

# 17<sup>th</sup> Annual Outsourcing in Clinical Trials West Coast 2025



## AI Unleashed: Transforming Biotechnology with BeiGene's Cutting-Edge Innovations

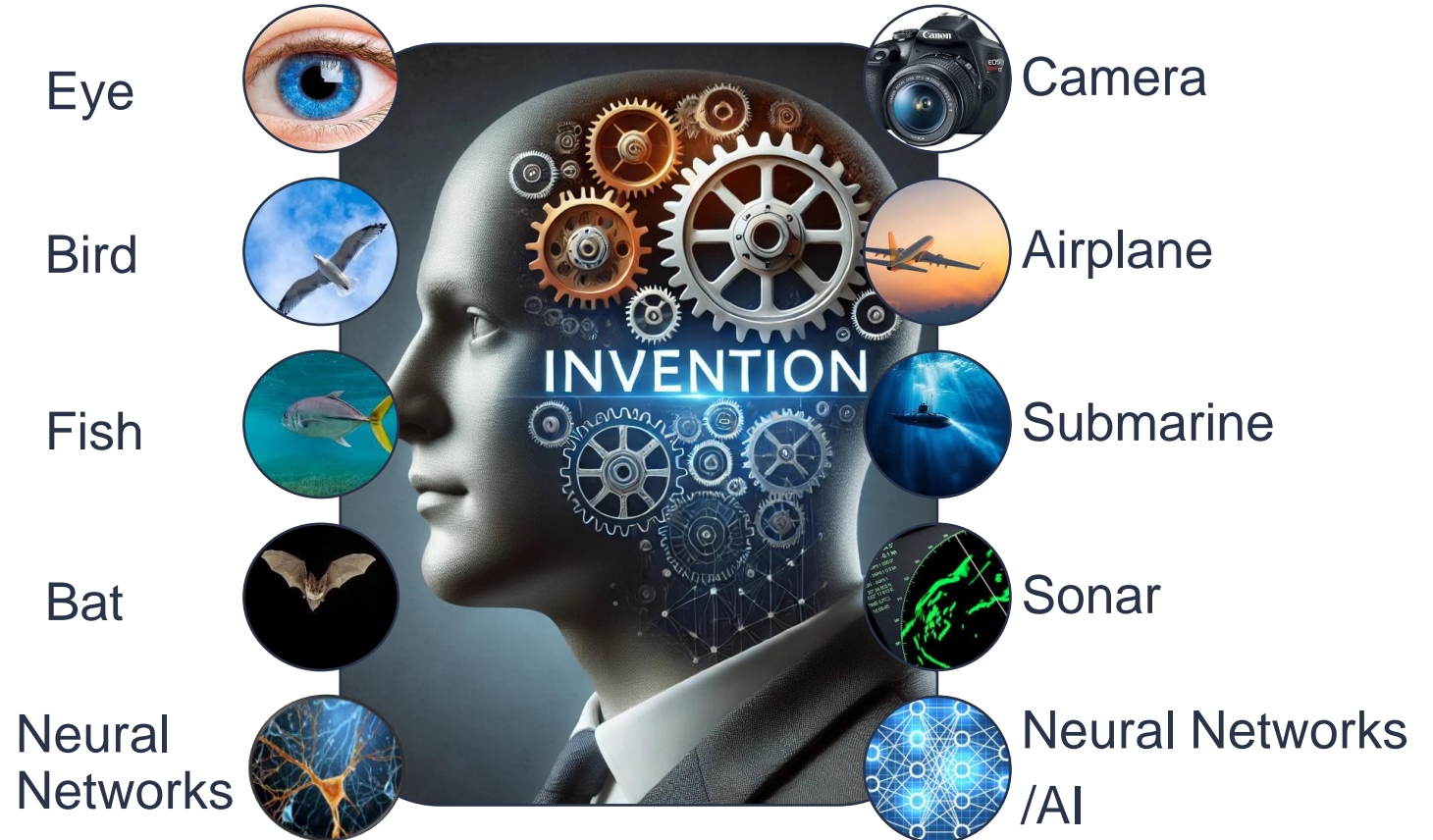
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# Quiz

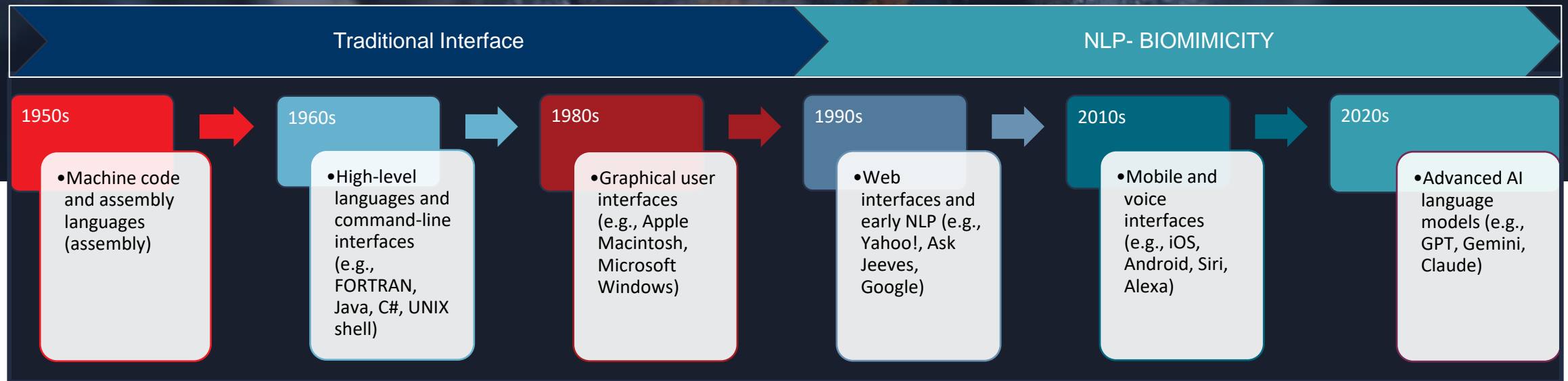
What Do These Inventions Have in Common?

## BIOMIMICITY



# Communicating with Machines

From Programming Languages to Natural Language Processing





# The Art of Prompt Engineering

As data scientists, we're accustomed to crafting precise algorithms and fine-tuning models. But with the rise of large language models (LLMs), a new skill has become essential: Prompt Engineering.



## Definition:

- Prompt Engineering: The practice of designing and refining input prompts to elicit desired outputs from LLMs.
- A blend of art and science, requiring both creativity and analytical thinking.

## Importance:

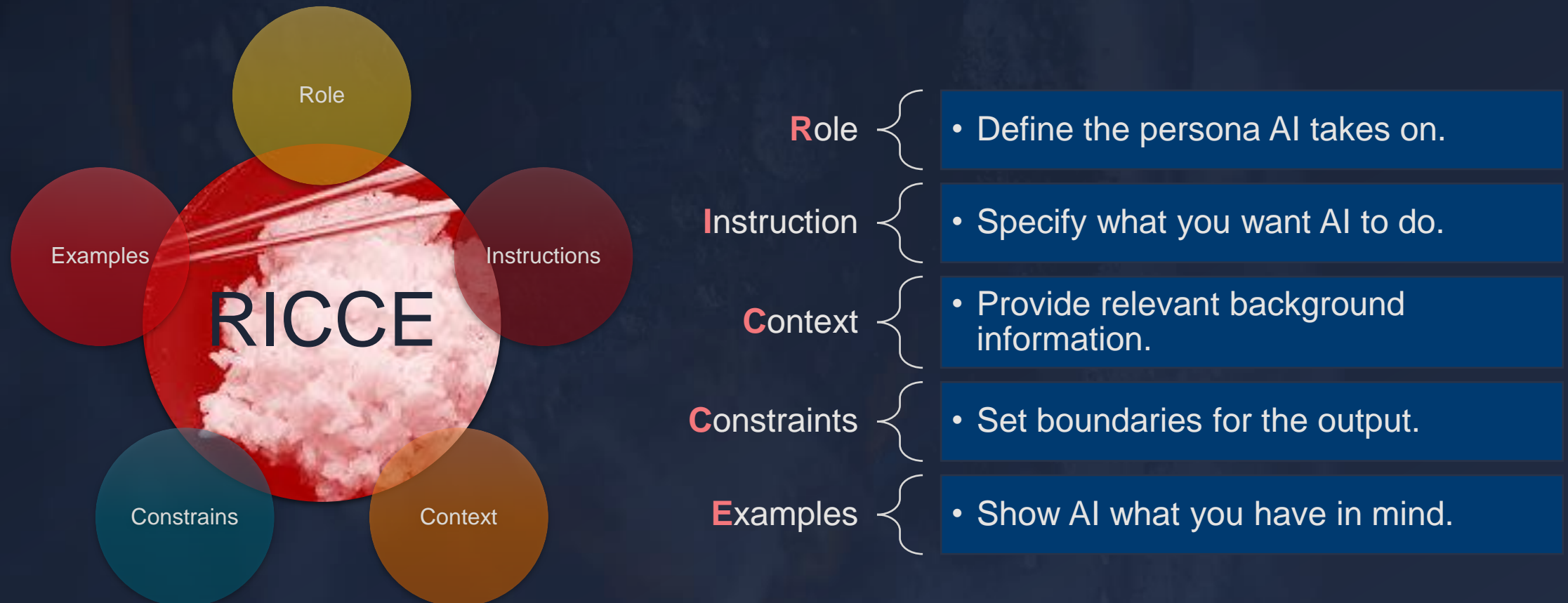
- Sensitivity: LLMs are powerful but sensitive to phrasing.
- Impact: A well-crafted prompt can mean the difference between vague responses and precise insights.

## Key Points

- Creativity: Use inventive prompts to guide LLMs effectively.
- Analytical Thinking: Test and refine prompts for optimal results.
- Precision: Aim for clear, specific questions to get actionable insights.

# The RICCE Framework

RICCE is a mnemonic device for the five key elements to consider when crafting prompts in data science applications



# Introduction to Meta-Prompting



## Meta-Prompting Defined:

Technique where AI generates its own prompts.

Ensures AI creates effective, tailored prompts for its architecture and functionality.

Enhances relevance and quality of AI outputs.

## Benefits of Meta-Prompting:

**Efficiency:** Rapid generation of optimized prompts without extensive manual input.

**Adaptation:** Automatically adjusts prompts to the current version and capabilities of AI models.

**Compatibility:** Addresses prompt drift and cross-model compatibility, making prompts usable across different AI platforms.

## Initial Prompt Creation:

*You are a prompt engineer. You write very bespoke, detailed, and succinct prompts.*

*I want you to write me a prompt that will **[desired task]**.*

## Instructions:

- *Output the prompt you generate in markdown*
- *Output the prompt in a code block*

# Software Development Life Cycle (SDLC)





# Case Study 1: From a Requirements Working Session to POC

## URS Prompt

Using the provided transcript of a requirements workgroup session gathering user requirements of the web application, produce a detailed and professional User Requirements Specification Document.

Requirements for the Document:

Structure: The document should include the following sections:

- Introduction
- Purpose
- Scope
- Functional Requirements
- Non-functional Requirements
- User Interface Requirements
- Assumptions and Constraints
- Glossary (if necessary)

Content Guidelines:

- Clearly and unambiguously state all requirements.
- Expand on the requirements for clarity, without altering their original intent.
- Use professional and formal language appropriate for a specification document.

Formatting:

- Utilize headings and subheadings for organization.
- Number requirements for easy reference.
- Incorporate bullet points, tables, and diagrams where appropriate for clarity.

Output:

- Provide a comprehensive User Requirements Specification Document based on the input above.

Input:

[Meeting transcript here]





# Case Study 2: Drug Safety, AE Narratives Automation BeiGene

## Problem Statement

“On 27-JUL-2021, the subject initiated study drug 2 milligram; The subject experienced PNEUMONIA (Pneumonia). The subject has been instructed to pay attention to rest and go to the hospital for treatment if necessary. The subject's body temperature was 37 Celsius degree at 7:00 and 37.5 Celsius degree at noon; accompanied by sore throat and phlegm; which was not easy to cough up; and felt a little difficulty in breathing and fatigue. The subject was instructed to concern about high fever and to use ibuprofen tablets if his body temperature was 37.5 Celsius degree. At 22:00 on 28-JUL-2021; the study doctor suggested that the subject monitor the oxygen in the finger pulse and go to the hospital for further diagnosis and treatment. The subject's wife did not want to go out at night due to the subject's mobility difficulties. On 28-JUL-2021; the subject presented with low fever; sore throat; phlegm; difficult cough; dyspnea; fatigue and other symptoms. Considered that the subject's roommate had been infected with covid-19; the subject was also infected with covid-19.

On 29-JUL-2021; the subject returned to the hospital for c5d1 follow-up. Because the subject's legs were weak, and he could not walk freely; so, he was carried downstairs by his wife. The subject back downstairs in the process; the subject's family strength; then telephone contact 120; the subject to the hospital. When waiting for 120; the subject appeared unconscious and was immediately rescued after 120 arrived at the scene (the details are not clear). After the rescue failed; the subject was declared dead. The subject experienced DIFFICULT BREATHING (Dyspnoea)(Grade 5); Life-threatening; death. Access report; the subject was diagnosed with lung adenocarcinoma complicated with brain and bone metastases. The subject died with dyspnea before death. combined with the overall situation of the subject; it was considered that the death of the subject was mainly caused by dyspnea. On 29-JUL-2021; the outcome of Dyspnoea was Fatal. No autopsy was performed.”

# Case Study 2: Drug Safety, AE Narratives Automation



## AI - Summarization

### Original Narrative

This Sponsored CT case, ABC, received from a study site 1234 is a report for subject x, an n years-old, Male enrolled in BGB-ABC-1234 A Phase 1 Study Investigating the Safety.....

The subject experienced diarrhea during .....

The subject's relevant medical history was not .....

Relevant concomitant medications included .....

Prior to initiation of study treatment, on 31-JUN-2024, the subject was hospitalized due to diarrhea (G 4). The subject was treated consequently Pantoprazole, inflammation, and supportive care.

On 23-JUN-2024, the subject was hospitalized. Subject already in hospital from previous SAE (.....)

Lab test done on 25-JUN-2024 with elevated liver function result, Alanine aminotransferase (ALT) 57 u/l (10 - 50 U/L), Aspartate aminotransferase (AST) 217 u/l (10 - 35 U/L), Gamma-glutamyltransferase (GGT) 1209 u/l, sodium 132mma/l. other hematology and chemistry test was unremarkable....

On 26-JUN-2024, On 26-JUN-2024, atient reported decreased appetite (Grade 3). Metronidazole 500mg intravenous was given to manage presumed infectious inflammatory. From 26-JUN-2024 to 01-JUL-2024, magnesium sulfate 10 mmol in 100ml normal saline .....

On 06-JUL-2024, For abdominal distension, ascites drainage was given. For hypoproteinemia, albumin intravenous drip was given to supplement albumin treatment. After symptomatic support treatment, the subject was discharged from the hospital after grade 3 improvement to grade 2....

The Investigator assessed the condition as Not Related to study drug.

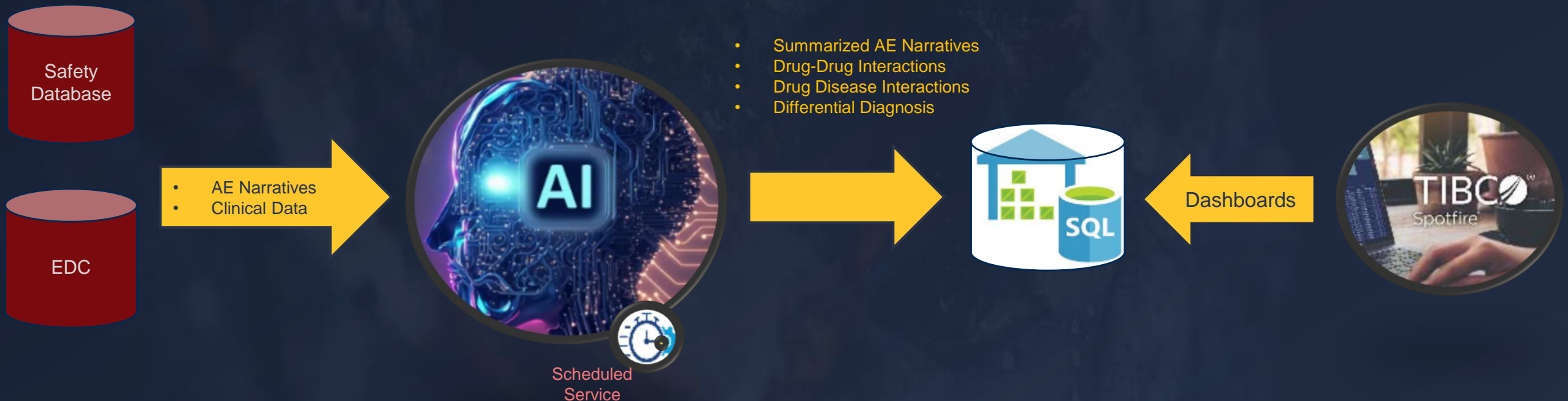
..... Up to another 10-20 lines of text



Day	Adverse Event/Condition	Grade / Inferred Grade	Outcome	Summary
23	Hypoglycaemia	NS/None Inferred	Hospitalized	On 23-JUN-2024 (day 23) - The subject was hospitalized due to a previous Serious Adverse Event of Hypoglycaemia.
25	Elevated liver function	NS/Grade 3 Inferred	Hospitalization Continued*	On 25-JUN-2024 (day 25) - Elevated liver function results: Alanine aminotransferase (ALT) 127 u/l (RR 10 - 50 U/L), Aspartate aminotransferase (AST) 200 u/l (RR 10 - 35 U/L), Gamma-glutamyltransferase (GGT) 1400 u/l.
26	Anorexia	Grade 3	Hospitalization Continued*	On 26-JUN-2024 (day 26) - Patient reported decreased appetite (Grade 3). Received Metronidazole 550mg intravenous; magnesium sulfate 12 mmol in 100ml normal saline.....
36	Elevated liver function	Grade 2	Discharged	On 06-JUL-2024 (day 36) - subject was discharged from the hospital after grade 3 improvement to grade 2. Treatment included: abdominal distension - ascites drainage; albumin intravenous drip

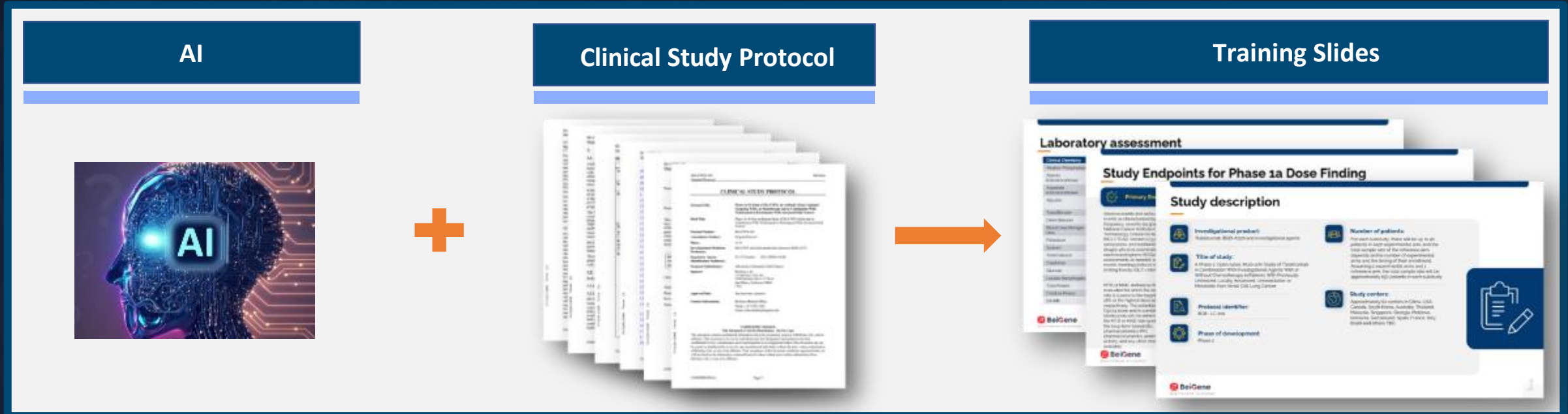
## Case Study 2: Drug Safety, AE Narratives Automation

- The project aims to enhance patient safety reviews by automating the extraction and summarization of adverse event narratives using AI, significantly reducing dependence on external partners and manual processes.
- It includes identifying Drug-Drug Interactions, Drug-Disease Interactions, and generating Differential Diagnoses. This initiative promises significant reduction in cycle times and annual cost savings.
- It is providing real-time patient data access and precise. Ultimately, this project exemplifies BeiGene's commitment to advancing patient care, and safety through innovative AI-driven solutions.



# Case Study 3: Clinical Protocol eLearning Automation

**Purpose:** The Clinical Protocol eLearning Automation tool utilizes AI to extract information from clinical protocols and automatically generate training slides. This tool provides essential training materials for clinical operations staff.



## 1. Grab information from protocol

Capture relevant text and the table content from clinical study protocol

## 2. Content Processing

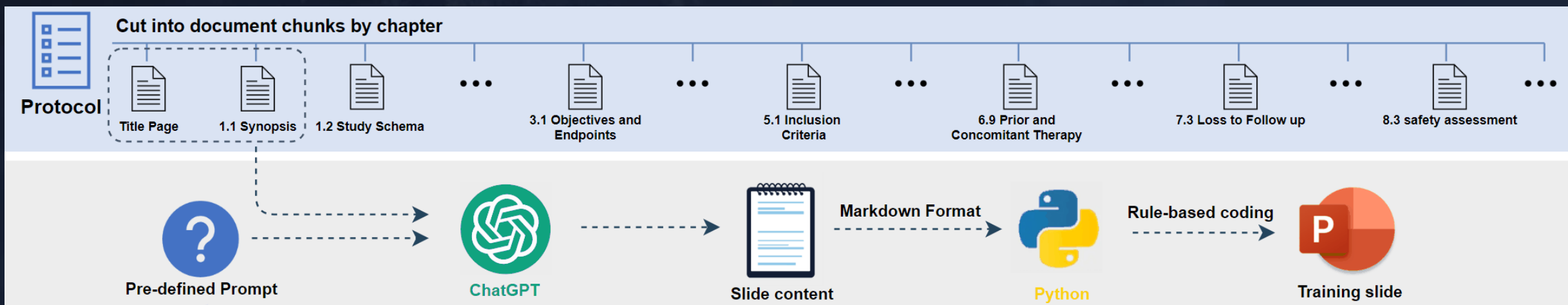
- Summarize text
- Select key points
- Text formatting

## 3. Create Training slides

Insert content into the slides template and create layout automatically



# Case Study 3: Clinical Protocol eLearning Automation



**Role**  
You are a Medical Writer tasked with extracting information from clinical study protocols.

**Context**  
The provided material includes sections of the protocol, such as the Title page and synopsis.

**Instructions**  
Extract and present the content of the study description, specifically including:

- Investigational Medicinal Product(s)
- Protocol Title
- Protocol Number
- Phase
- Number of patients

**Constraints**  
Provide only the original content from the text without any modifications.

**Output Format**  
Present the extracted information in Markdown format.

**Example**

AI Prompt


[Heading Label] # Study description  
[Subheading Label] ## Investigational Medicinal Product(s)  
[Text Label] - ABC-111  
## Protocol Title  
- Phase 1a/1b Study of ...  
## Protocol Number  
- ABC-222-123  
## Phase  
- 1a/1b  
...

AI Response



Generate slides using rule-based coding

# Case Study 4: Medical Coding



Medical coding is a critical process in clinical trials, ensuring that adverse events and diagnoses are accurately classified using standardized systems like MedDRA.



This practice facilitates clear communication, regulatory compliance, and data analysis.



Accurate coding is essential for maintaining consistency and reliability in reporting clinical study outcomes.

# Challenges Manual Coding

## Inconsistency

- Possibility of different terms picked for the same event description depending on the user

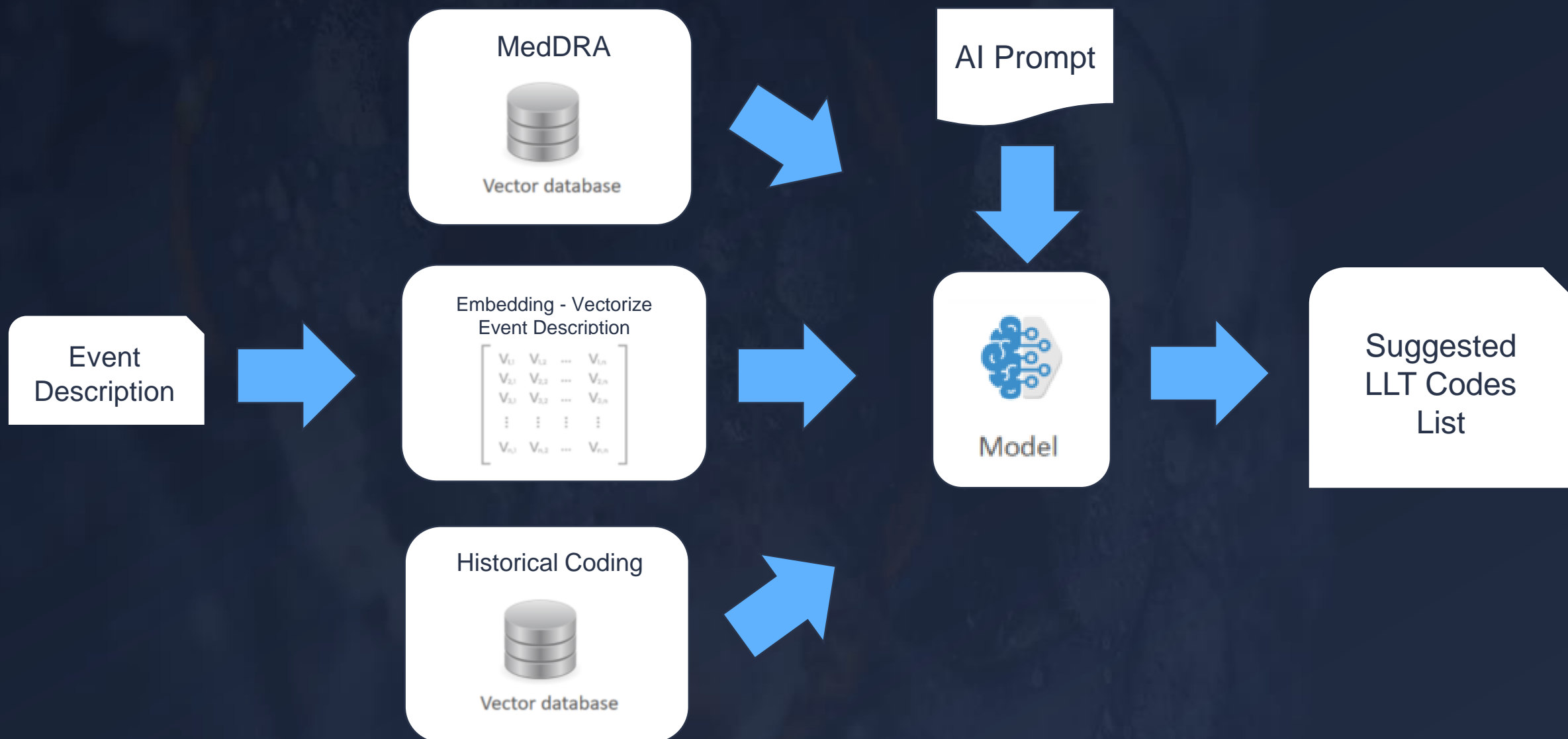
## Time Consuming

- Event description being free text, Medical coders may need to refer multiple sources to code events

## Identify all AEs from Source document

- Source documents are long – Adverse event terms could be in multiple paragraphs of the document

# Vector RAG (Retrieval Augmented Generation) - Precision and Efficiency in Medical Coding





# AI-Powered Clinical Study Data Analysis



AI models thoroughly examine detailed summary tables from studies, which encompass patient medical data.

The outcome is a structured and in-depth analysis that provides a succinct summary of the integrated clinical data.

This methodology successfully conveys intricate findings, merging sophisticated analytics with scientific writing to serve both clinical and academic audiences.

# AI-Powered Document Review

- This solution presents software powered by AI that features specialized agents, each with expertise in areas pertinent to your documents.
- Overseen by an AI document editor, these agents integrate smoothly into the workflow for reviewing corporate documents, thereby improving accuracy, compliance, and efficiency.
- By decreasing the time dedicated to evaluations and reducing errors, this solution speeds up the review process, resulting in faster publication and execution while enhancing overall quality.



**Thank You!**  
**Q/A**