

ML07

UNLOCKING BIOPHARMA INSIGHTS

A RAG-Enabled AI Framework for Rapid Access to
Clinical and Nonclinical Study Data

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DISCLAIMER



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Background and
Industry context

01

05

Query processing model

Study data access
challenges in Biopharma

02

06

Governance Principles
For Regulated AI

RAG-enabled
conversational AI vision

03

07

Key Learnings

System architecture

04

08

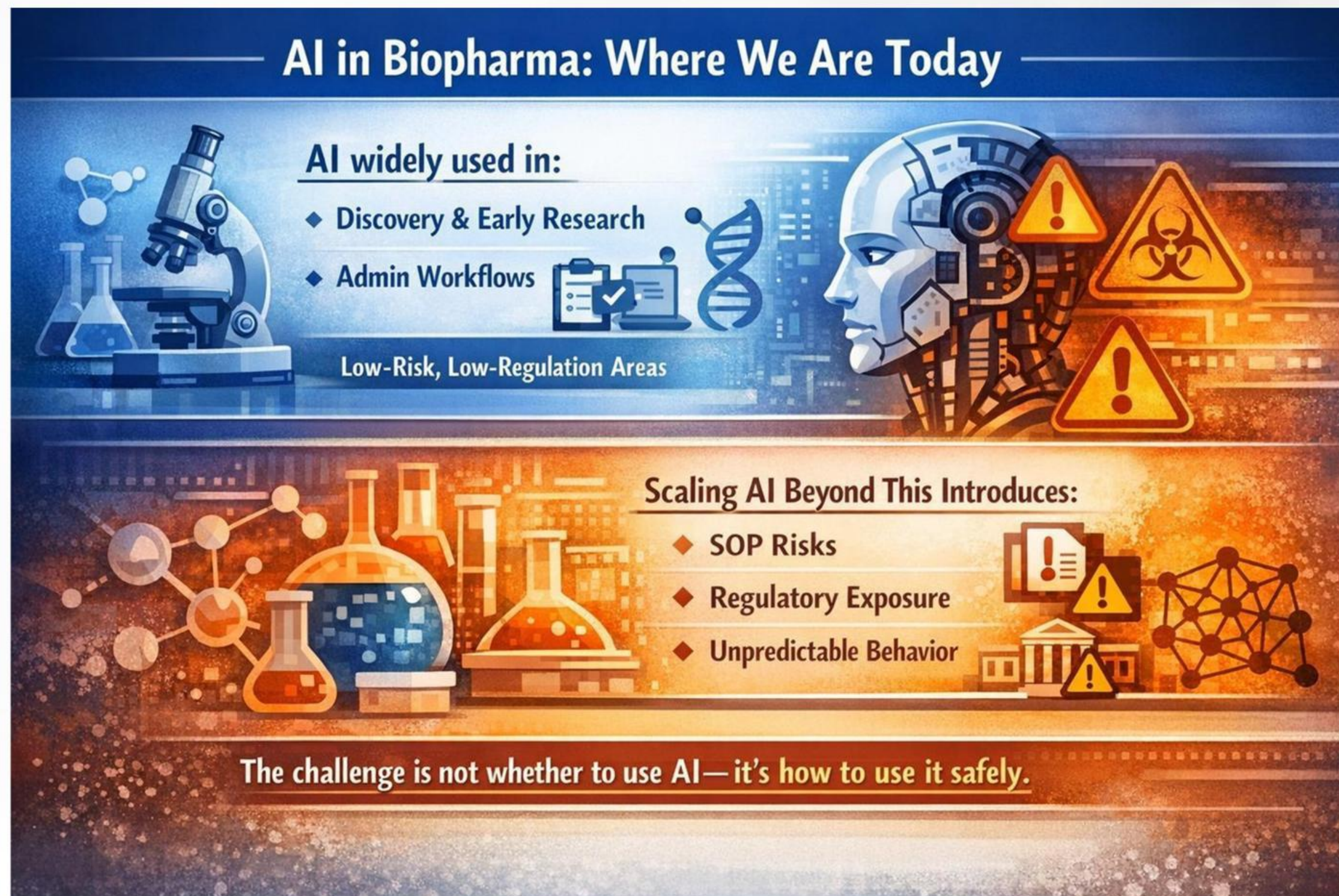
Future Enhancement

AGENDA

INDUSTRY BACKGROUND & CONTEXT

- AI/LLMs accelerate biopharma decisions
- Use limited by regulatory risk
- Clinical & nonclinical data highly restricted
- Data access remains complex and expert-driven

AI in Biopharma: Where We Are Today



AI widely used in:

- ◆ Discovery & Early Research
- ◆ Admin Workflows

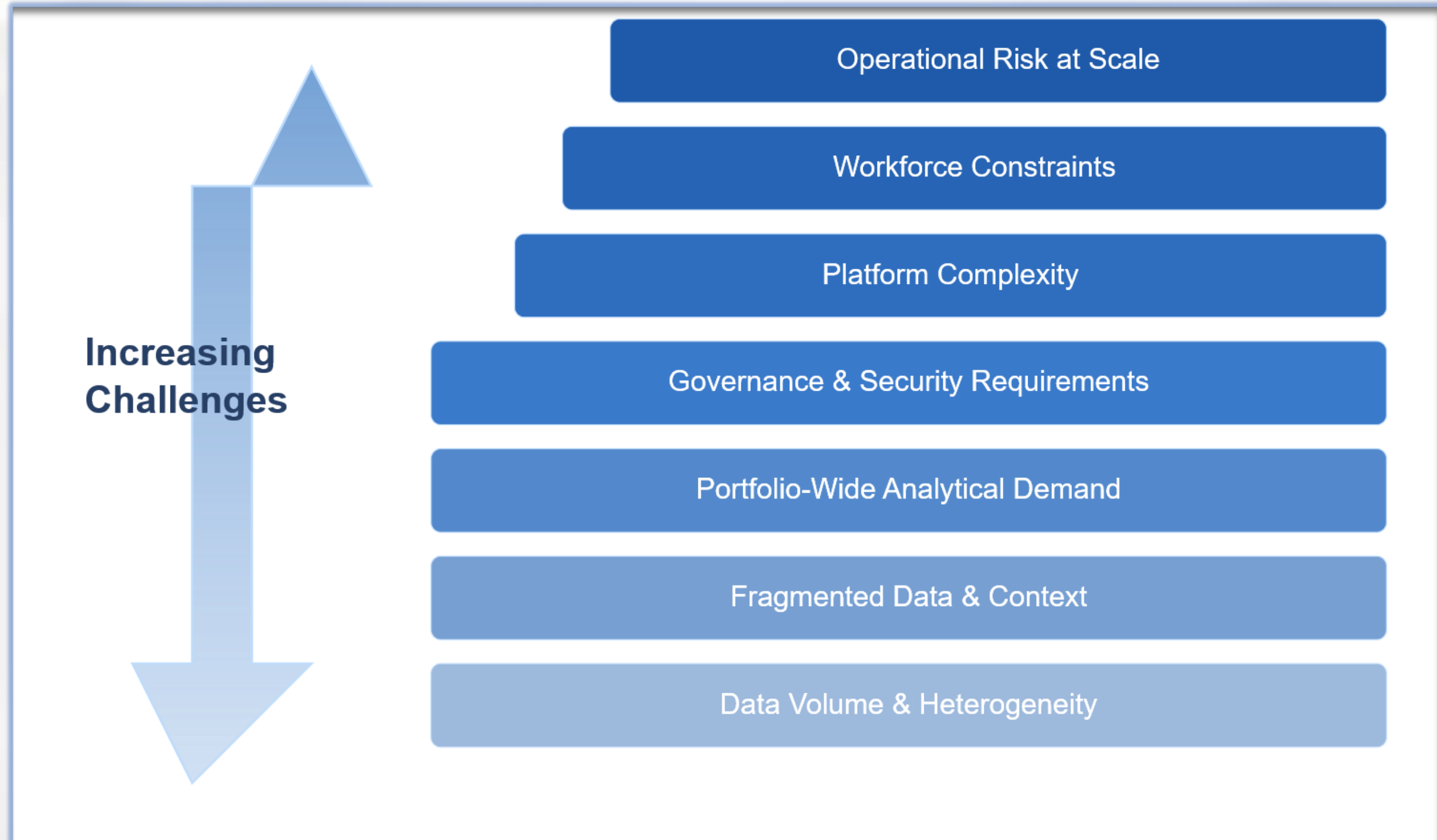
Low-Risk, Low-Regulation Areas

Scaling AI Beyond This Introduces:

- ◆ SOP Risks
- ◆ Regulatory Exposure
- ◆ Unpredictable Behavior

The challenge is not whether to use AI— it's how to use it safely.

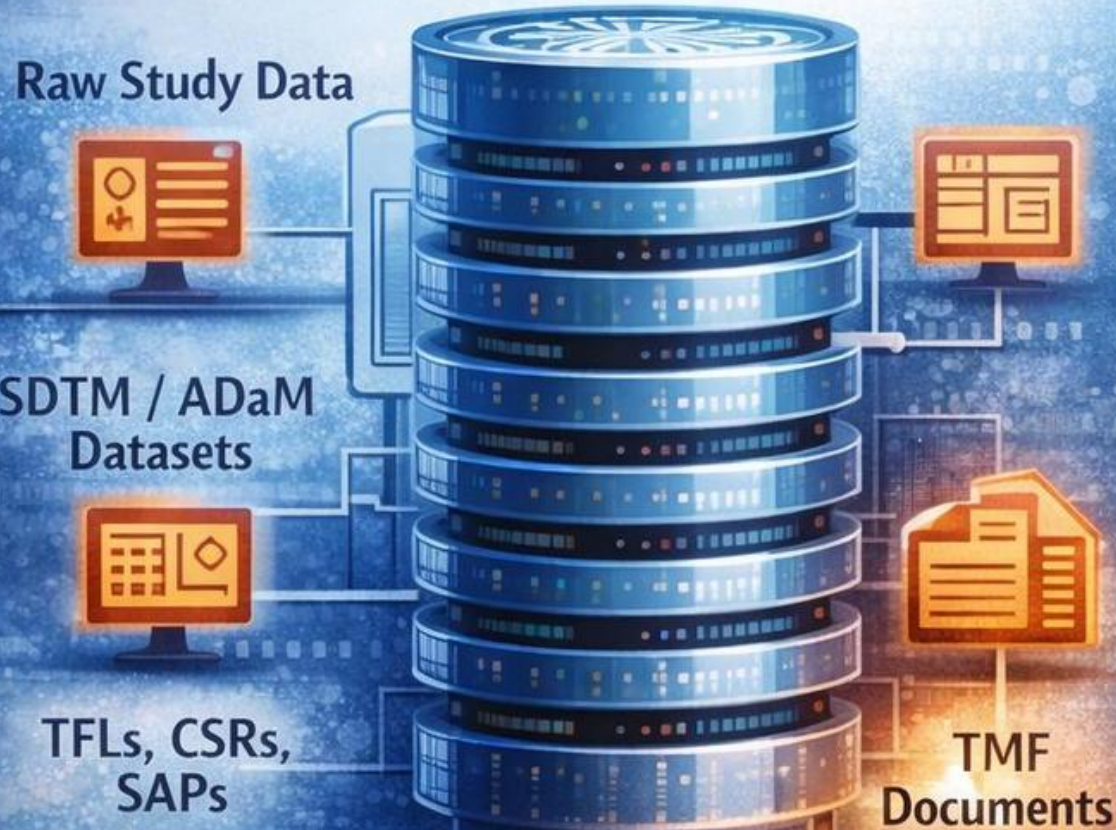
CORE ACCESS CHALLENGES



STUDY DATA ACCESS CHALLENGES

The Reality Inside Pharma Organizations

Huge Centralized Repositories Exist



But Data Is Locked Behind:

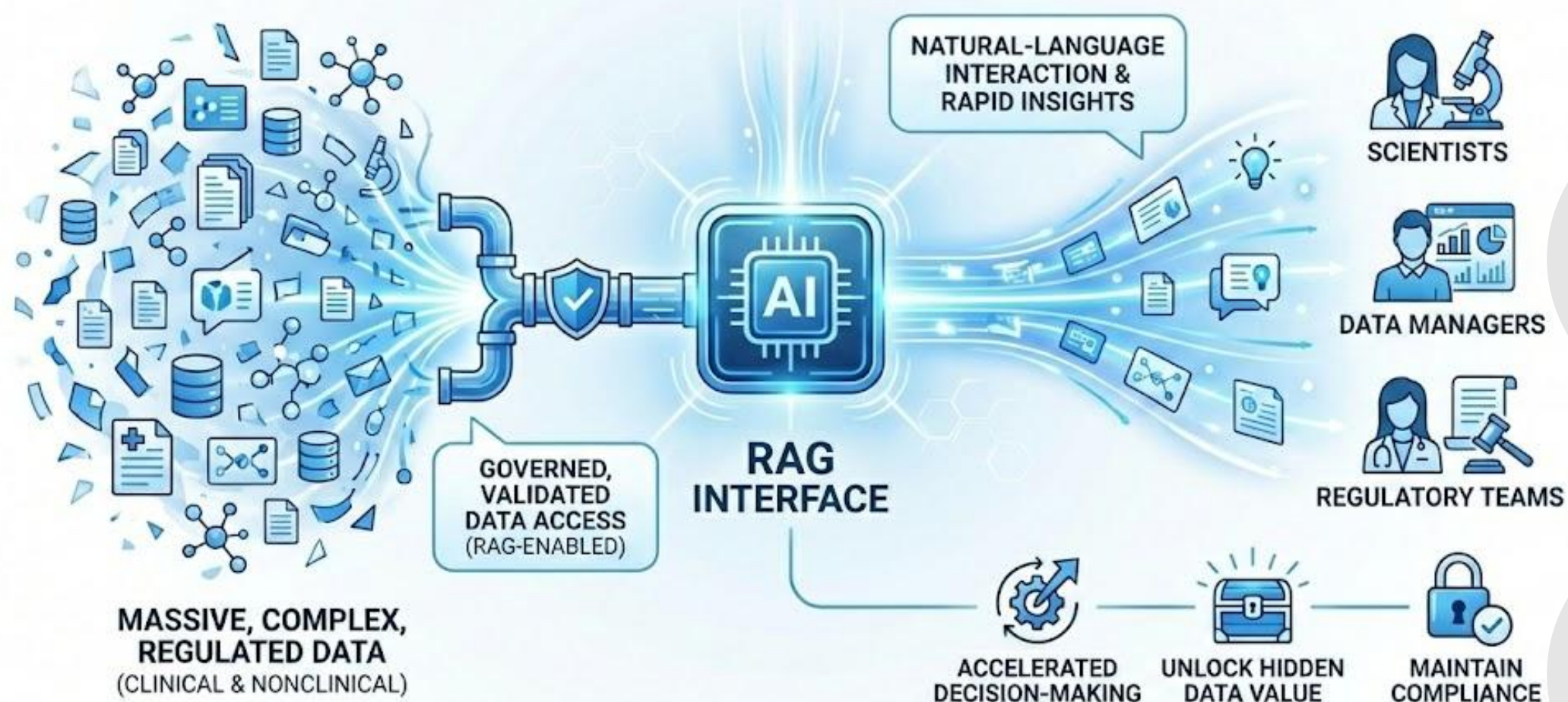


Result:  High investment, low usability.

- Centralized data
- Fragmented access
- Expert-dependent systems
- Ethical and Legal Sensitivity
- Low usability, High Investment

WHY IT MATTERS?

RAG INTERFACE: BRIDGING AI, DATA, AND DECISIONS



1

Delays in insight slow down critical development decisions

2

Limited access reduces the value of expensive clinical data

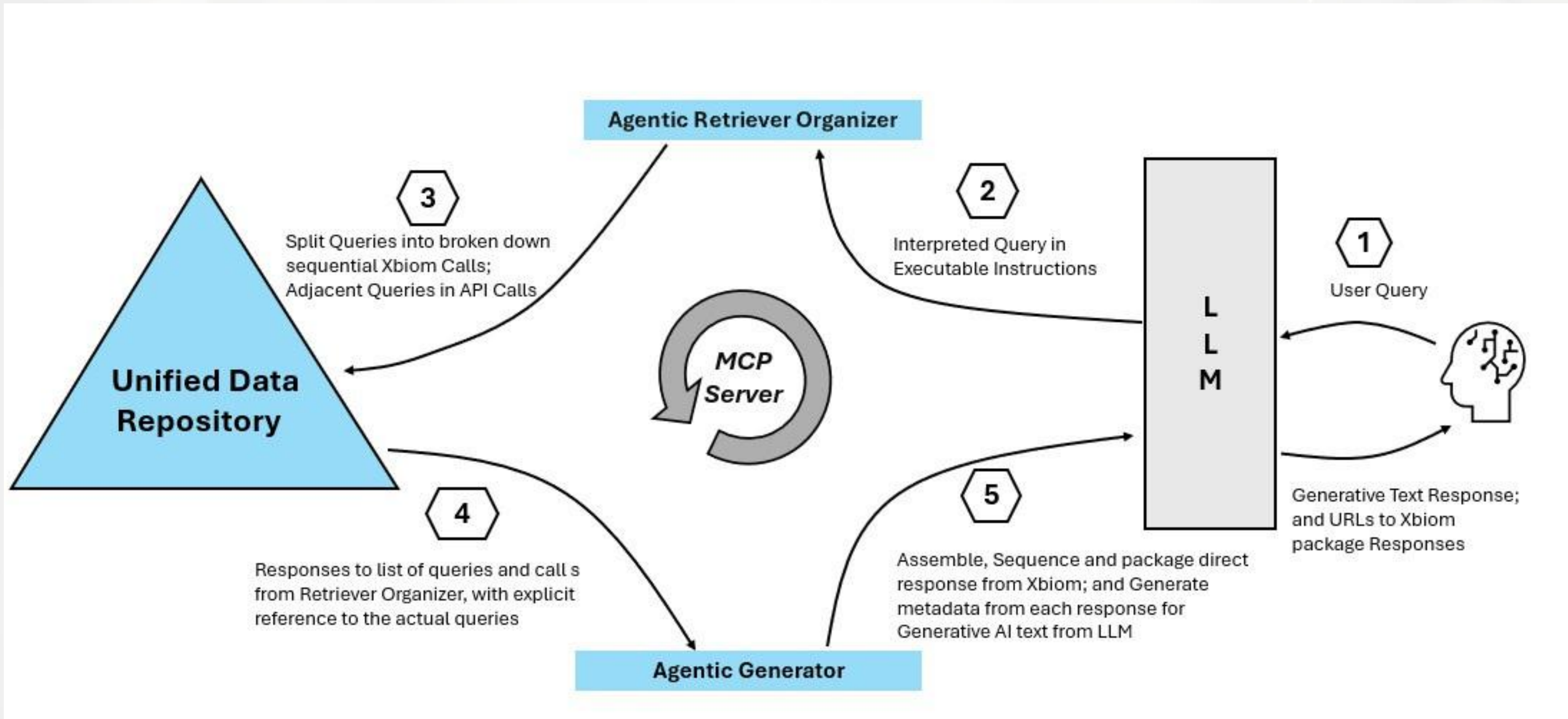
3

A governed AI approach enables faster, trusted, and compliant decision-making

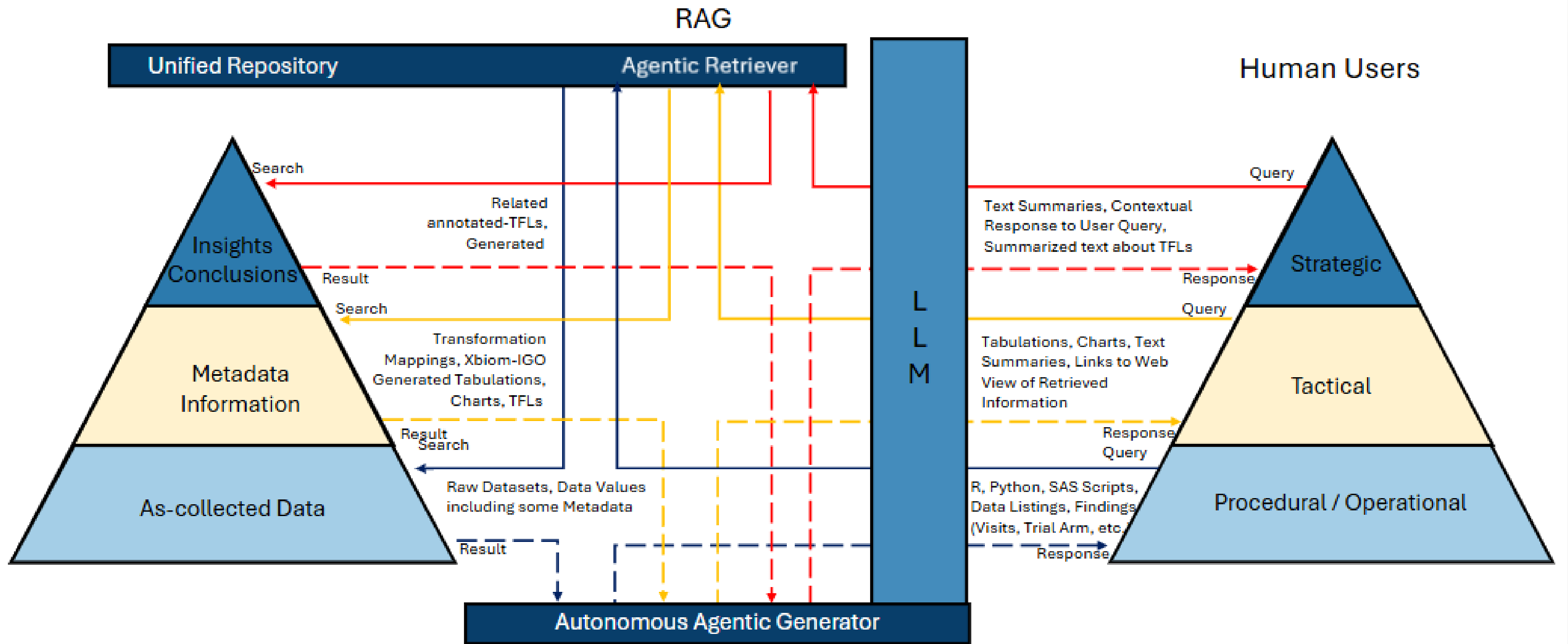
CORE COMPONENTS



VISION: CONVERSATIONAL RAG FOR BIOPHARMA



RAG: THREE-LAYER ARCHITECTURE



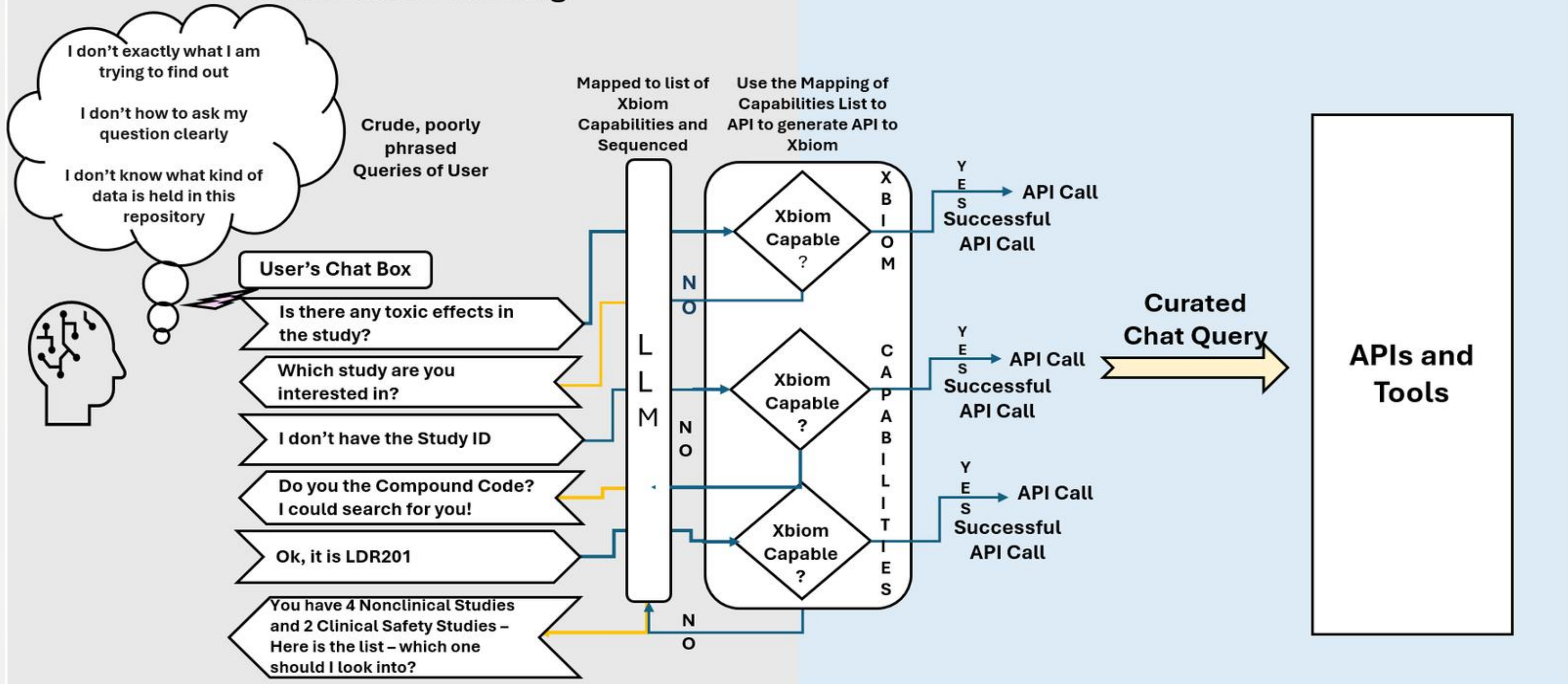
HIGH LEVEL ARCHITECTURE



The system ensures AI-driven answers are always grounded in validated, governed data, preserving compliance at every step.

Holistic, Contextual, Language based, Meaning and Intent Driven Thinking

Rigid, Brittle, Analytical Thinking with Traceability



DECISION LOGIC FLOW

The system employs intelligent routing logic with multiple decision nodes:

1. Scope Assessment: Check if the query is within the application's defined domain.

2. Feature Availability: Verify the requested capability is supported and implemented.

3. Information Type Classification: Determine whether the query requires data-driven evidence versus static system information.

4. Tool Requirement Determination: Identify whether RAG tool execution is required to answer the query.

5. Topic Alignment Validation: Confirm the query aligns with supported application-specific topics.

6. Query Context Analysis: Extract explicit and implicit constraints such as study identifiers or scope.

7. Resource Availability Check: Validate that required indexed documents or datasets are accessible.

8. RAG Execution Routing: Route the query to the RAG pipeline for retrieval and response generation.



I would like to know in which studies CRP analyses were performed and I would like to see and compare the results

✂ Reasoning ▾

✂ I have located CRP (C-Reactive Protein) biomarker data in two studies: **CBER-POC** and **RABBITV1**. CRP measurements from these studies include individual subject values, with results reported in mg/L. The data covers various subjects but lacks detailed visit or treatment group metadata in the retrieved records.

Summary of findings:

| Study ID | CRP Range (mg/L) | Notes |
|----------|-----------------------------|---|
| CBER-POC | Approximately 0.18 to 232.0 | Wide range of CRP values observed |
| RABBITV1 | Approximately 1.2 to 190.11 | Consistent CRP measurements across subjects |

You can explore detailed CRP data interactively, filter by subject, cohort, or timepoint, and visualize trends using the IGO module linked below.

Usable URLs:

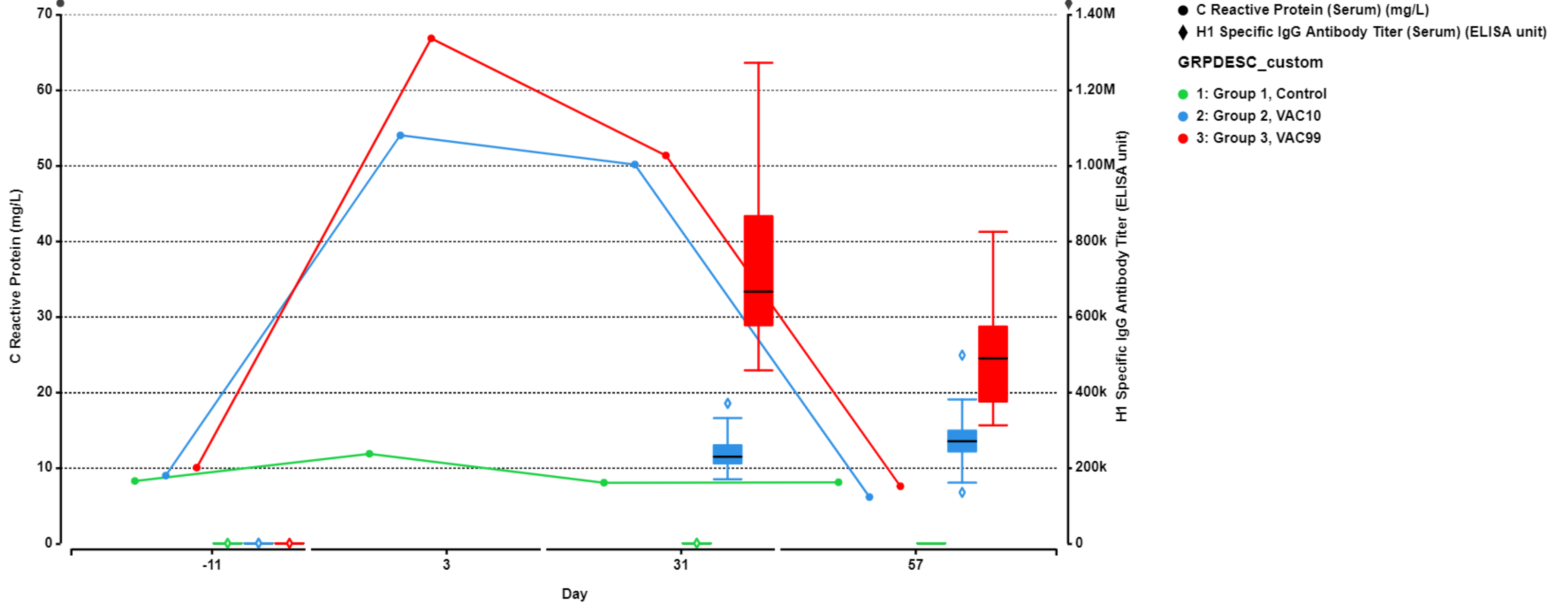
- [CBER-POC Study](#)
- [RABBITV1 Study](#)



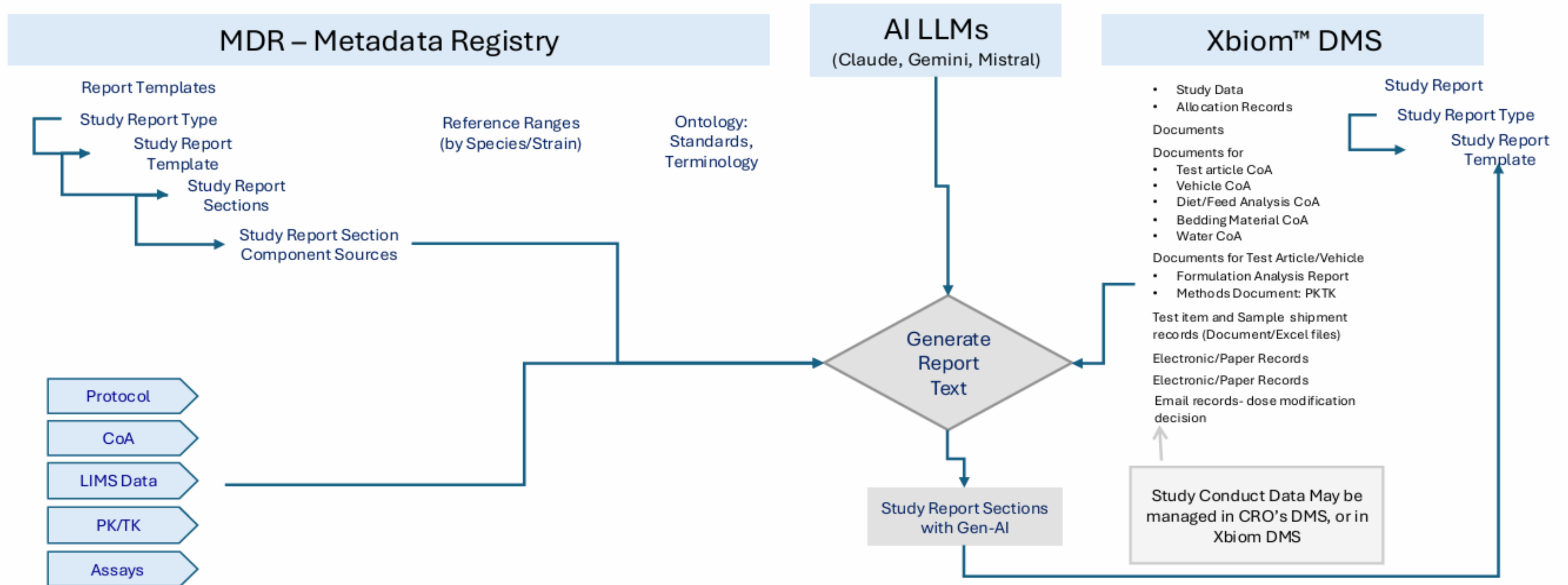
Ask Xbiom Whisperer



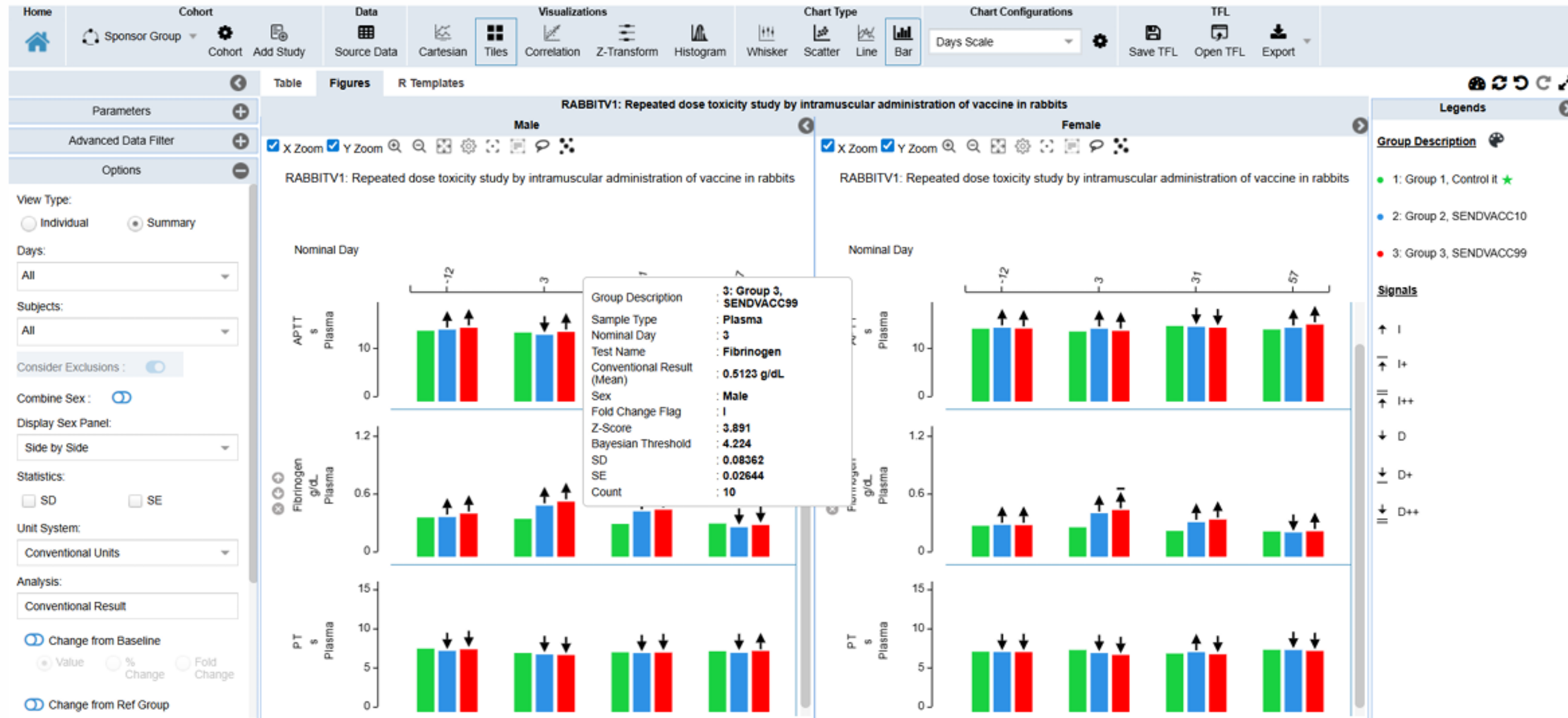
Repeated dose toxicity study by intramuscular administration of vaccine in rabbits
 C Reactive Protein (mg/L), H1 Specific IgG Antibody Titer (ELISA unit)



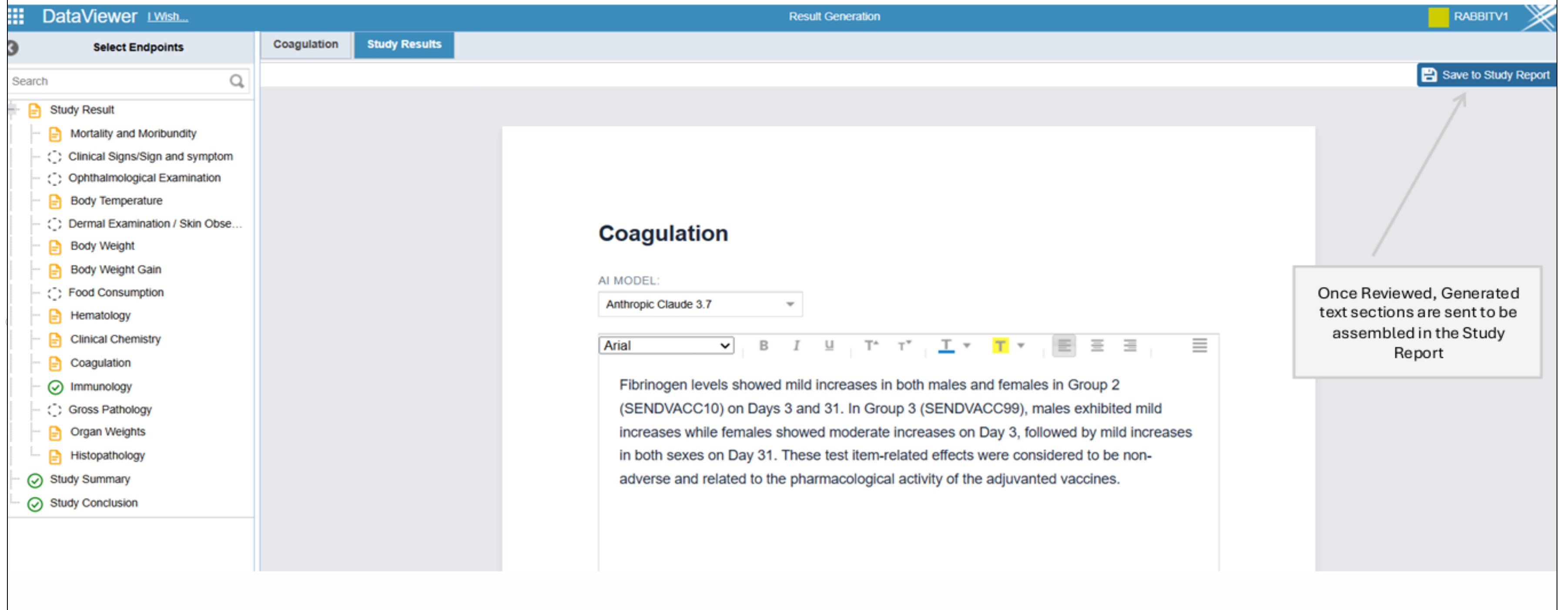
Management of Report Templates & Study Report Section Generation and Assembly



Computed Signals



Report Section Generation from Results with AI



The screenshot displays the 'DataViewer' software interface. The top navigation bar includes 'DataViewer', a user profile 'I Wish...', 'Result Generation', and a study identifier 'RABBITV1'. Below this, there are tabs for 'Coagulation' and 'Study Results', with 'Study Results' currently selected. On the left, a 'Select Endpoints' sidebar lists various categories such as 'Study Result', 'Mortality and Moribundity', 'Clinical Signs/Sign and symptom', 'Ophthalmological Examination', 'Body Temperature', 'Dermal Examination / Skin Obse...', 'Body Weight', 'Body Weight Gain', 'Food Consumption', 'Hematology', 'Clinical Chemistry', 'Coagulation', 'Immunology', 'Gross Pathology', 'Organ Weights', 'Histopathology', 'Study Summary', and 'Study Conclusion'. The main workspace is titled 'Coagulation' and features an 'AI MODEL:' dropdown menu set to 'Anthropic Claude 3.7'. Below the model selection is a rich text editor with a toolbar containing options for font (Arial), bold (B), italic (I), underline (U), text color (T), background color (T), and alignment. The generated text reads: 'Fibrinogen levels showed mild increases in both males and females in Group 2 (SENDVACC10) on Days 3 and 31. In Group 3 (SENDVACC99), males exhibited mild increases while females showed moderate increases on Day 3, followed by mild increases in both sexes on Day 31. These test item-related effects were considered to be non-adverse and related to the pharmacological activity of the adjuvanted vaccines.' A 'Save to Study Report' button is located in the top right corner of the workspace. A callout box with an arrow pointing to this button contains the text: 'Once Reviewed, Generated text sections are sent to be assembled in the Study Report'.

PREVENTING HALLUCINATION AND RISK

■ DATA

AI answers only from retrieved, validated data.

■ INFERENCE

Unsupported inferences or guesses are not allowed.

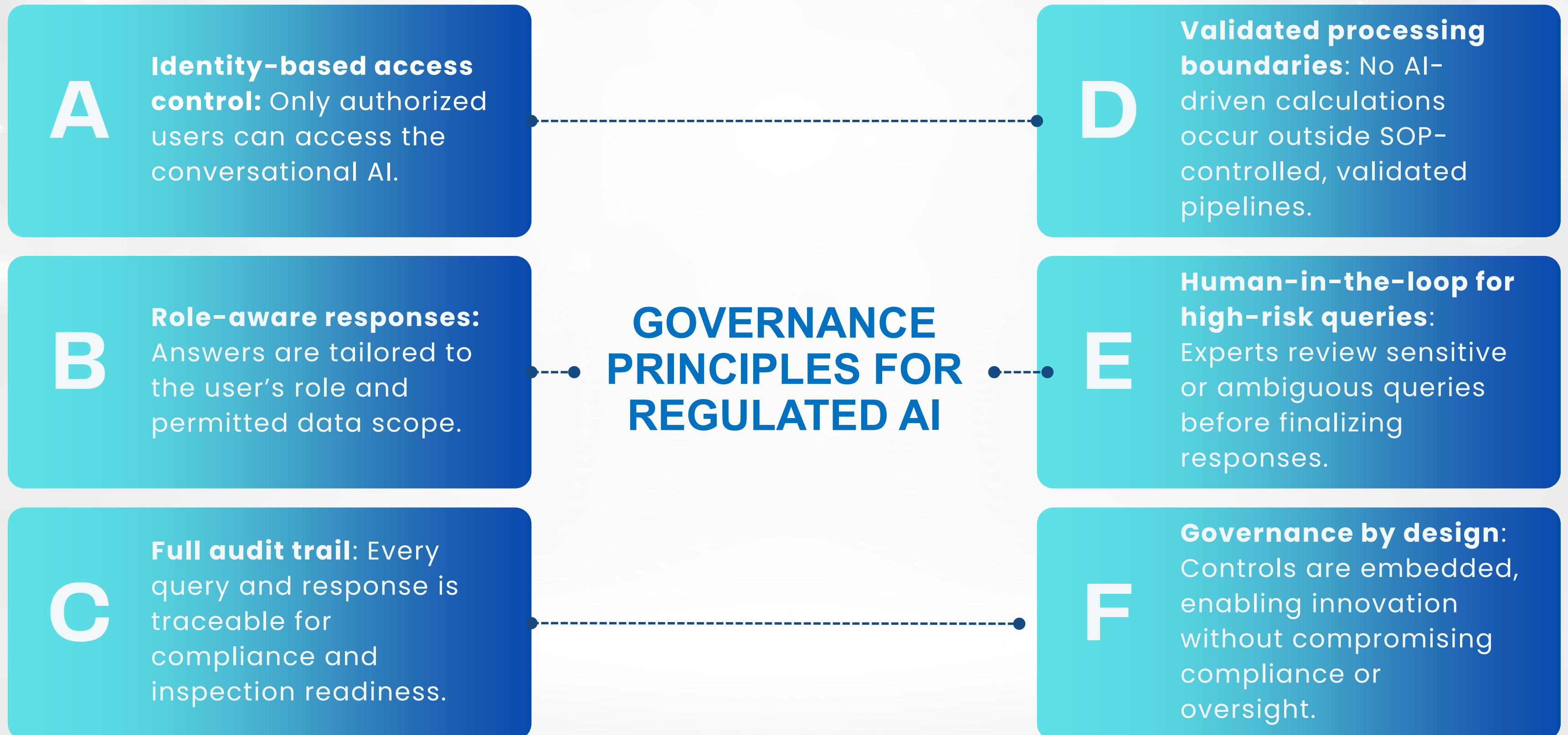
■ MODEL

Smaller, domain-specific models are preferred over generic LLMs.

■ SCOPE

Clear scope boundaries ensure predictable, explainable behavior.

A BALANCED
PERSPECTIVE





KEY LEARNINGS

1

Improved Query Resolution Speed

Faster query resolution in pilots.

2

Conversational Access Benefits

Simpler access increased adoption.

3

Challenges with Semantic Mismatches

Terminology gaps reduced accuracy.

4

Importance of Data Freshness

Outdated data risk reliability

FUTURE ENHANCEMENTS

DYNAMIC KNOWLEDGE UPDATES

Will enable AI to adapt to evolving regulatory guidance through dynamic knowledge updates.

WORKFLOW INTEGRATION

Deeper workflow integration will support submission processes, streamlining regulatory and research tasks

ADVANCED ANALYTICAL INSIGHTS

Will provide longitudinal and cross-study insights, enhancing research depth and accuracy.





THANK YOU

ANY QUESTIONS?

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