

> **Transparency by Design: How to Use AI Tools Without Compromising Your Validation Framework**

PHUSE Frankfurt 2026 | Technical Briefing

Alistair Dootson, Vice President Life Sciences, EQTY Lab



ChatGPT

Claude

Gemini

Copilot

Perplexity

Poe

You

Hugging Chat

DALL-E

Midjourney

Stable Diffusion

Leonardo.Ai

Runway

Ideogram

Runway

Jasper

Writesonic

Copy.ai

Notion AI

Grammarly

QuillBot

Wordtune

Rytr

Surfer

Frase

Outreach

Elai AI

HeyGen AI

HeyGen

Hour One

Hour One

Motion

Descript

Synthesia

Pictory

InVideo

Lumen5

VEED

Fliki

Runway

OpusClip

Krisp

Otter.ai

Fireflies.ai

Fathom

tl;dv

Avoma

MeetGeek

Bland.ai

SEMBLY AI

Murf AI

Tome

Gamma

Beautiful.ai

SlidesAI

Plus AI

Presentations AI

Canva AI

Adobe Firefly

Kittl

Designs.ai

Looka

Brandmark

Tailor Brands

Durable

Zyro

Hostinger AI

10Web

Framer

Dora

Webflow

Cohere

Anthropic

Mistral AI

Gemma

Llama

Meta AI

Falcon

groq

Hugging Face

Kagi

Andi

Neeva

Glean

Mem

yep

DeepL

LanguageTool

Pi

Cursor

WindSurf

Replit

GitHub Copilot

Codeium

Tabnine

Amazon CodeWhisperer

Imagen

Krea

NightCafe

Civitai

Deep Dream Generator

Hotpot

Leonardo.Ai

Lexica

Kaiber

Wombo

Artbreeder

PicLumen

Tensor.Art

Dexgo

Playground AI

Pika Labs

Soundful

Ecret Music

LALAL.AI

Moises

Audio

Riffusion

Beatoven.ai

Voice.ai

JotBot

NoteBookLM

Mem.ai

Reflect

Notion AI

Obsidian

Roam

Amplenote

Haiku

AIPRM

PromptHero

FlowGPT

PromptBase

PromptPerfect

Supermaven

Gamma

Figma AI

Cursor

Framer AI

uizard

TeleportHQ

Galileo AI

Visily

Zapier

Make

n8n

Bardeen

Phantombuster

Browse AI

Magical

Tally

Tome

Relevance AI

Lindy

Agent GPT

BabyAGI

Auto-GPT

ChainGPT

BeeAI

Phala

Stable Video

Pika

Runway

Genmo

Kaiber

Colossyan

Synthesia

D-ID

Luma AI

Sloyd

Meshy

Point-E

Shap-E

Spline AI

uMake

Archi AI

Hoppy Copy

WriteCream

Conversion.ai

Outplay

Smartwriter.ai

Quickchat AI

Sybill

Qwen

Yi

Baichuan

InternLM

ChatGLM

ERNIE Bot

SparkDesk

Mixtral

StableLM

OpenLLM

Dolly

RedPajama

Phi

MPT

Janitor AI

Character.AI

SpicyChat

Chai

Moemate

Talkie

Poly.AI

Figgs

C.AI Tools

Sakura FM

RolePlai

AI Dungeon

NovelAI

GhostWrite

Sudowrite

WriteHolo

MyShell

Dify

Flowise AI

LangChain

LlamaIndex

Haystack

Pinecone

Weaviate

ddrnt

Chroma

Milvus

FAISS

Vespa

LanceDB

Astra DB

Supabase

Neon

Databricks

DataRobot

H2O.ai

Dataiku

Pecan

Alteryx AI

Knime

RapidMiner

Domino

Anaconda AI

Google Vertex AI

AWS Bedrock

Azure AI Studio

IBM watsonx

Oracle AI

SAP AI Core

Adobe Sensei

NVIDIA AI

OpenAI API

Anthropic API

Cohere API

Hugging Face API

Replicate API

Stability API

Groq API

Together API

Deepgram API

ElevenLabs API

Pinecone API

Stripe AI

Algolia AI

Unity Muse

CLINICAL TRIALS & RESEARCH

Trial Design & Protocol

castor

Florence

Deep 6 AI

Patient Recruitment & Engagement

antidote

Simplicity

AiCure

myTomorrows

Site Selection & Feasibility

TrialSite

TrialsRx

Accellacare

PMT

Clinical Data Management

Medidata

Veeva

DATATRAK

Clinfo

eConsent & eCOA

Signant Health

mConsent

Science 37

ObvioHealth

CTMS

Veeva

MEDIDATA

ORACLE Health

MasterControl

Safety & Pharmacovigilance

IQVIA Vigilance

ArisGlobal

PVAI

SIGNAL AI

Patient Monitoring & Remote

Medable

Bioclinica

Rave

CURRENT HEALTH

AI/ML for Trials

BENCHMARK

unlearn

Trials.ai

saama

Real-World Data & Evidence

TriNetX

komodo

Evidation

veradigm

Medical Imaging

Paige

AIBTLS MEDICAL

Biostatistics & Data Analysis

Certara

nQuery

Beacon

LAPPS

CLINICAL PROGRAMMING & PHARMACEUTICAL DEVELOPMENT

CDISC Standards & Tools

cdisc

Pinnacle 21

TransCelerate

ardoq

SDTM

SAS

EHUSE

SDTM-Builder

OpenCDISC

ADaM

SAS

ADaM

ADaM-Builder

ARDENT

Define-XML

Jemurai

Globetech

Open CDISC

X-Design

TFL & Data Standards

TransCelerate

OHDSI

HL7 FHIR

OMOP

Statistical Programming

SAS

R

SPSS

stata

Python

Data Validation

Pinnacle 21

DataVantage

SAS Data Validator

Submission & eCTD

Lorenz

EXTEDO

IDNS

Veeva

Programming Efficiency

SAS Viya

ValGenesis

PyStudio

Code Companion

Automation & AI for Programming

innoplexus

Pinnacle 21

AI Seed

KXEN

Data Visualization

SAS Visual Analytics

TIBCO Spotfire

R Shiny

Regulatory Intelligence

Clarivate

Citeline

RegDesk

PharmaPendium

DRUG DISCOVERY & DEVELOPMENT

Target ID & Validation

Exscientia

BenevolentAI

Insilico Medicine

Molecular Modeling

Schrödinger

Biovia

DeepMind

OpenEye

Clinical Development

Veeva

Certara

IQVIA

PAREXEL

Manufacturing & Supply

TraceLink

Tulip

Rockwell Automation

PHARMA AI PLATFORMS

Insilico Medicine

BenevolentAI

Exscientia

Recursion

Atomwise

Merck KGaA AI

EQRx

Verge Genomics

ENTERPRISE & INTEGRATION

Veeva Vault AI

IQVIA Connected Intelligence

Databricks

AWS HealthLake

Google Cloud Healthcare API

Microsoft Cloud for Healthcare

Snowflake Health

Palantir Foundry

Your Tumor is GONE!
I photoshopped it away!
No need to thank me!



HIPPOPOTAMUS

1968

JUSTIFICATIF
NON VALABLE POUR ENCAISSEMENT

BORDEAUX MERIGNAC

GHO BORDEAUX AEROPORT
80 AVENUE KENNEDY
33700 MERIGNAC FRANCE FRANCE
TVA FR70 319 280 611

jeudi 27 mars 2025 20:53:14

1 REPAS COMPLET

TABLE : 509

QTE	DESIGNATION	P.U.	TOTAL T
1	TVA 10%	29,50	29,50
	TOTAL TTC		29,50€

Nombre de lignes articles : 1

CODE	10%	TVA	HT	TTC
1	10%	26,82	28,82	29,50

Totaux

Pos:1 Opération: VENTE

R:KATE-28 E:KATE-28 N:KATE-28

REPAS COMPLET R1-011978

Nombre d'impression : 0

EPIC STEAKHOUSE

369 THE EMBARCADERO
SAN FRANCISCO, CA 94105

RECEIPT

2	FILET MIGNON	\$98.00
1	RIB EYE	\$52.00
1	CAESAR SALAD	\$14.50
1	CREAMED SPINACH	\$11.00
1	BAKED POTATO	\$9.50

SUBTOTAL	\$185.00
TAX	17.02
TIP	\$75.00

TOTAL \$277.02

HIPPOPOTAMUS

1968

JUSTIFICATIF
NON VALABLE POUR ENCAISSEMENT

BORDEAUX MERIGNAC

GHO BORDEAUX AEROPORT
80 AVENUE KENNEDY
33700 MERIGNAC FRANCE
SIRET 819 280 611 00040 CODE NAF 5610
TVA FR70 819 280 611

lundi 2 décembre 2024 20:37:27

1 REPAS COMPLET

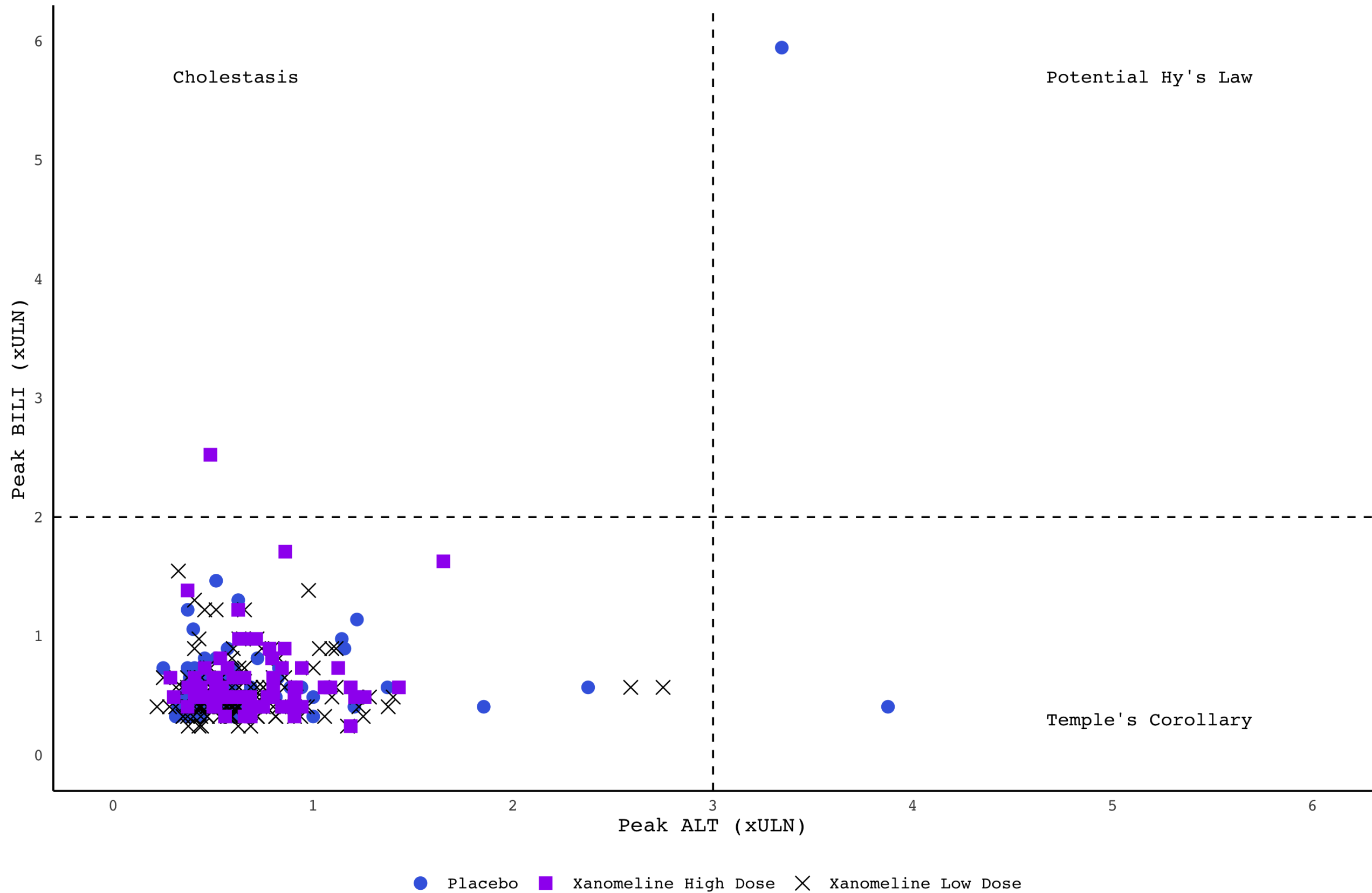
TABLE : 311

QTE	DESIGNATION	P.U.	TOTAL
1	TVA 10%	29,00	29,00
	TOTAL TTC		29,00€

Nombre de lignes articles : 1

CODE	10%	TVA	HT	TTC
1	10%	2,64	26,36	29,00
Totaux		2,64	26,36	29,00

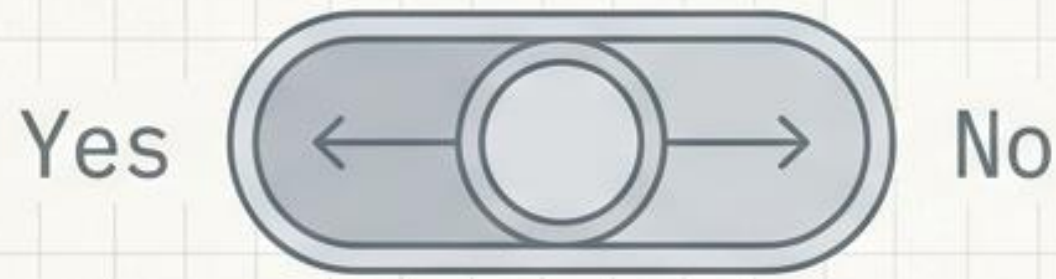
Study: CDISCPIL0T01
Figure F15_1_1
Potential Drug Induced Liver Injury Plot
Analysis Set: Safety Set



Scatter plot showing Peak ALT (xULN) on the X-axis and Peak BILI (xULN) on the Y-axis. The plot is divided into four quadrants by dashed lines at Peak ALT = 3 and Peak BILI = 2. The quadrants are labeled: Cholestasis (top-left), Potential Hy's Law (top-right), Temple's Corollary (bottom-right), and a bottom-left quadrant. The legend indicates: Placebo (blue circle), Xanomeline High Dose (purple square), and Xanomeline Low Dose (black cross).

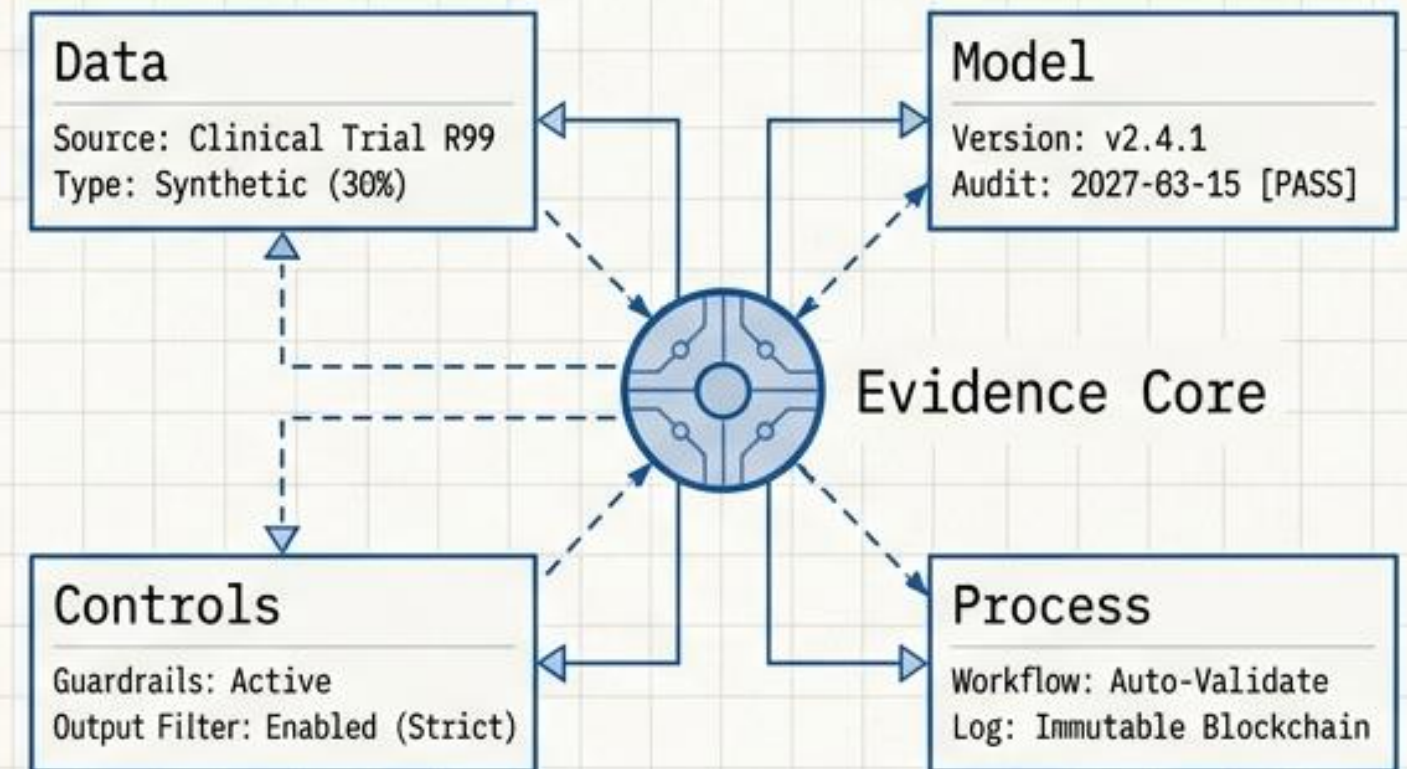
The Old Question

Did you use AI?



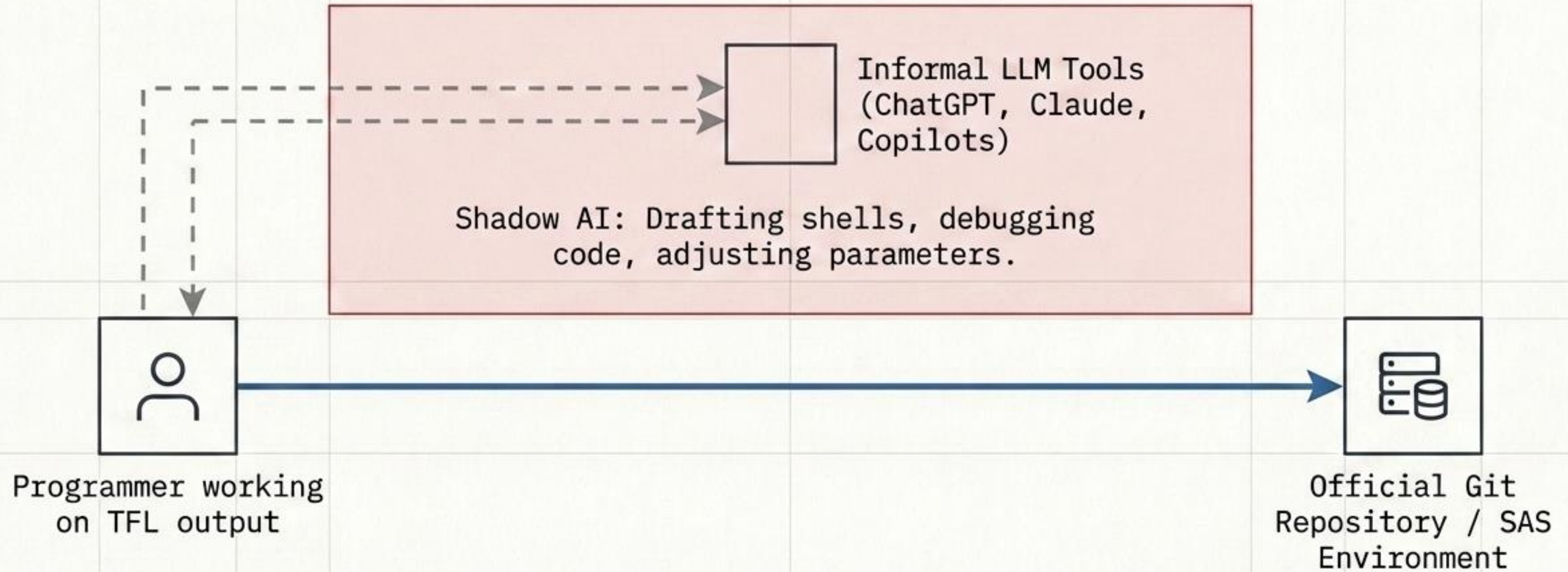
The New Mandate

Prove what it did.



Continuous monitoring is the new standard.
Single-point validation is obsolete.

The Shadow AI Anatomy



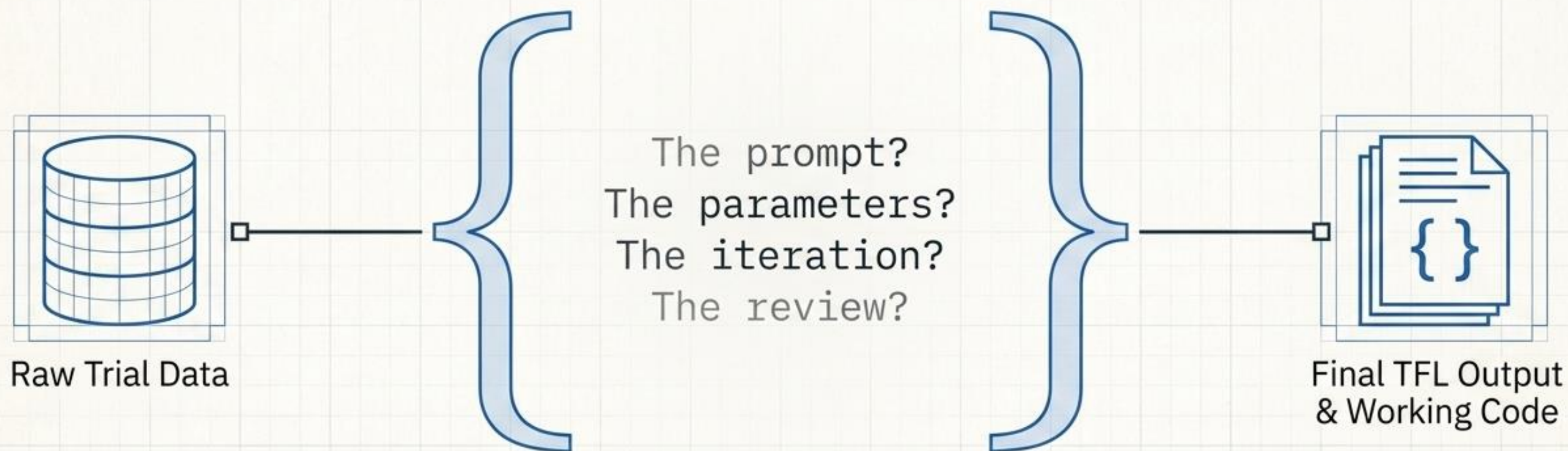
Leadership looks the other way because it is useful. But useful is not evidenced.

The Validation Framework Diagnostic Matrix

Validation Dimension	Traditional CSV (GAMP 5 / 21 CFR 11)	AI-Assisted Workflows
Code Authoring	Human-authored	Black-box model generation
Version Control Anchor	Clear, linear Git commits	Iterative, untracked prompt engineering
Audit Trail Source	Validated system logs	Missing / Unrecorded
Failure Point	Assumes system stability	Which model? What parameters? What prompt?

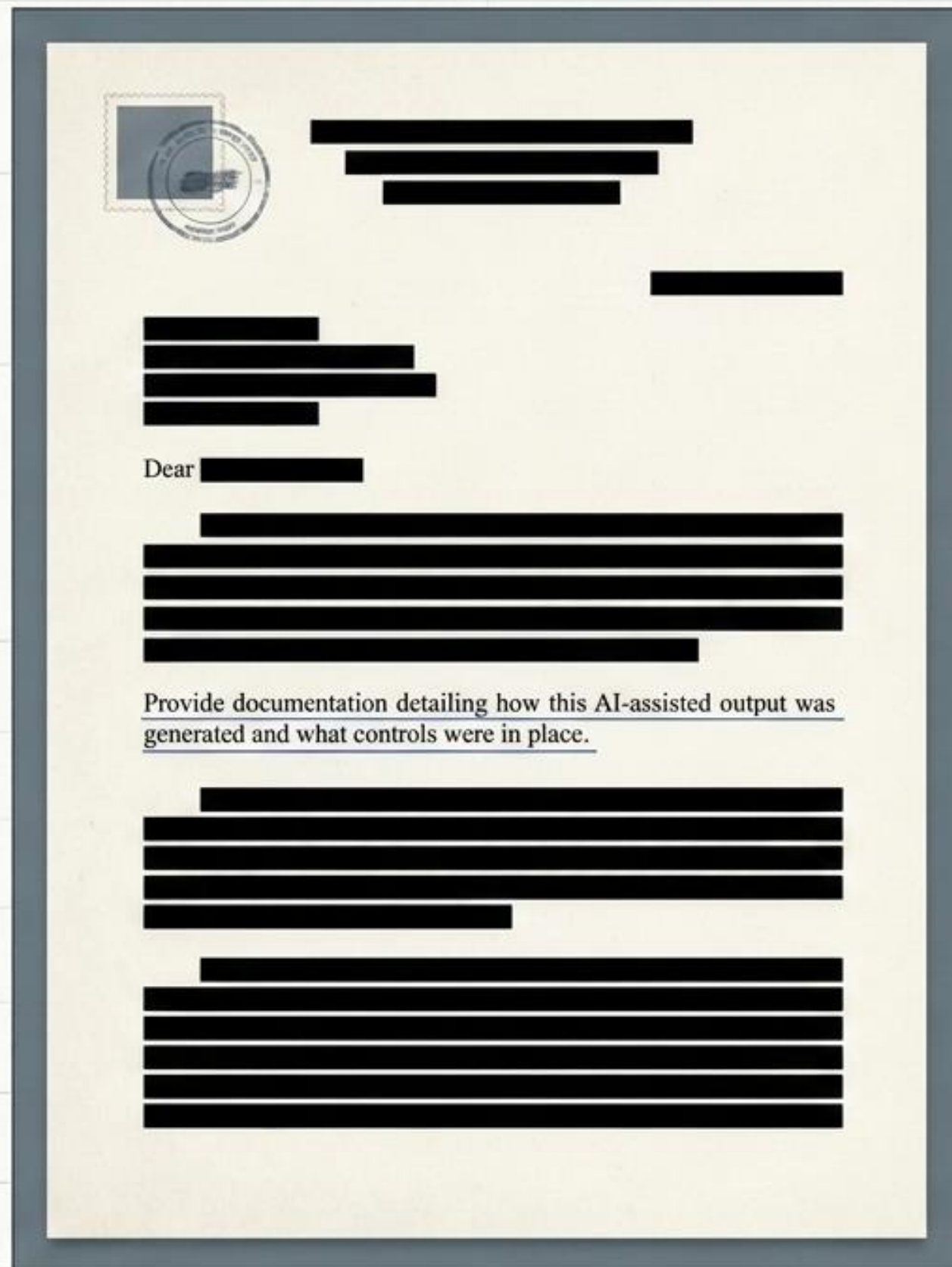
Traditional frameworks were built for a different world. They assume you can point to a validated system and say “this is what ran.”

The Evidence Gap



The final code works. But there is no record of how it came to exist.

This is not a quality gap.
It is an **evidence gap**.

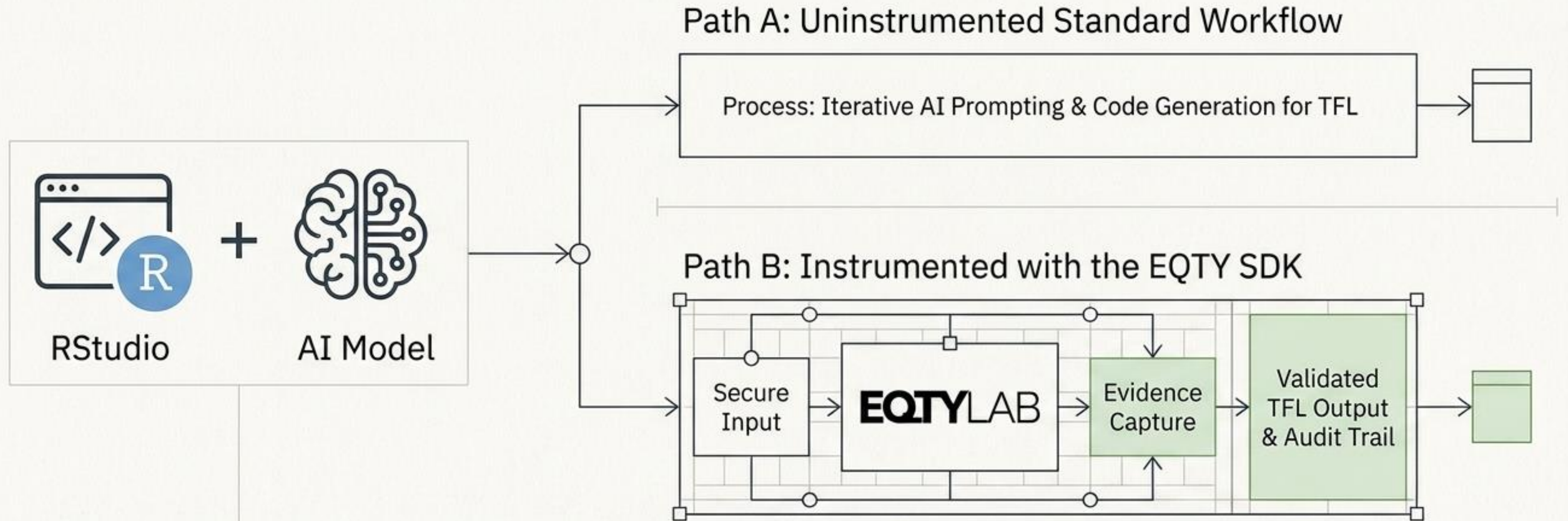


The Trigger Event

When this arrives, every analytics team's **inbox fills up overnight.**

The organisations at risk are not the ones using AI—almost everyone is. The ones at risk are those who **cannot prove** what their AI did.

The PHUSE US Workshop Example



The Challenge: Use an AI model to generate a TFL table, altering parameters and refining prompts until the output is correct.

Source on Save

Run

Source

10 MiB

R

Global Environment

library(ellmer)

library(tidyverse)

library(gt)

Pull in helper functions and prompts

source("../utils.R")

source("../breakout_1/prompts_1.R")

Load CDISC data from the pharmaverseadam package

adsl <- pharmaverseadam::adsl

adae <- pharmaverseadam::adae

Create chat objects for the production and QC agents.

Note we're keeping these separate so that they don't share

chat histories with each other and can preserve only the specific contexts

that we want them to have.

prod_agent_chat <- chat_anthropic(

model = "claude-sonnet-4-5-20250929",

)

prod_agent_chat <- chat_openai(

model="gpt-5"

)

qc_agent_chat <- chat_anthropic(

model = "claude-sonnet-4-5-20250929",

)

qc_agent_chat <= chat_openai(

model="gpt-5"

)

Use a helper function to create the production prompt. You can find each of the

indepdent pieces of this prompt within the prompts.R file.

prod_prompt <- prod_generate_prompt(

gen_purpose,

get_data_context(), # This is a helper function that gives the context of the data to the LLM.

gen_packages,

Values

adlbc_path	"./data/adlbc.xpt"
adsl_path	"./data/adsl.xpt"
data_path	"./data"
github_ba...	"https://raw.githubusercontent.com/..."
manifest_...	"./outputs-ali/manifest_..."
pathlib	<module 'pathlib' from '...'>
plot	Large ggplot2::ggplot (2...)
result	Large ggplot2::ggplot (2...)
tfl_path	"./outputs-ali"

Files

Plots

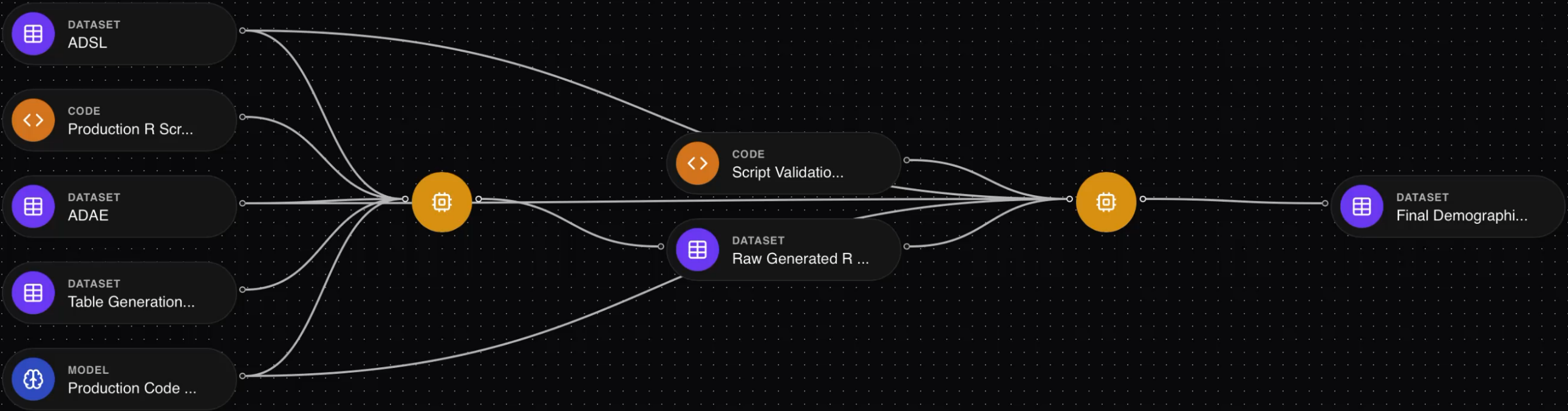
Packages

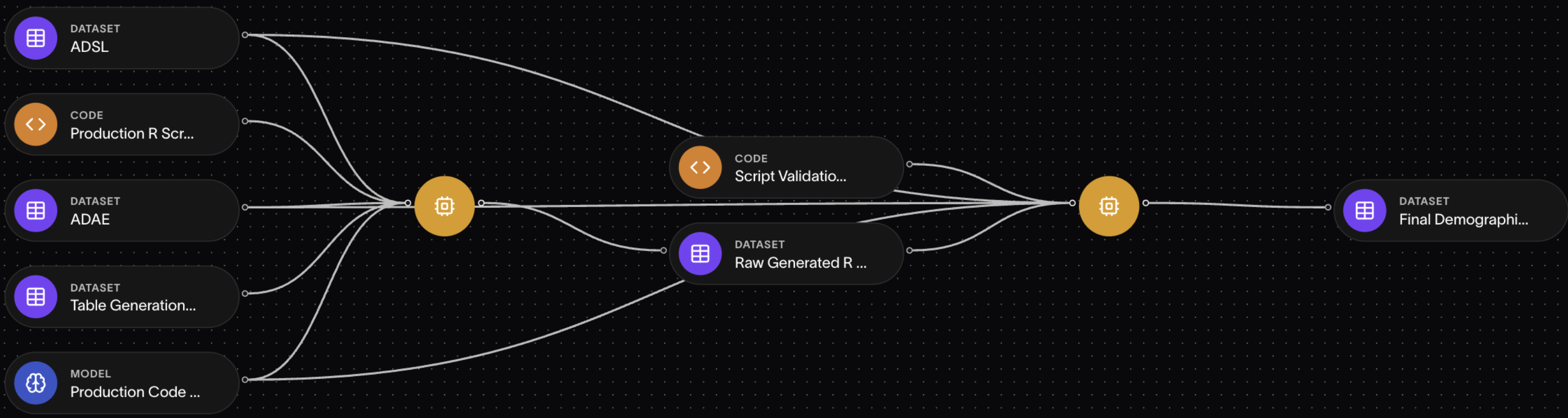
Help

Viewer

Zoom

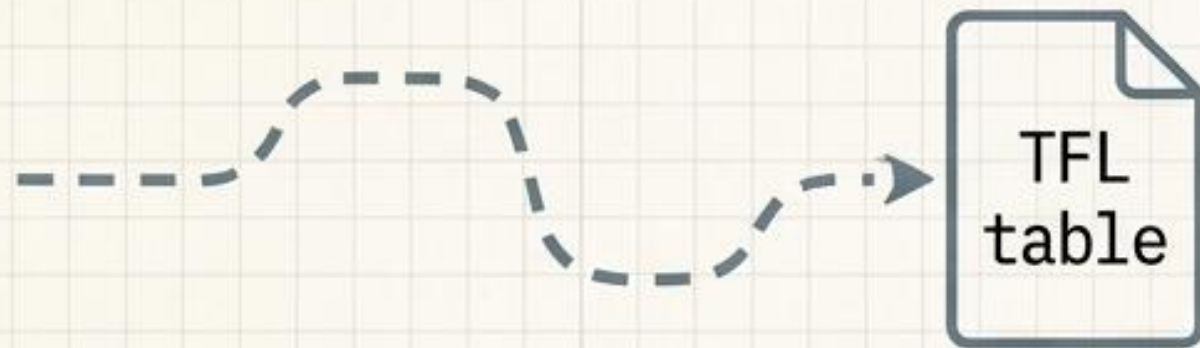
Export





The PHUSE Workshop Outcomes Matrix

Without Instrumentation



- ✓ Output generated successfully
- ✗ Prompt captured?
- ✗ Model version locked?
- ✗ Lineage cryptographically signed?

Result: 'I used AI'
(Explanation, no evidence)

With EQTY SDK Instrumentation

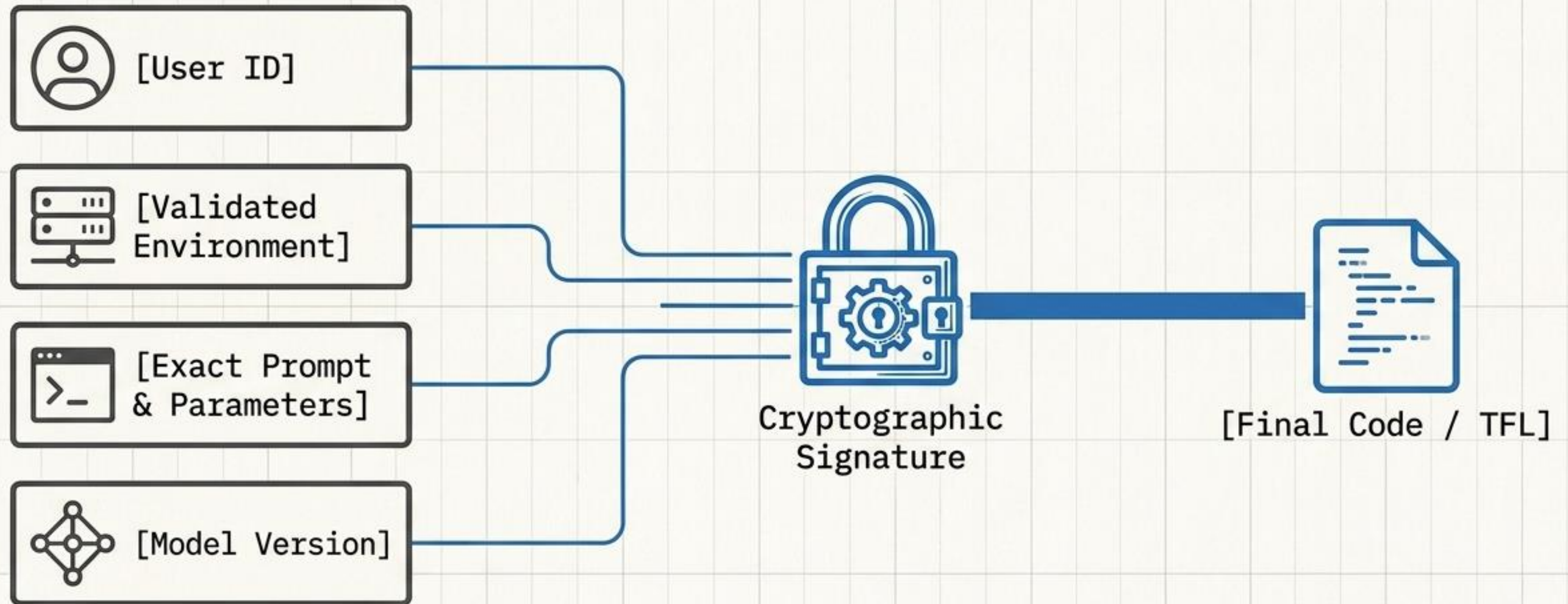


- ✓ Prompt captured
- ✓ Model version recorded
- ✓ Output bound to provenance

Result: Complete Lineage Record
(Artefact of proof)

What the guidance asks for is not a policy that says 'we review AI outputs'—it is an artefact that proves it.

The Cryptographic Lineage Node Map



Tamper-Evident Lineage: The output is inextricably bound to its provenance. Regulators can interrogate the entire chain independently.

The Evolution of SOP Evidence

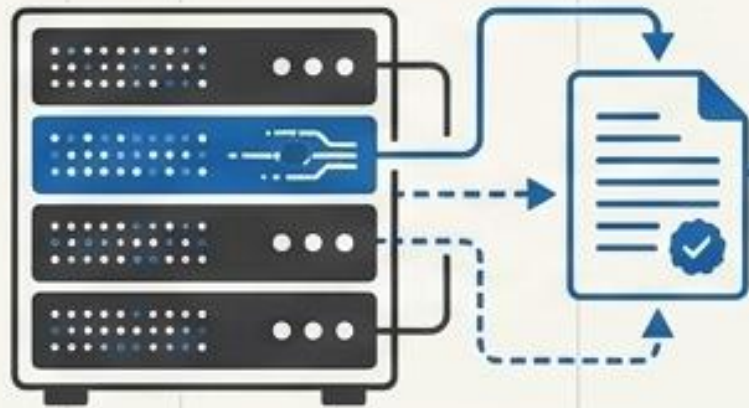
Traditional / Self-Reported



Self-Reported
Subjective
Incomplete
After-the-fact

We assert we followed the SOP.

Modern / System-Generated



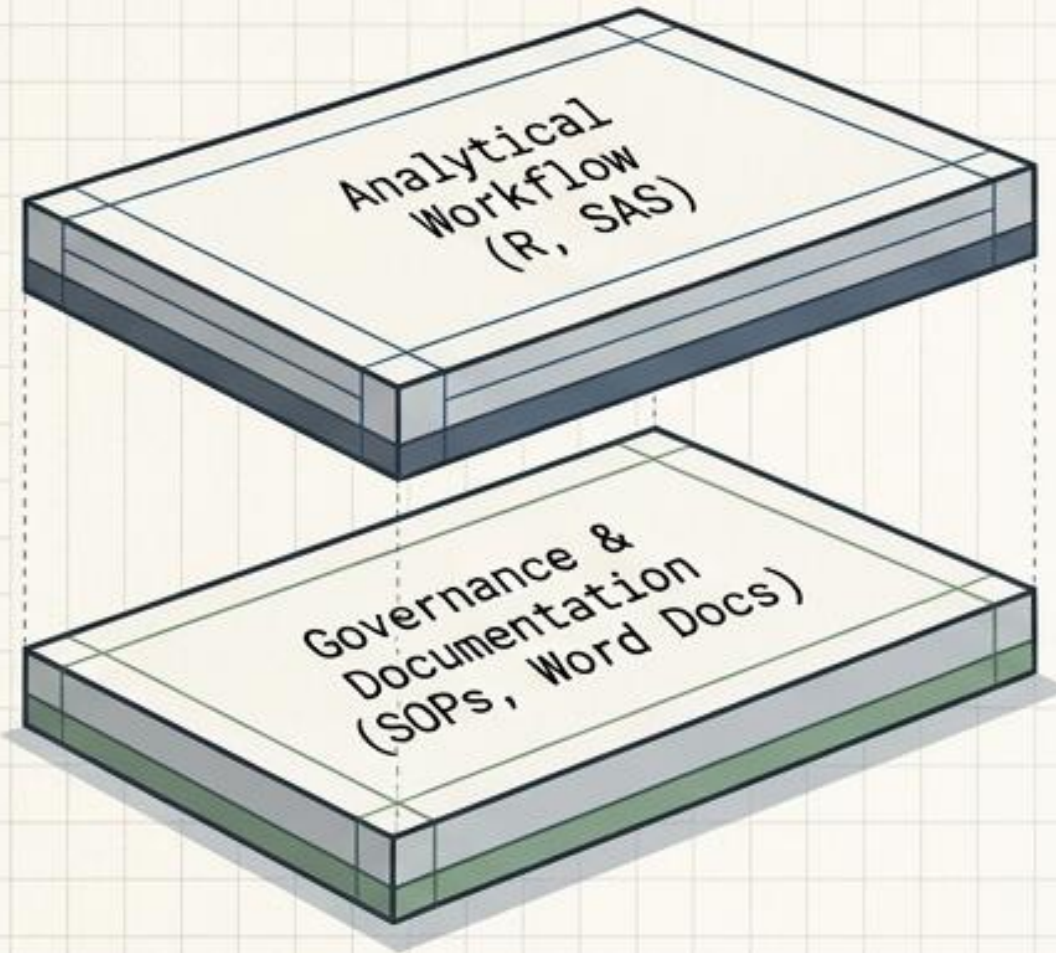
Automated
Objective
Tamper-evident
Real-time

Here is the cryptographic proof we followed the SOP.

[The governance layer becomes the evidence layer.]

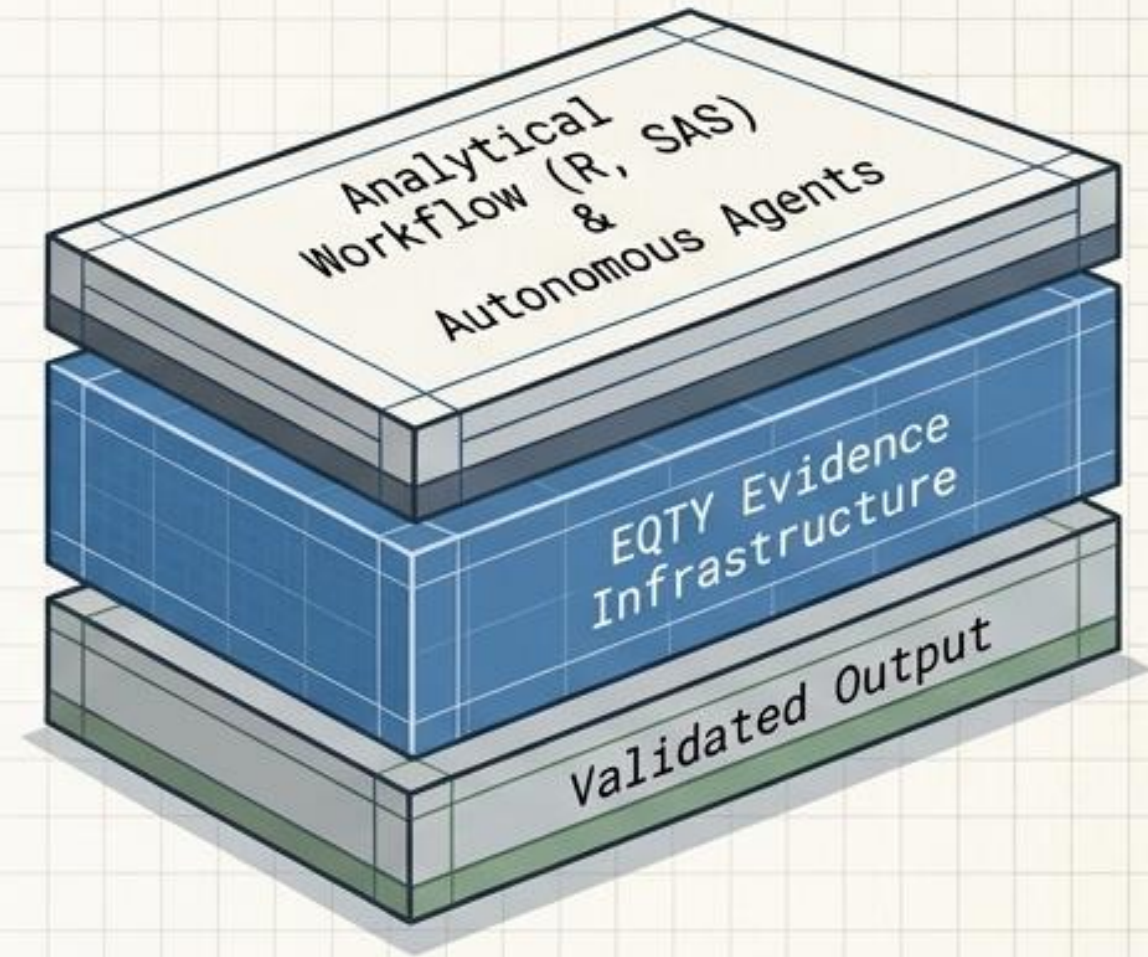
From Bolted On to Built In

The Old Way



If you wait until deploying agents to think about this, you are retrofitting governance into something never designed for it.

The New Way



Treating evidence infrastructure as foundational. The same infrastructure that governs an AI-assisted script today governs an autonomous agent tomorrow.

If a regulator asked you today
how your last AI-assisted
output was produced...

...could you answer
with evidence?

...or only with
explanation? ■

Expanding Your Horizons

From 'Restricted Pilots' to 'Global Scale'



The New Reality

When your AI is a "Glass Box," fear disappears. You can deploy agents into critical workflows (Finance, HR, Legal) because you have total visibility.

Active vs. Passive

We move you from passive logging (checking what went wrong yesterday) to active enforcement (guaranteeing nothing goes wrong today).

The Competitive Edge

In a world of deepfakes, Truth is your most valuable asset. Proving your agent's integrity is the ultimate brand differentiator.

Thank you!



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