinuation - ITT population

9 Baseline EDSS scores - ITT population

10 Baseline MRI evaluation - ITT population

11 Medical History at baseline – ITT population

12 Time on study – ITT population

13 Summary of annualized relapse rate (INEC confirmed relapses) - ITT population

14 Summary of annualized relapse rate (INEC confirmed relapses) up to Last PatientLast Treatment

19 Number of new or newly-enlarging T2 lesions at Week 96 - ITT population

20 Summary of time to 3-months sustained disability progression measured by increase in EDSS - IT

30 Summary of proportion of subjects relapsed (INEC confirmed relapses) -

31 Summary of proportion of subjects with a ≥7.5 point worsening from baseline at Week 96 – ITT p

Generate

1 Listing of Adverse Events

| Subject ID | Sex | Age | Body System | Preferred Term | Serious Event | Causality |
|------------|-----|-----|-------------|----------------|---------------|-----------|
|------------|-----|-----|-------------|----------------|---------------|-----------|

User can define the listing/table template they want to start generating

Pre-loaded dataset



**User enters
the col name**

System intelligently matches the input to the required dataset variables

Adverse Events matched ae_listing, dataset adae

Body System -> `adae.aebodsys` (Body System or Organ Class)
Term Code -> `adae.aeptcd` (Preferred Term Code)



How It Works: Spec-to-Code Workflow

Step 3: Generate & review the code

Pick Shell Edit Shell Code Evaluations

Macro description and template

Edit Shell...

Available Macros

The following macros are defined and on the path. Reuse when possible. Do not re-implement macros:

setup macro

The %setup macro is a SAS utility that establishes library references for commonly used data directories. It checks for the existence of three specific paths: ../data/adam, ../data/sdtm, and ../output/tlf. If these directories exist, the macro creates corresponding library references named adam, sdtm, and out respectively, using the SAS V9 engine. This macro takes no parameters and is called simply with %setup;. It uses relative paths, so it should be run from the appropriate working directory to ensure correct path resolution.

listing macro

The SAS macro %listing generates a formatted report from a given dataset. It sorts the data by usubjid and retains the specified columns. The macro uses the ODS system to produce an HTML report, applying customizable titles, footnotes, and a landscape orientation. The proc report step dynamically creates a report layout based on the input columns and their corresponding labels. Each column's alignment and width are controlled within the report. The macro facilitates flexible and automated report generation, allowing the user to specify the dataset, output file, titles, footnotes, and column details.

Template

Copy all the following code:

```
```sas
options insert = (sasautos = ("../macros", "../macros", "../macros"));
%setup;
```

Generate Code

Run Code

```
```sas
options insert = (sasautos = ("../macros", "../macros", "../macros"));
%setup;

%listing(
  data=adam.adae,
  file=temp.html,
  title=Adverse Events,
  columns=aebodsys aeptcd,
  labels=Body System#Term Code
);
```
```

System intelligently retrieves the required Macro

Generated code

temp.html

temp.log

### Adverse Events

| Body System                                          | Term Code |
|------------------------------------------------------|-----------|
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | .         |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | .         |
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| SKIN AND SUBCUTANEOUS TISSUE DISORDERS               | .         |
| CARDIAC DISORDERS                                    | .         |
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Final Output



# Validation: 3 Pillars of Verification

**The burning question: How do we make sure its GxP-Compliant?**



+



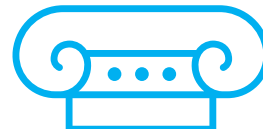
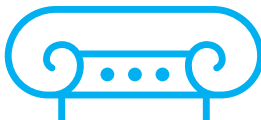
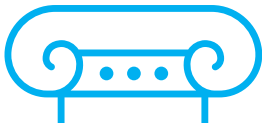
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**Macro Library**

**Secure AI env**

**Human-in-Loop**

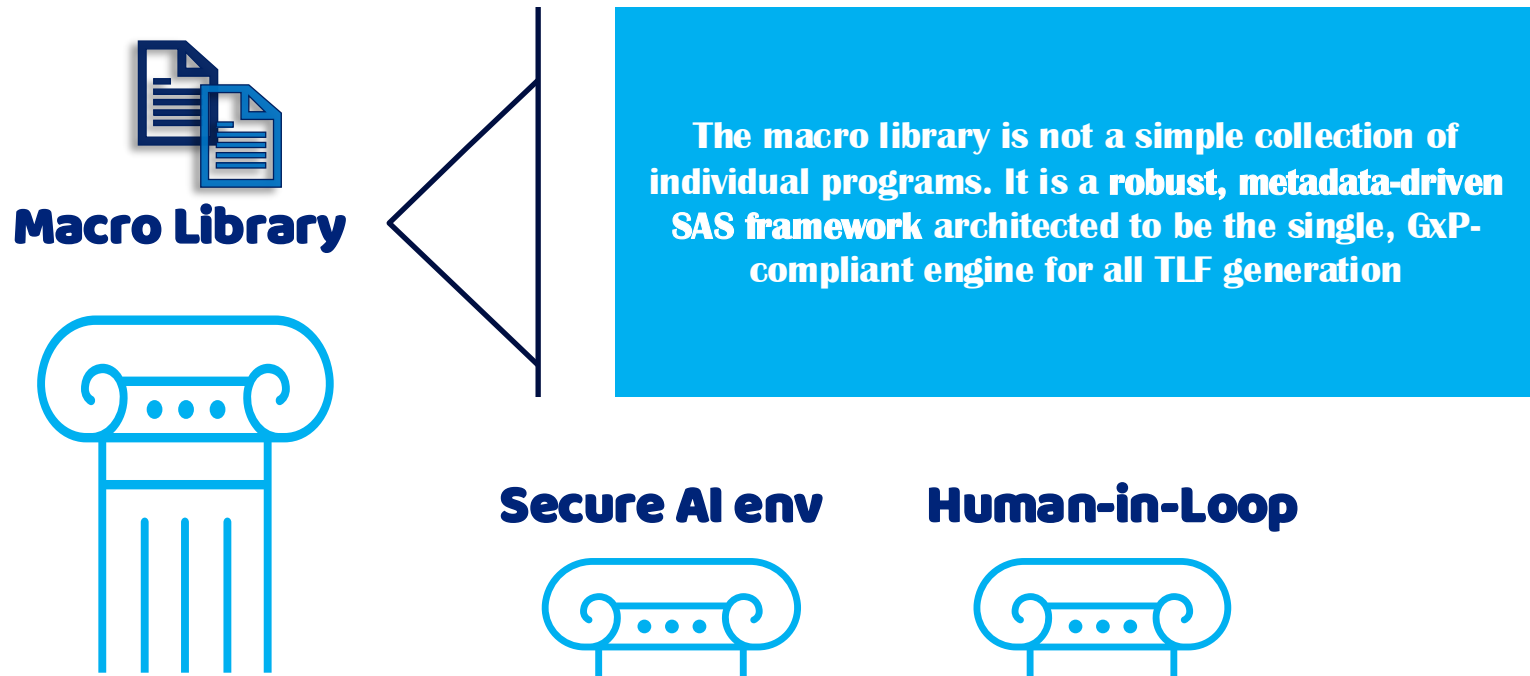






# Validation: 3 Pillars of Verification

**The burning question: How do we make sure its GxP-Compliant?**





# Validation: 3 Pillars of Verification

## The burning question: How do we make sure its GxP-Compliant?



### Macro Library

Edit Shell...

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Generate Code Run Code

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```
```

AI Generated detailed
Macro descriptions

temp.html temp.log

Adverse Events

| Body System | Term Code |
|--|-----------|
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| GASTROINTESTINAL | . |



Validation: 3 Pillars of Verification

The burning question: How do we make sure its GxP-Compliant?



Macro Library

```
## Template
Copy all the following code:
```sas
options insert = (sasautos = ("../macros", "../macros", "../
%setup;

%listing(
 data=adam.adae,
 file=ae_listing_expected.html,
 title1=Listing 16.1.2 Listing of Adverse Events,
 title2=Safety Population,
 footnote1=Adverse events are coded using MedDRA,
 columns=usubjid sex age aebodsys aeterm aeser aere,
 labels=Subject ID#Sex#Age#Body
System#Preferred*Term#Serious*Event#Causality
);
```

# INSTRUCTIONS
Make a listing to file temp.html. Title: Adverse Events.
```

Generate Code Run Code

```
```sas
options insert = (sasautos = ("../macros", "../
%setup;

%listing(
 data=adam.adae,
 file=temp.html,
 title1=Adverse Events,
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```
```

temp.html temp.log

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Final Output

Verified Macro Template

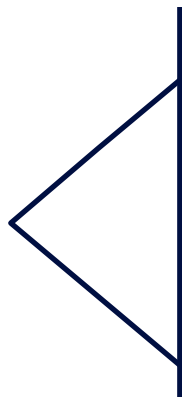


Validation: 3 Pillars of Verification

The burning question: How do we make sure its GxP-Compliant?

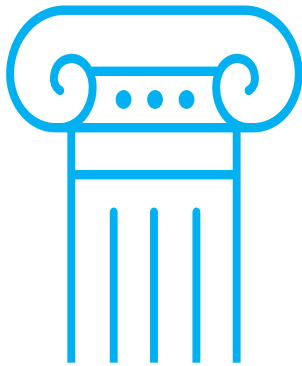


Secure AI env

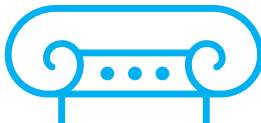


The entire system, including the domain-tuned LLM, is hosted within a secure, private, and traceable environment.

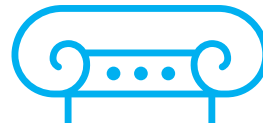
The platform adheres to strict industry standards for access control and data encryption



Macro Library



Human-in-Loop



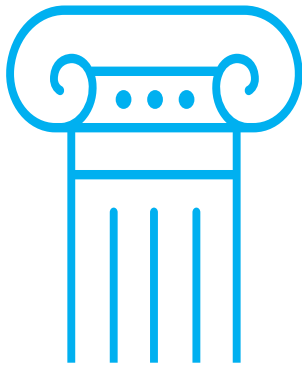


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Human-in-Loop

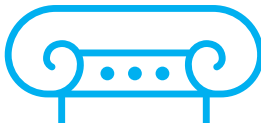


The tool is designed as a **programmer's co-pilot**, not an autonomous system

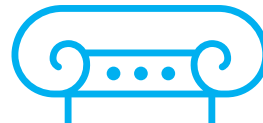
The "Code" tab is the built-in, mandatory QC checkpoint.

The programmer performs final verification before execution.

Secure AI env



Macro Library





The Impact: Weeks to Hours

From Manual Bottleneck to Strategic Accelerator

The Programmer

Eliminates the 80% of repetitive, boilerplate work.

This frees you to focus on the 20% of complex, novel analyses where your expertise truly matters.

**Impact:
Empowerment & Focus**



**Impact:
Speed & Iteration**

The Statistician

The "spec-to-output" cycle:

Reduces the timeline from weeks to hours. This enables rapid, data-driven decisions

The Submission

Guaranteed Quality & standardization:

Enforces 100% consistency by using a validated macro framework.

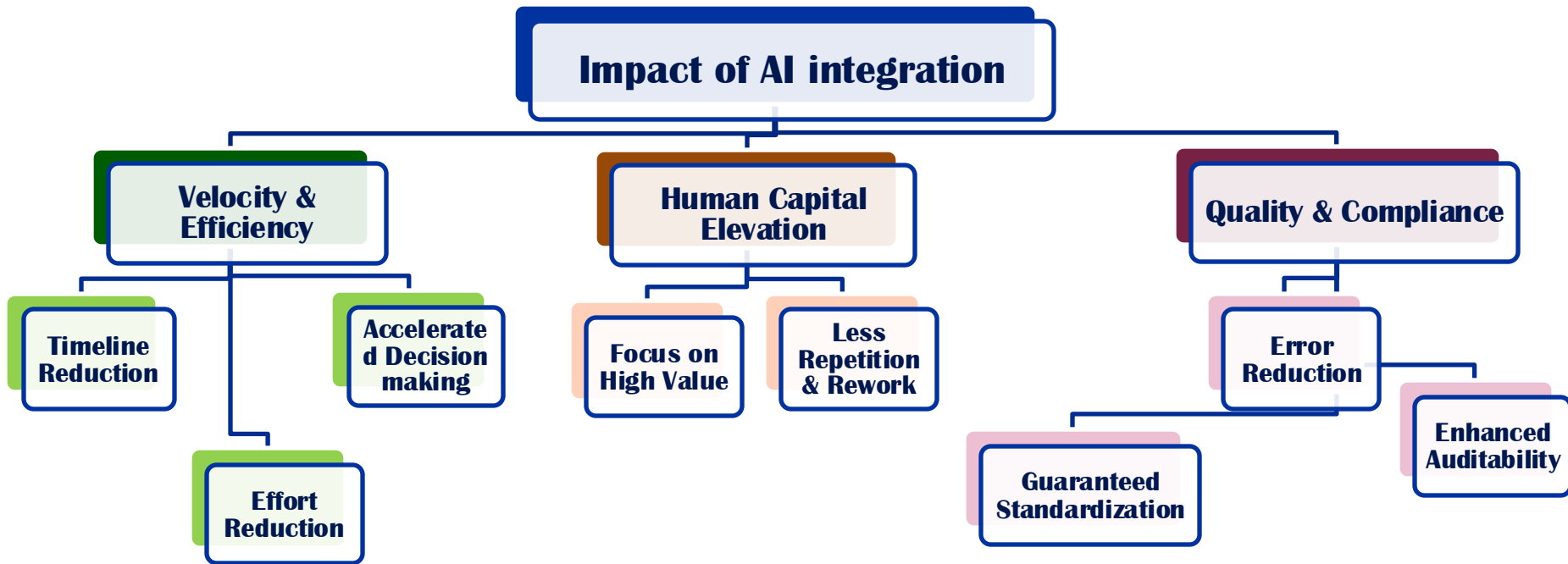
Produces error-free, transparent, editable code with the ability to run and produce outputs rapidly within a much smaller timeline.

**Impact:
Quality & Velocity**



The Impact: Weeks to Hours

From Manual Bottleneck to Strategic Accelerator





Conclusion & Final Thoughts

"The challenge is not *if* we should use Generative AI, but *how* we can leverage it responsibly.

We have demonstrated a way to bridge innovation with compliance, moving the industry from manual programming to AI-assisted review."

Q&A

Thank You!



**The Global Healthcare
Data Science Community**

Contact Channels

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🌐 phuse.global

Social Media

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📘 [/phusebook](https://facebook.com/phusebook)
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🌐 [/company/phuse](https://linkedin.com/company/phuse)