

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

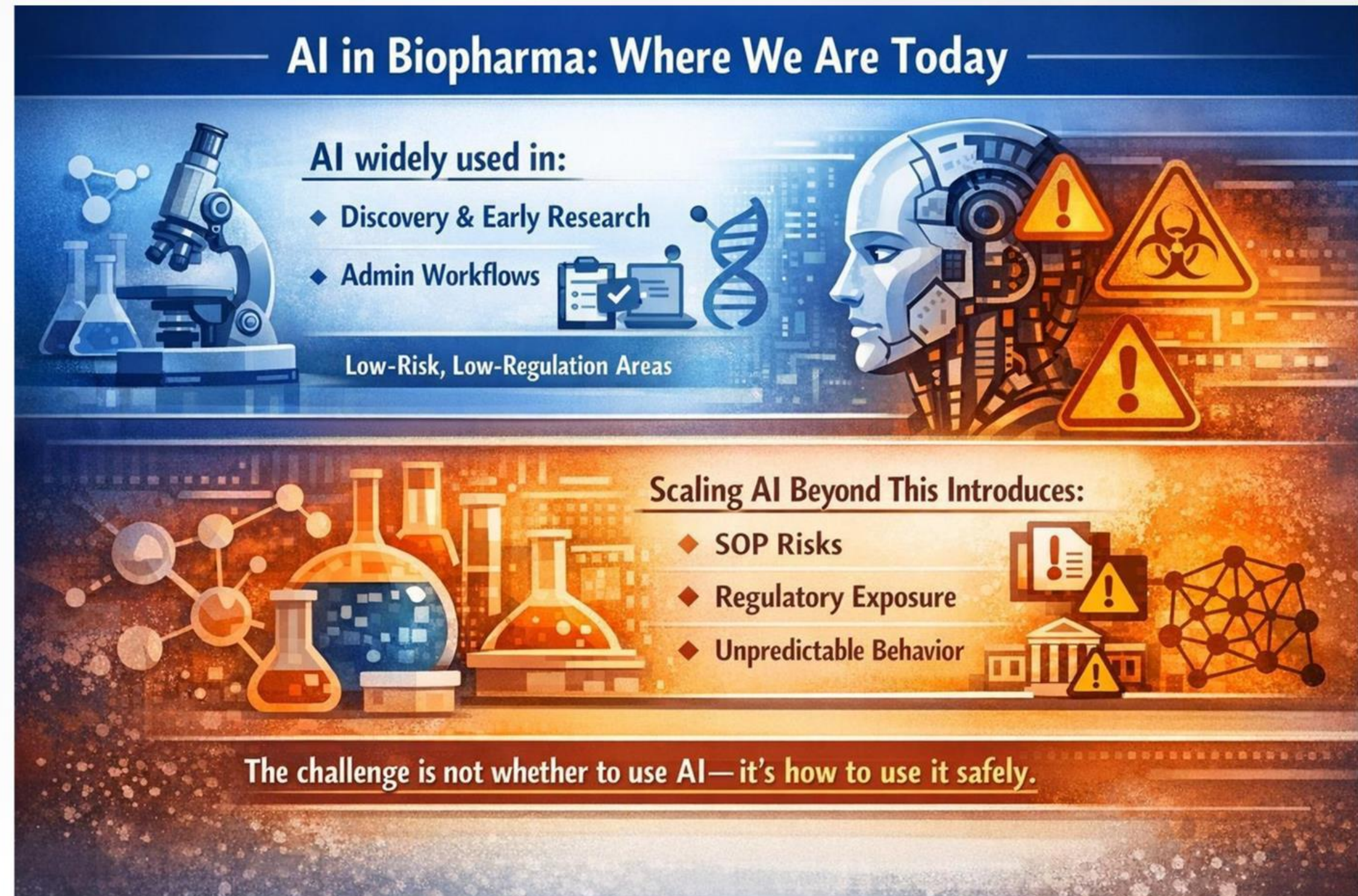
08

Future Enhancement

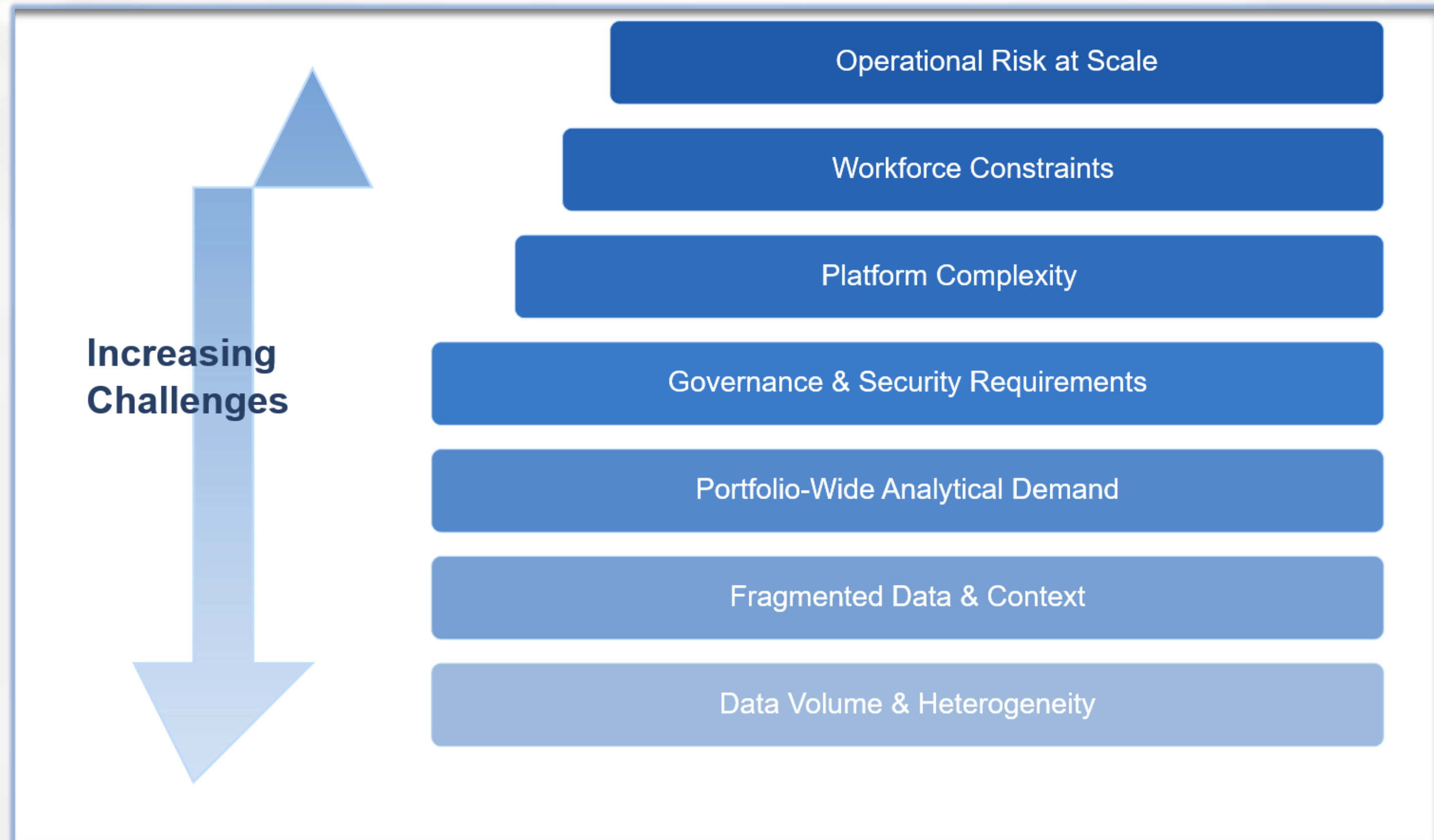
AGENDA

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



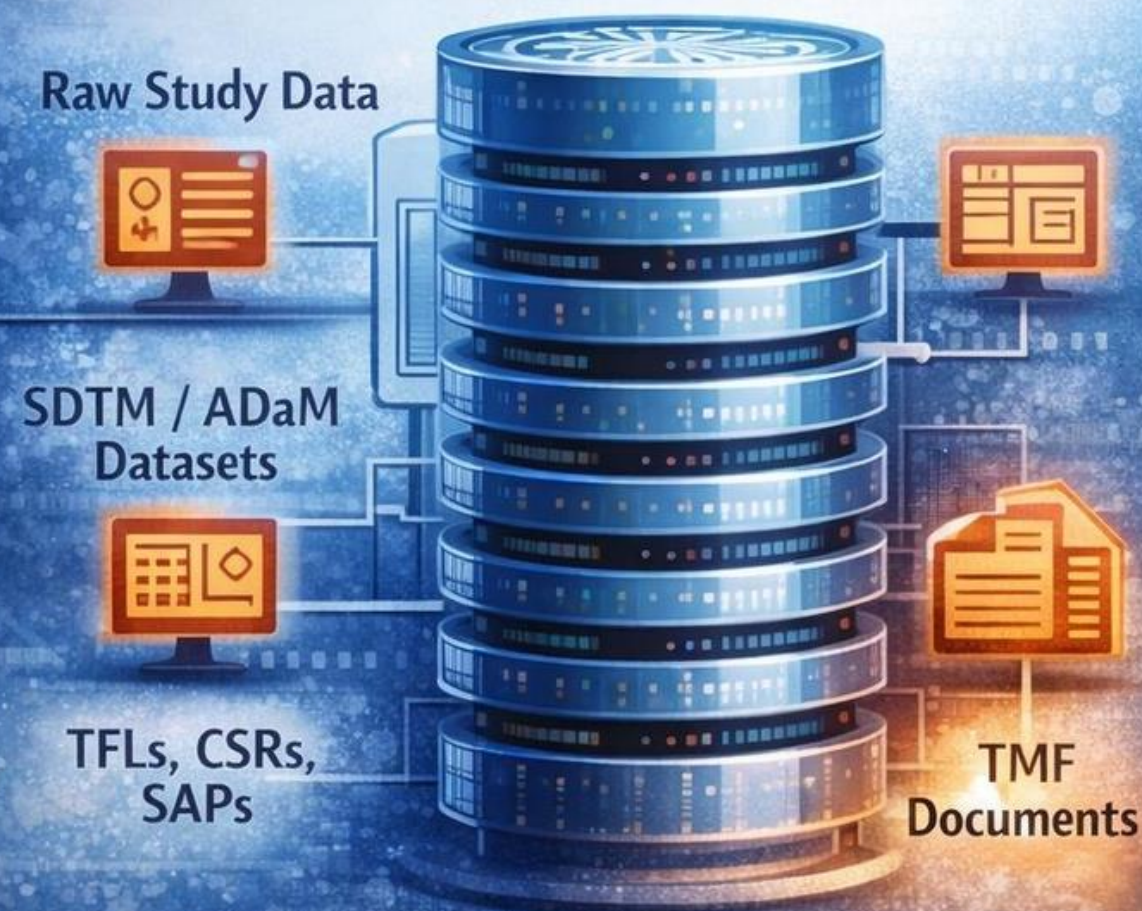
CORE ACCESS CHALLENGES



STUDY DATA ACCESS CHALLENGES

The Reality Inside Pharma Organizations

Huge Centralized Repositories Exist



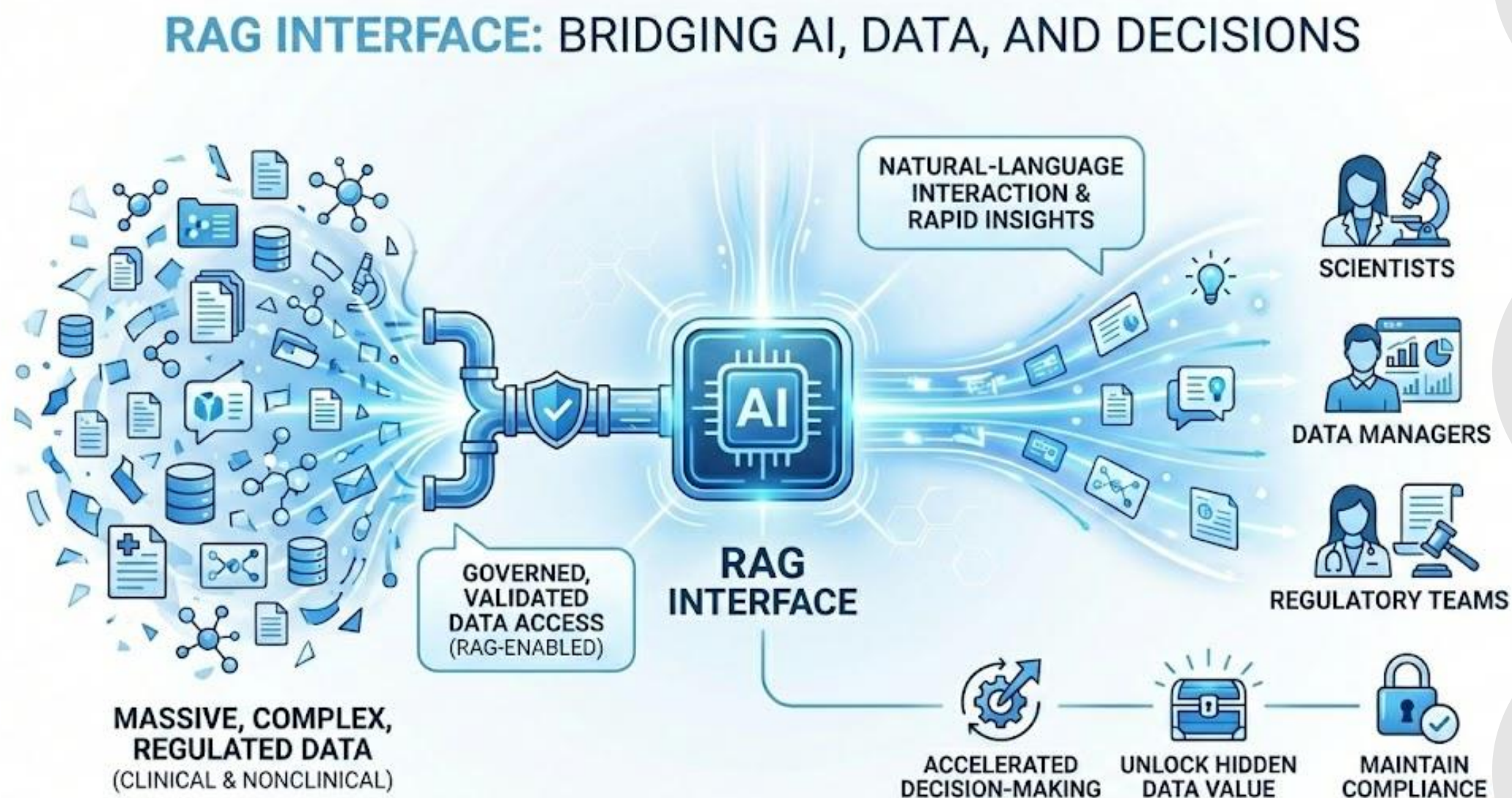
But Data Is Locked Behind:



Result:  High investment, low usability.

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

WHY IT MATTERS?



1

Delays in insight slow down critical development decisions

2

Limited access reduces the value of expensive clinical data

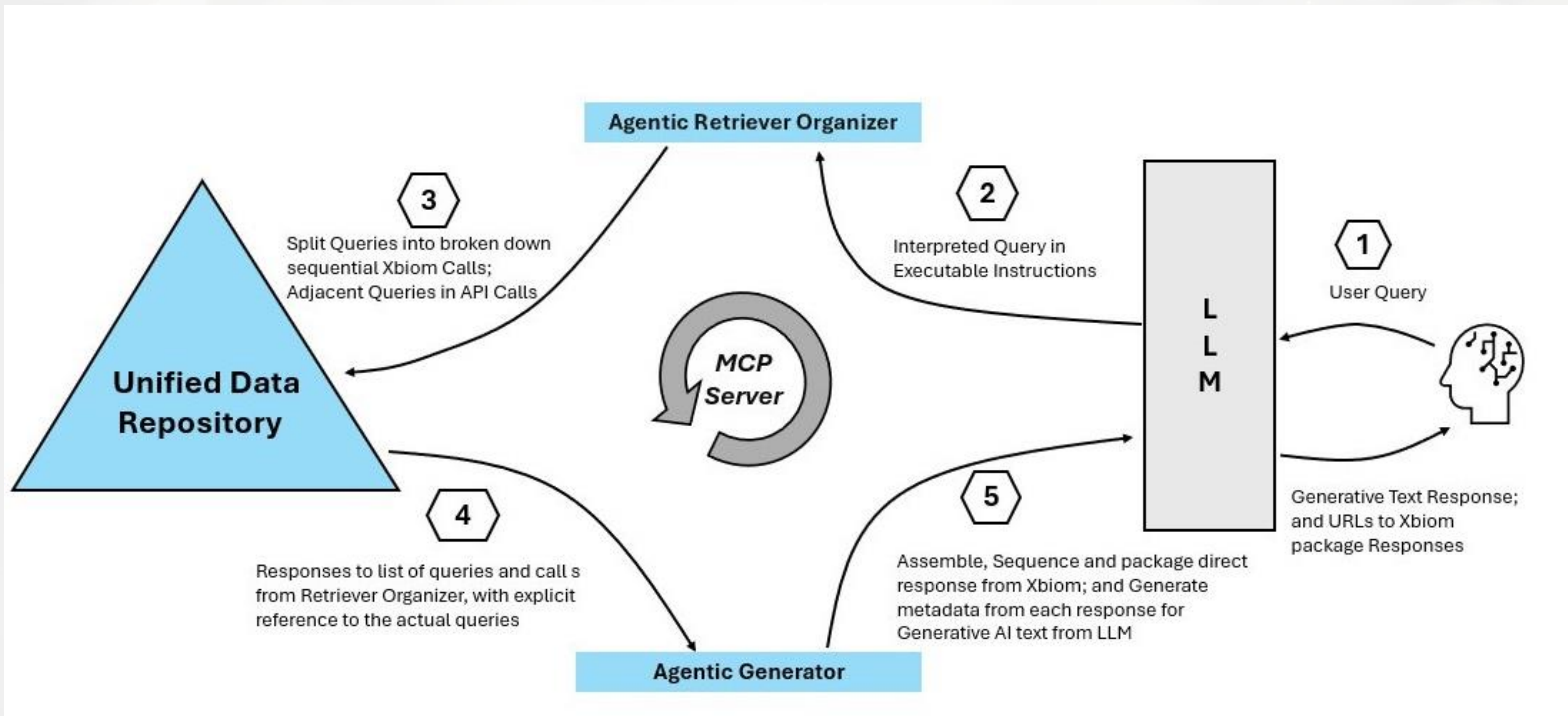
3

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

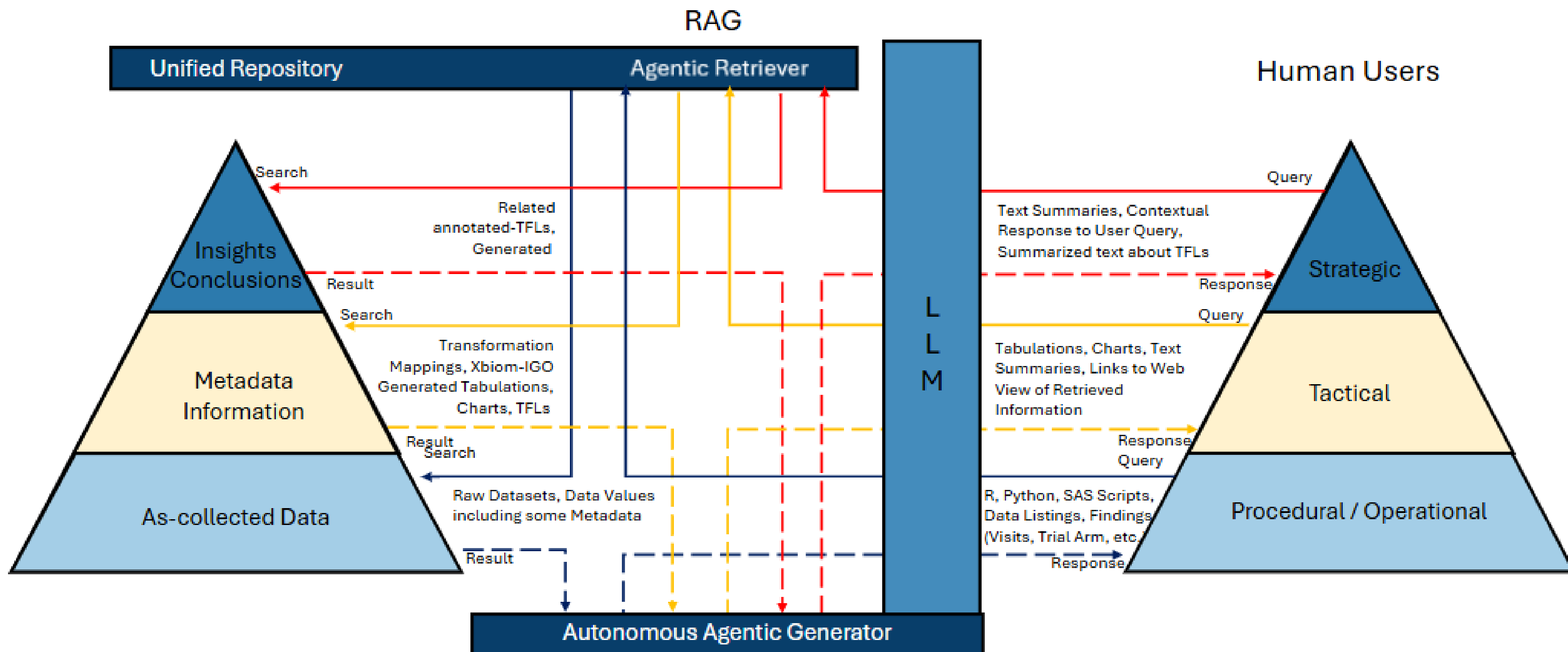
CORE COMPONENTS



VISION: CONVERSATIONAL RAG FOR BIOPHARMA



RAG: THREE-LAYER ARCHITECTURE

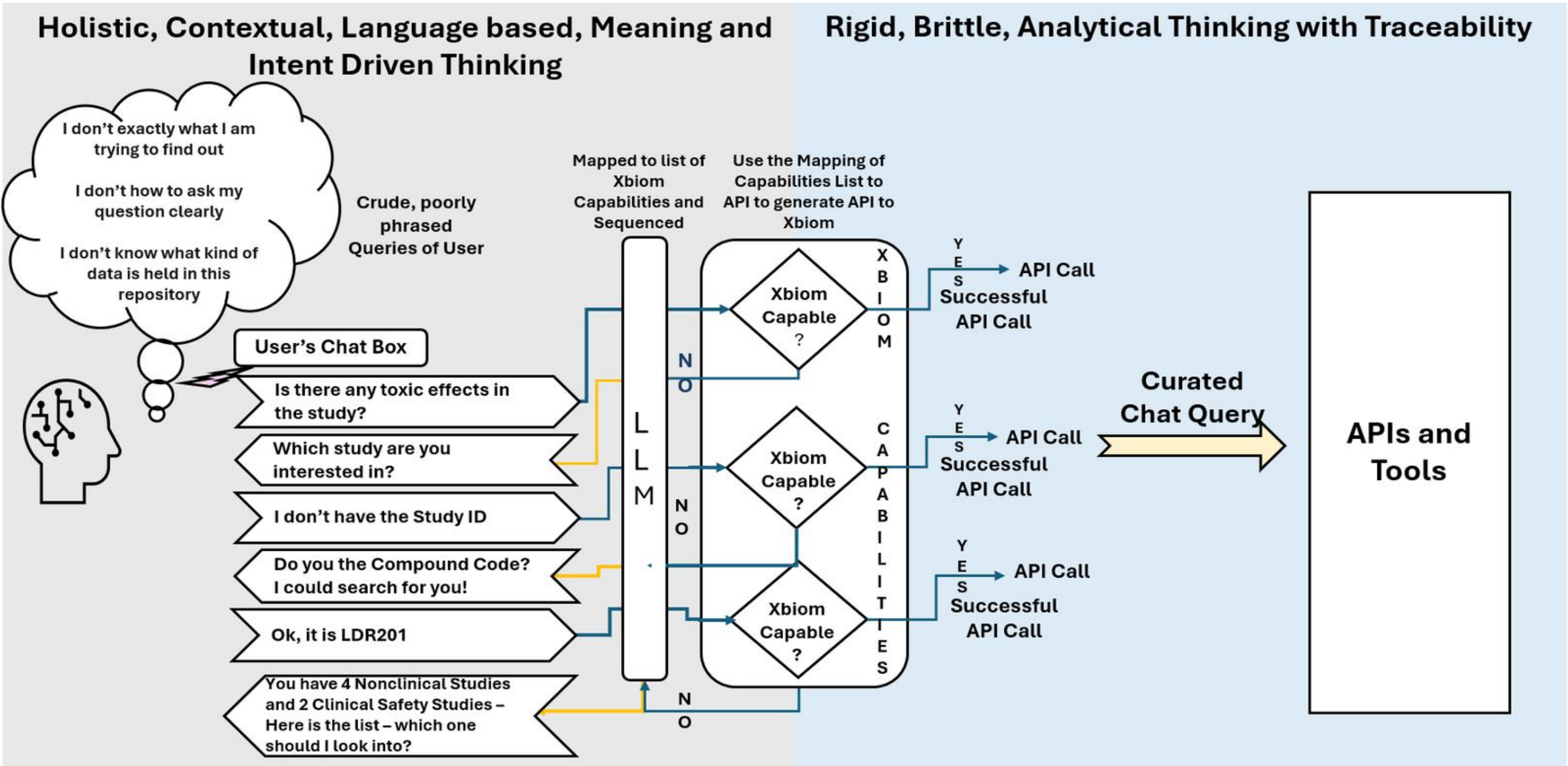


HIGH LEVEL ARCHITECTURE



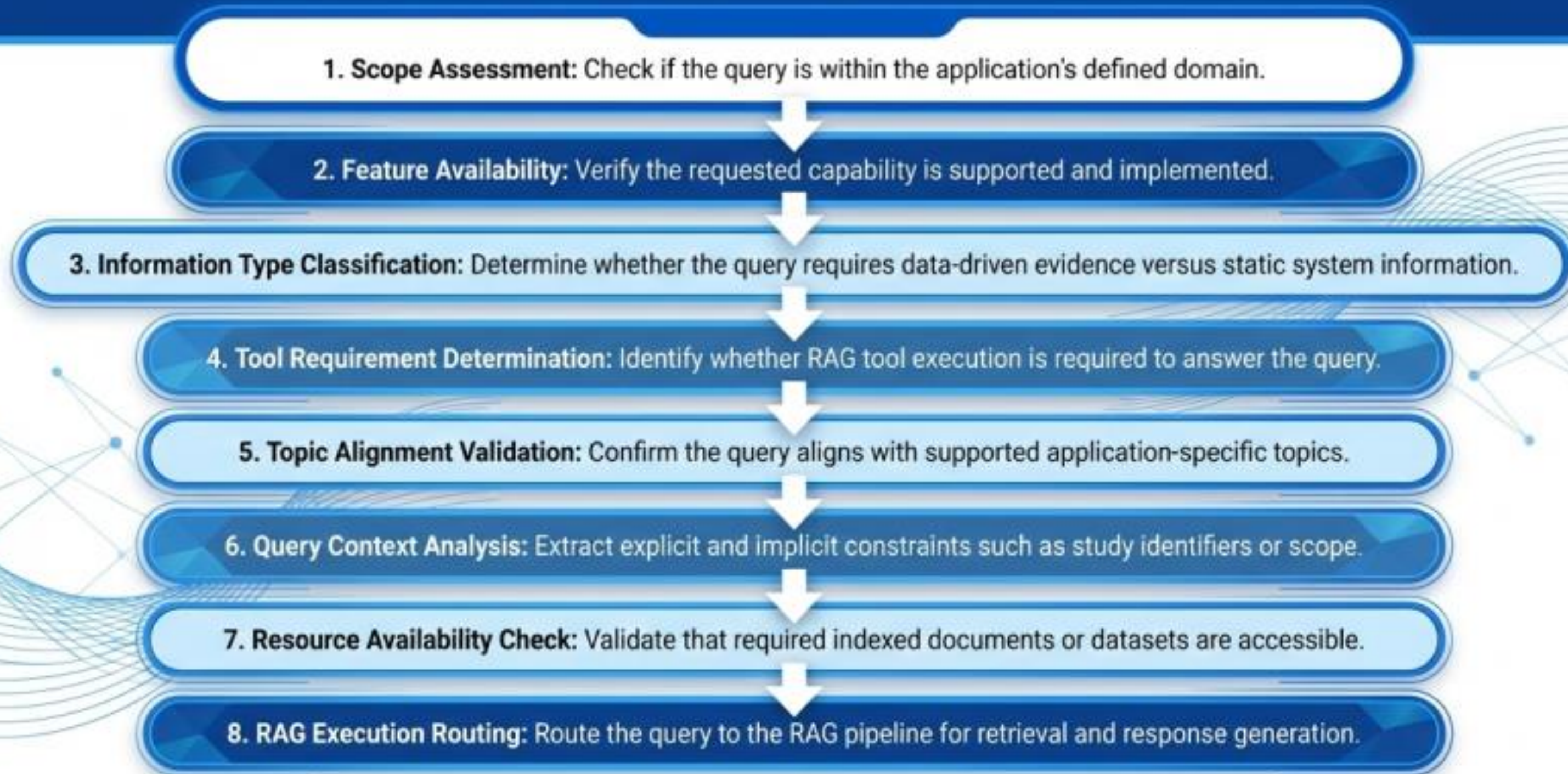
The system ensures AI-driven answers are always grounded in validated, governed data, preserving compliance at every step.

DUAL MODE QUERY PROCESSING



DECISION LOGIC FLOW

The system employs intelligent routing logic with multiple decision nodes:



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.

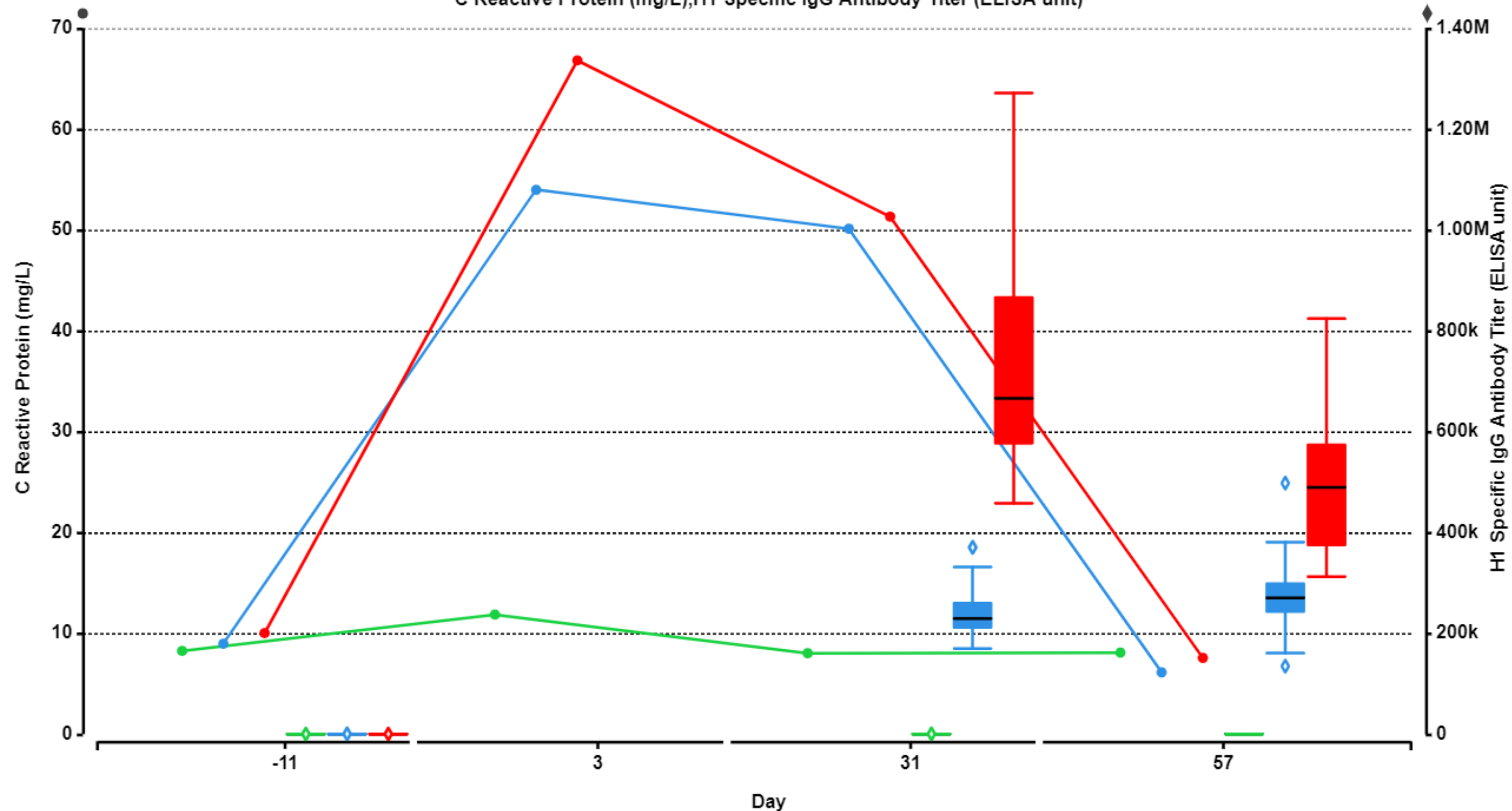
Usable URLs:

• [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)



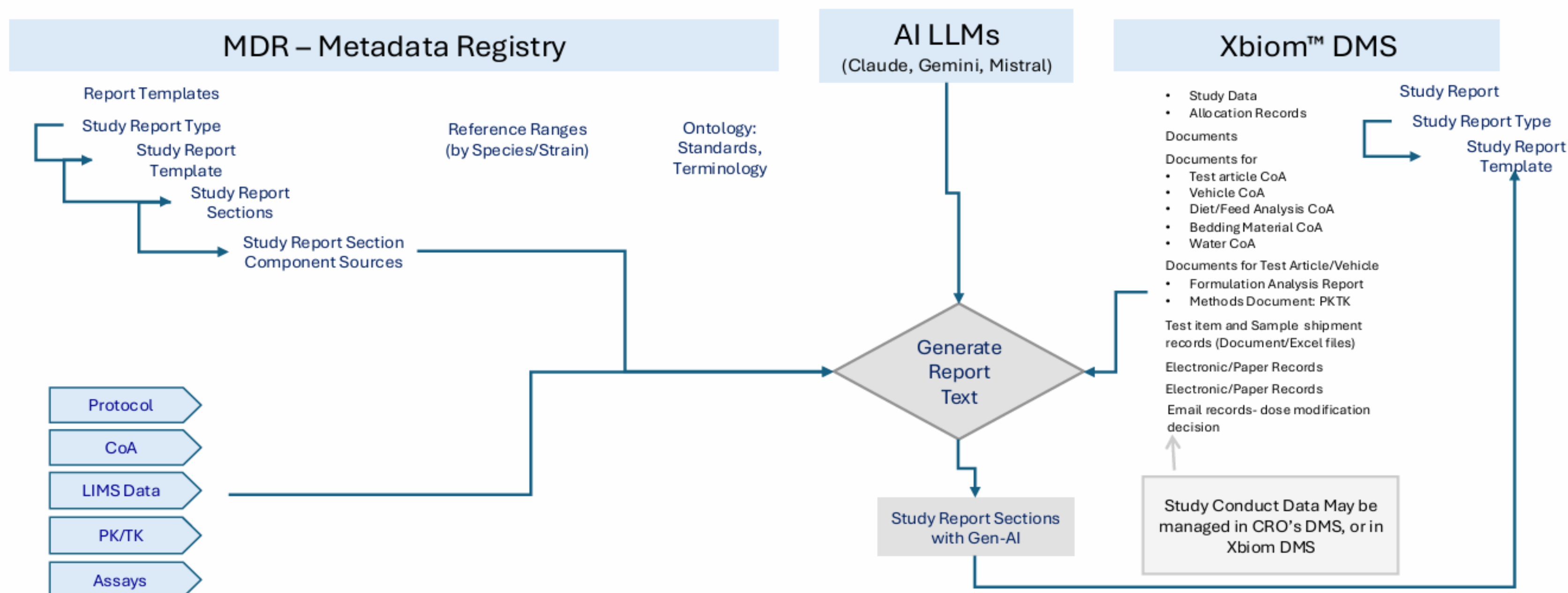
Test Name

- C Reactive Protein (Serum) (mg/L)
- ◆ H1 Specific IgG Antibody Titer (Serum) (ELISA unit)

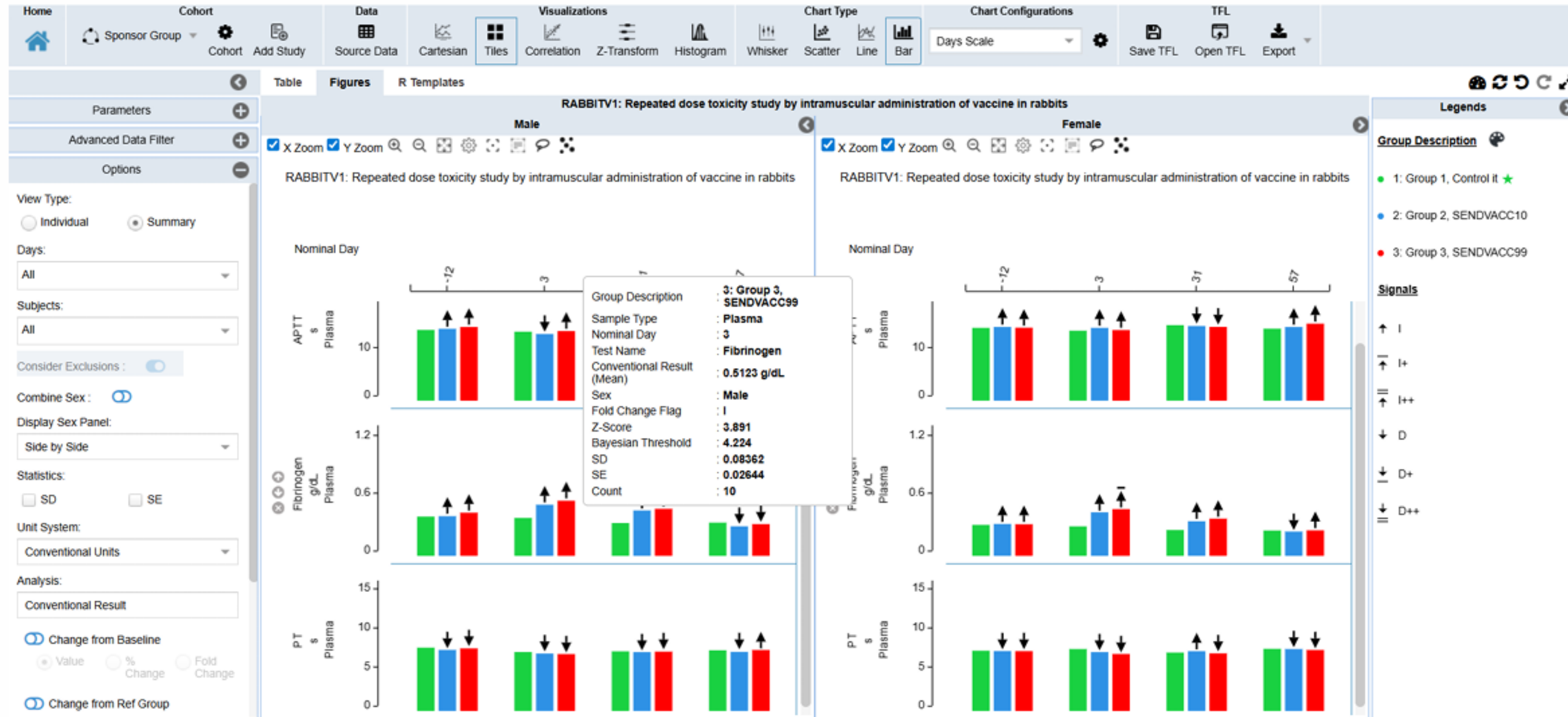
GRPDESC_custom

- 1: Group 1, Control
- 2: Group 2, VAC10
- 3: Group 3, VAC99

Management of Report Templates & Study Report Section Generation and Assembly



Computed Signals



Report Section Generation from Results with AI

3

Select Endpoints

Search

Q

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

Study Conclusion

Coagulation

Study Results

Save to Study Report

Coagulation

AI MODEL:
Anthropic Claude 3.7

Arial

B I U T⁺ T⁻ T₁ T₂ T₃ T₄ T₅ T₆ T₇ T₈ T₉ T₁₀ T₁₁ T₁₂ T₁₃ T₁₄ T₁₅ T₁₆ T₁₇ T₁₈ T₁₉ T₂₀ T₂₁ T₂₂ T₂₃ T₂₄ T₂₅ T₂₆ T₂₇ T₂₈ T₂₉ T₃₀ T₃₁ T₃₂ T₃₃ T₃₄ T₃₅ T₃₆ T₃₇ T₃₈ T₃₉ T₄₀ T₄₁ T₄₂ T₄₃ T₄₄ T₄₅ T₄₆ T₄₇ T₄₈ T₄₉ T₅₀ T₅₁ T₅₂ T₅₃ T₅₄ T₅₅ T₅₆ T₅₇ T₅₈ T₅₉ T₆₀ T₆₁ T₆₂ T₆₃ T₆₄ T₆₅ T₆₆ T₆₇ T₆₈ T₆₉ T₇₀ T₇₁ T₇₂ T₇₃ T₇₄ T₇₅ T₇₆ T₇₇ T₇₈ T₇₉ T₈₀ T₈₁ T₈₂ T₈₃ T₈₄ T₈₅ T₈₆ T₈₇ T₈₈ T₈₉ T₉₀ T₉₁ T₉₂ T₉₃ T₉₄ T₉₅ T₉₆ T₉₇ T₉₈ T₉₉ T₁₀₀ T₁₀₁ T₁₀₂ T₁₀₃ T₁₀₄ T₁₀₅ T₁₀₆ T₁₀₇ T₁₀₈ T₁₀₉ T₁₁₀ T₁₁₁ T₁₁₂ T₁₁₃ T₁₁₄ T₁₁₅ T₁₁₆ T₁₁₇ T₁₁₈ T₁₁₉ T₁₂₀ T₁₂₁ T₁₂₂ T₁₂₃ T₁₂₄ T₁₂₅ T₁₂₆ T₁₂₇ T₁₂₈ T₁₂₉ T₁₃₀ T₁₃₁ T₁₃₂ T₁₃₃ T₁₃₄ T₁₃₅ T₁₃₆ T₁₃₇ T₁₃₈ T₁₃₉ T₁₄₀ T₁₄₁ T₁₄₂ T₁₄₃ T₁₄₄ T₁₄₅ T₁₄₆ T₁₄₇ T₁₄₈ T₁₄₉ T₁₅₀ T₁₅₁ T₁₅₂ T₁₅₃ T₁₅₄ T₁₅₅ T₁₅₆ T₁₅₇ T₁₅₈ T₁₅₉ T₁₆₀ T₁₆₁ T₁₆₂ T₁₆₃ T₁₆₄ T₁₆₅ T₁₆₆ T₁₆₇ T₁₆₈ T₁₆₉ T₁₇₀ T₁₇₁ T₁₇₂ T₁₇₃ T₁₇₄ T₁₇₅ T₁₇₆ T₁₇₇ T₁₇₈ T₁₇₉ T₁₈₀ T₁₈₁ T₁₈₂ T₁₈₃ T₁₈₄ T₁₈₅ T₁₈₆ T₁₈₇ T₁₈₈ T₁₈₉ T₁₉₀ T₁₉₁ T₁₉₂ T₁₉₃ T₁₉₄ T₁₉₅ T₁₉₆ T₁₉₇ T₁₉₈ T₁₉₉ T₂₀₀ T₂₀₁ T₂₀₂ T₂₀₃ T₂₀₄ T₂₀₅ T₂₀₆ T₂₀₇ T₂₀₈ T₂₀₉ T₂₁₀ T₂₁₁ T₂₁₂ T₂₁₃ T₂₁₄ T₂₁₅ T₂₁₆ T₂₁₇ T₂₁₈ T₂₁₉ T₂₂₀ T₂₂₁ T₂₂₂ T₂₂₃ T₂₂₄ T₂₂₅ T₂₂₆ T₂₂₇ T₂₂₈ T₂₂₉ T₂₃₀ T₂₃₁ T₂₃₂ T₂₃₃ T₂₃₄ T₂₃₅ T₂₃₆ T₂₃₇ T₂₃₈ T₂₃₉ T₂₄₀ T₂₄₁ T₂₄₂ T₂₄₃ T₂₄₄ T₂₄₅ T₂₄₆ T₂₄₇ T₂₄₈ T₂₄₉ T₂₅₀ T₂₅₁ T₂₅₂ T₂₅₃ T₂₅₄ T₂₅₅ T₂₅₆ T₂₅₇ T₂₅₈ T₂₅₉ T₂₆₀ T₂₆₁ T₂₆₂ T₂₆₃ T₂₆₄ T₂₆₅ T₂₆₆ T₂₆₇ T₂₆₈ T₂₆₉ T₂₇₀ T₂₇₁ T₂₇₂ T₂₇₃ T₂₇₄ T₂₇₅ T₂₇₆ T₂₇₇ T₂₇₈ T₂₇₉ T₂₈₀ T₂₈₁ T₂₈₂ T₂₈₃ T₂₈₄ T₂₈₅ T₂₈₆ T₂₈₇ T₂₈₈ T₂₈₉ T₂₉₀ T₂₉₁ T₂₉₂ T₂₉₃ T₂₉₄ T₂₉₅ T₂₉₆ T₂₉₇ T₂₉₈ T₂₉₉ T₃₀₀ T₃₀₁ T₃₀₂ T₃₀₃ T₃₀₄ T₃₀₅ T₃₀₆ T₃₀₇ T₃₀₈ T₃₀₉ T₃₁₀ T₃₁₁ T₃₁₂ T₃₁₃ T₃₁₄ T₃₁₅ T₃₁₆ T₃₁₇ T₃₁₈ T₃₁₉ T₃₂₀ T₃₂₁ T₃₂₂ T₃₂₃ T₃₂₄ T₃₂₅ T₃₂₆ T₃₂₇ T₃₂₈ T₃₂₉ T₃₃₀ T₃₃₁ T₃₃₂ T₃₃₃ T₃₃₄ T₃₃₅ T₃₃₆ T₃₃₇ T₃₃₈ T₃₃₉ T₃₄₀ T₃₄₁ T₃₄₂ T₃₄₃ T₃₄₄ T₃₄₅ T₃₄₆ T₃₄₇ T₃₄₈ T₃₄₉ T₃₅₀ T₃₅₁ T₃₅₂ T₃₅₃ T₃₅₄ T₃₅₅ T₃₅₆ T₃₅₇ T₃₅₈ T₃₅₉ T₃₆₀ T₃₆₁ T₃₆₂ T₃₆₃ T₃₆₄ T₃₆₅ T₃₆₆ T₃₆₇ T₃₆₈ T₃₆₉ T₃₇₀ T₃₇₁ T₃₇₂ T₃₇₃ T₃₇₄ T₃₇₅ T₃₇₆ T₃₇₇ T₃₇₈ T₃₇₉ T₃₈₀ T₃₈₁ T₃₈₂ T₃₈₃ T₃₈₄ T₃₈₅ T₃₈₆ T₃₈₇ T₃₈₈ T₃₈₉ T₃₉₀

A BALANCED PERSPECTIVE

PREVENTING HALLUCINATION AND RISK

■ DATA

AI answers only from retrieved, validated data.

■ INFERENCE

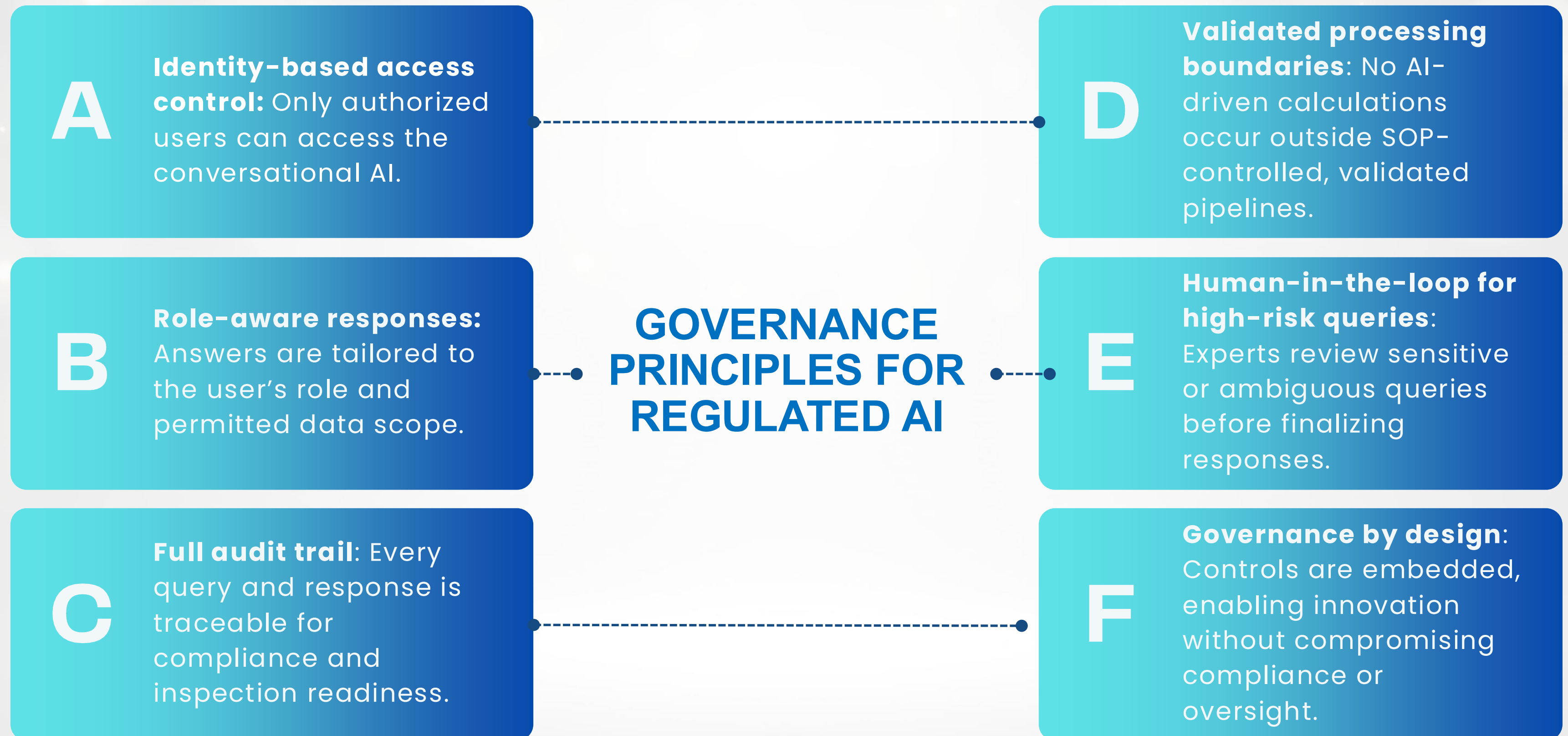
Unsupported inferences or guesses are not allowed.

■ MODEL

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

■ SCOPE

Clear scope boundaries ensure predictable, explainable behavior.





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?

CONTACT INFORMATION

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