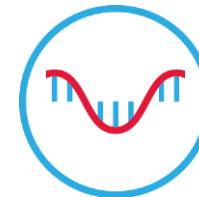


AI Agents for Accelerating Data Analysis in Clinical Development

PharmaSUG SDE – Boston, Oct 15th 2025

Weijie Zhang, Ph.D., Zoe Wu, and Xing Chen, Sc.D.



The Way We work



PEOPLE

People

- Statisticians , Data Scientist , Data Engineer
- Builder mindset
- Cross-functional domain experts



PROCESS

Process

- TLF and cross study data needs
- Ongoing statistical needs & agile workstreams
- Ad-hoc exploratory analyses
- Translational analyses



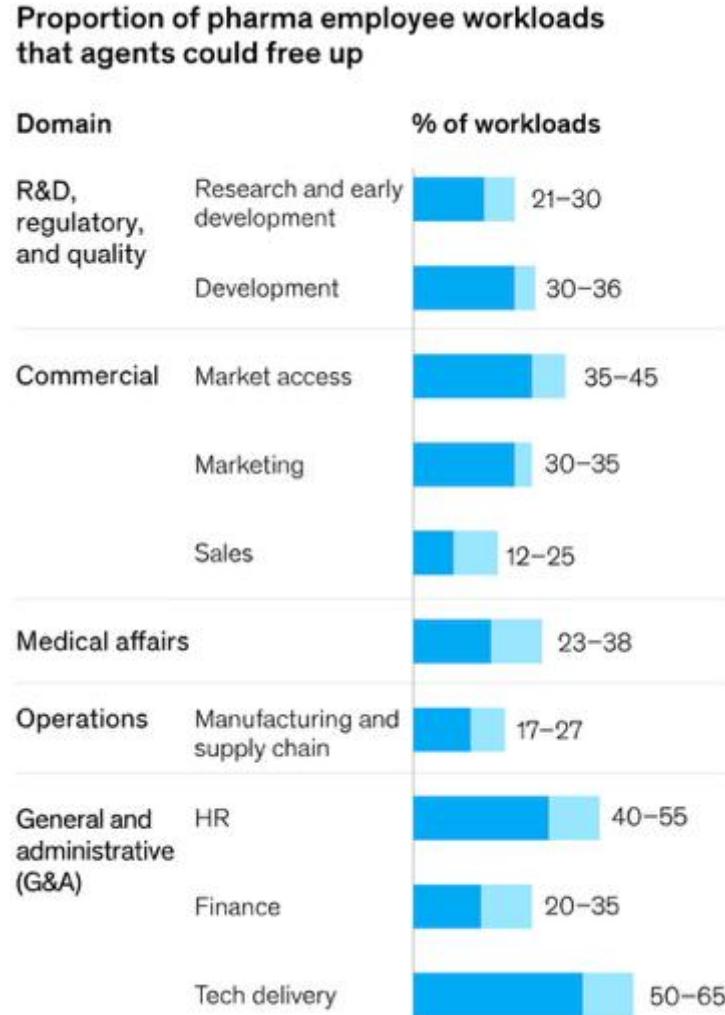
TECHNOLOGY

Technology

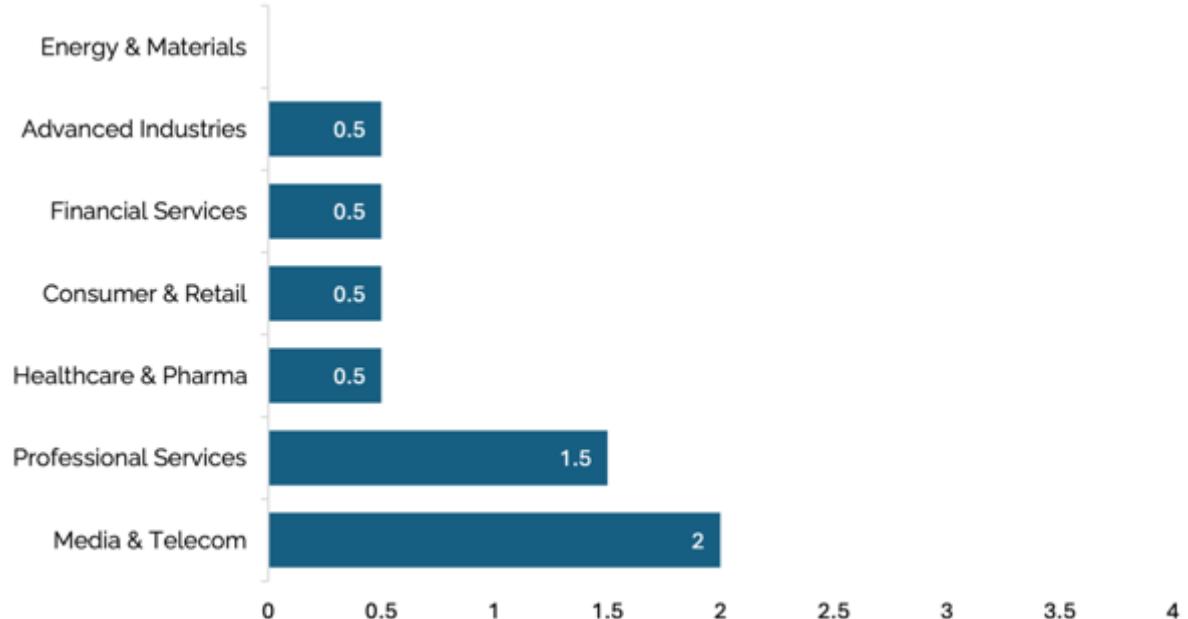
- R/Python
- ML/GenAI
- Cloud, Database
- APIs and Pipeline integration and automations

Agentic AI reshapes pharmaceutical industry

Potential benefits from AI agents:



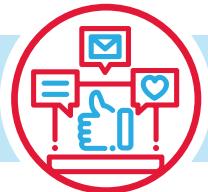
THE WRONG SIDE OF THE GENAI DIVIDE: HIGH ADOPTION, LOW TRANSFORMATION



Adopted from MIT NANDA: STATE of AI in Business 2025

Data from: McKinsey & Company

The AI Playbook—three major scenes of AI use in industry



Chatbots

Conversational Q&A applications. ChatGPT, Claude, Gemini, etc.

- Has become a staple item in everyday work.
- Suits diverse business settings and functions.
- Speeds up information sharing for specific tasks.



Copilots

Assistive tools embedded into workflows (e.g., Github Copilot, MS Copilot)

- Handles repetitive tasks.
- Helpful tool for programmers, statisticians, computational scientists, etc.



Agents

Autonomous systems that can plan, call APIs, and execute workflows end-to-end.

- Requires deep understanding of LLM frameworks.
- Scalable production-ready applications.
- Can automate traditionally complex and time-consuming repetitive tasks.

Use cases:

- Study protocol Q&A
- Meeting prep assist



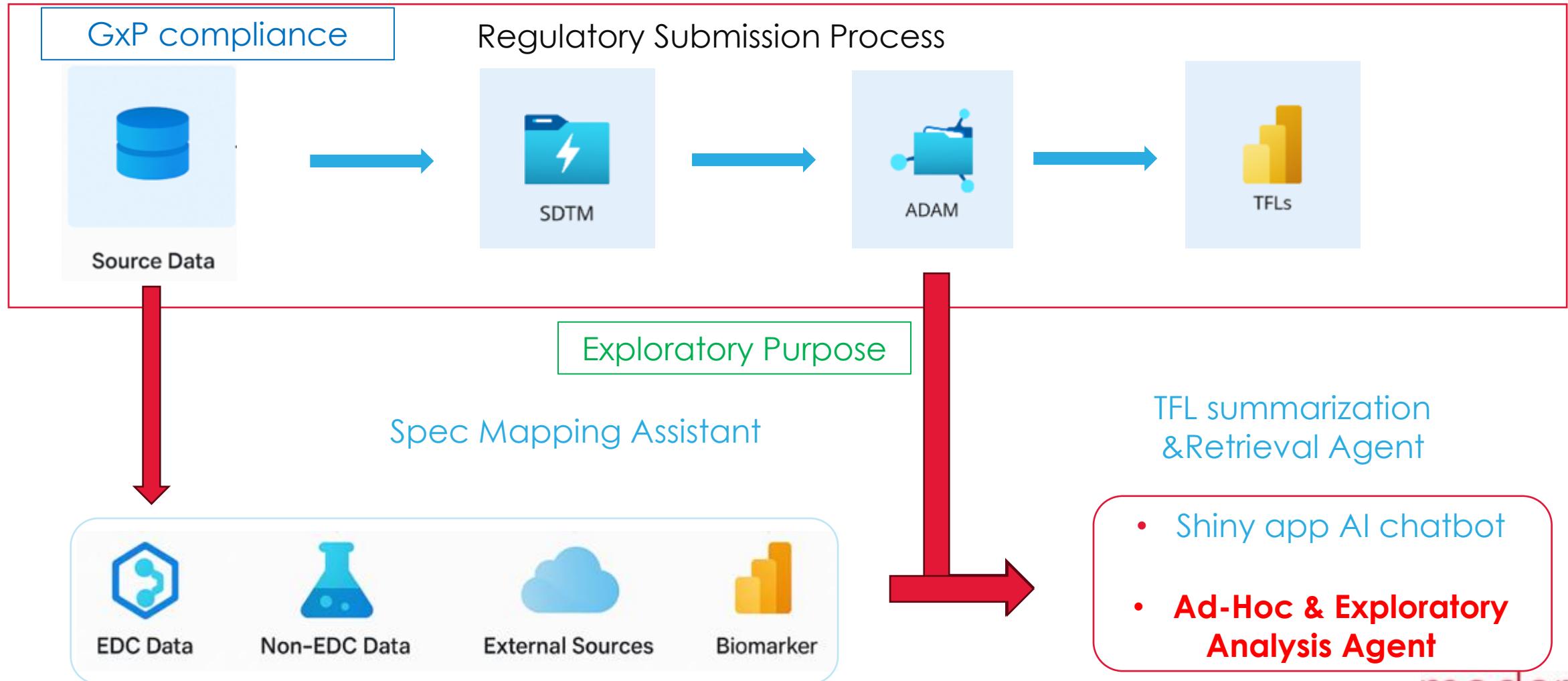
- Code autocompletion
- Github copilot PR review



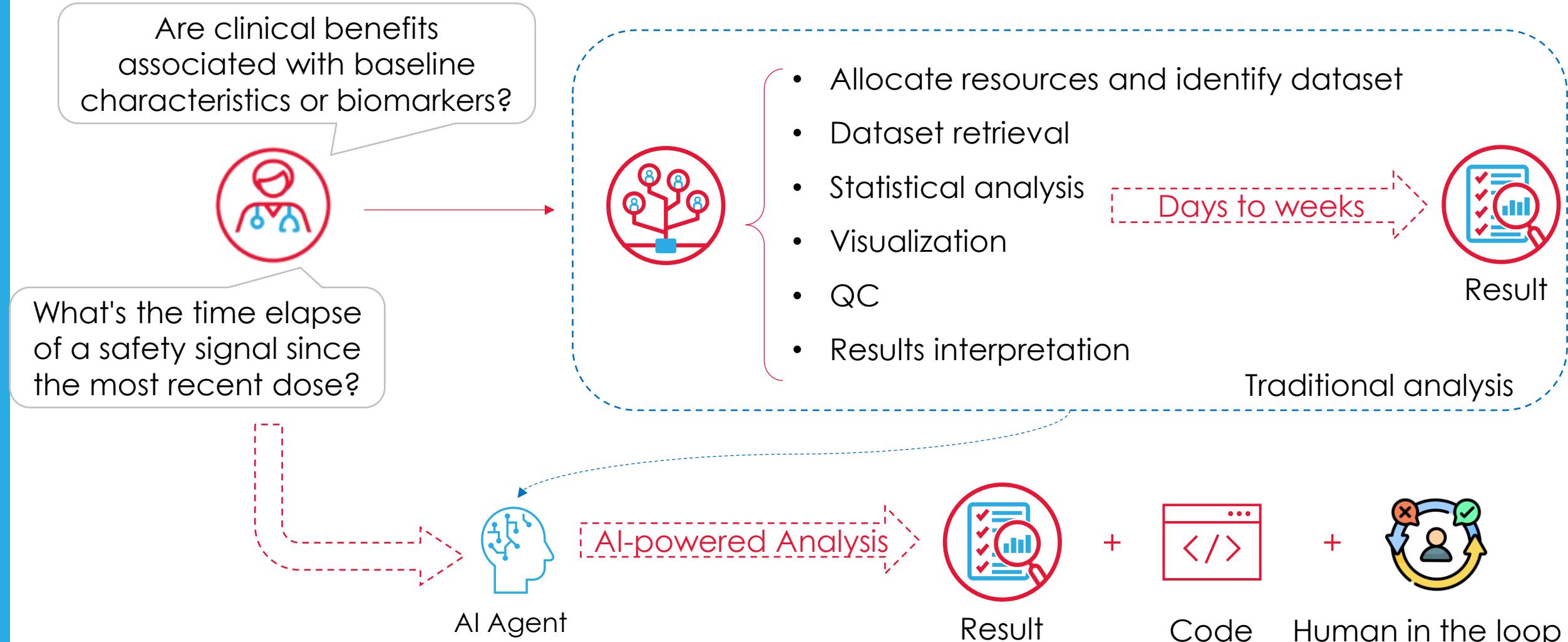
- Exploratory Analyses
- TFL generation streamline
- Compliance monitoring

A Data focused Journey of Exploring Added Business Values in Biometrics

Plan, Retrieve , Execute to Enable end-to-end statistical and analytical automation

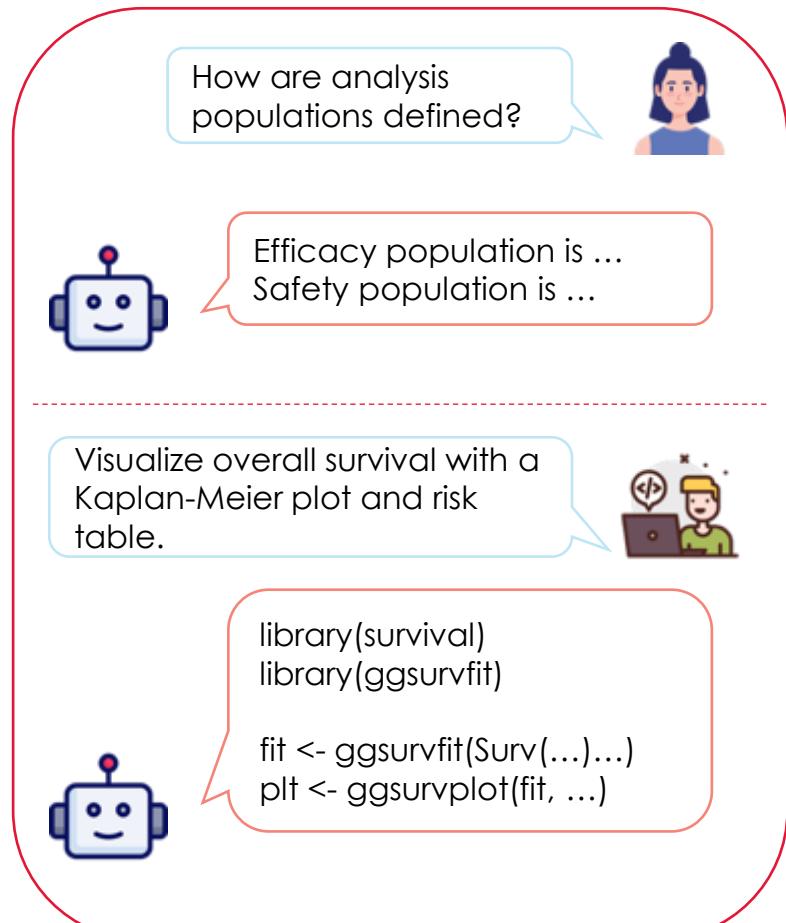


Clinical data is abundant, but insights are often delayed



AI has the potential **to drastically compress analysis timelines** and enable **faster, better decision-making**.

Smarter, faster clinical workflows with AI agents



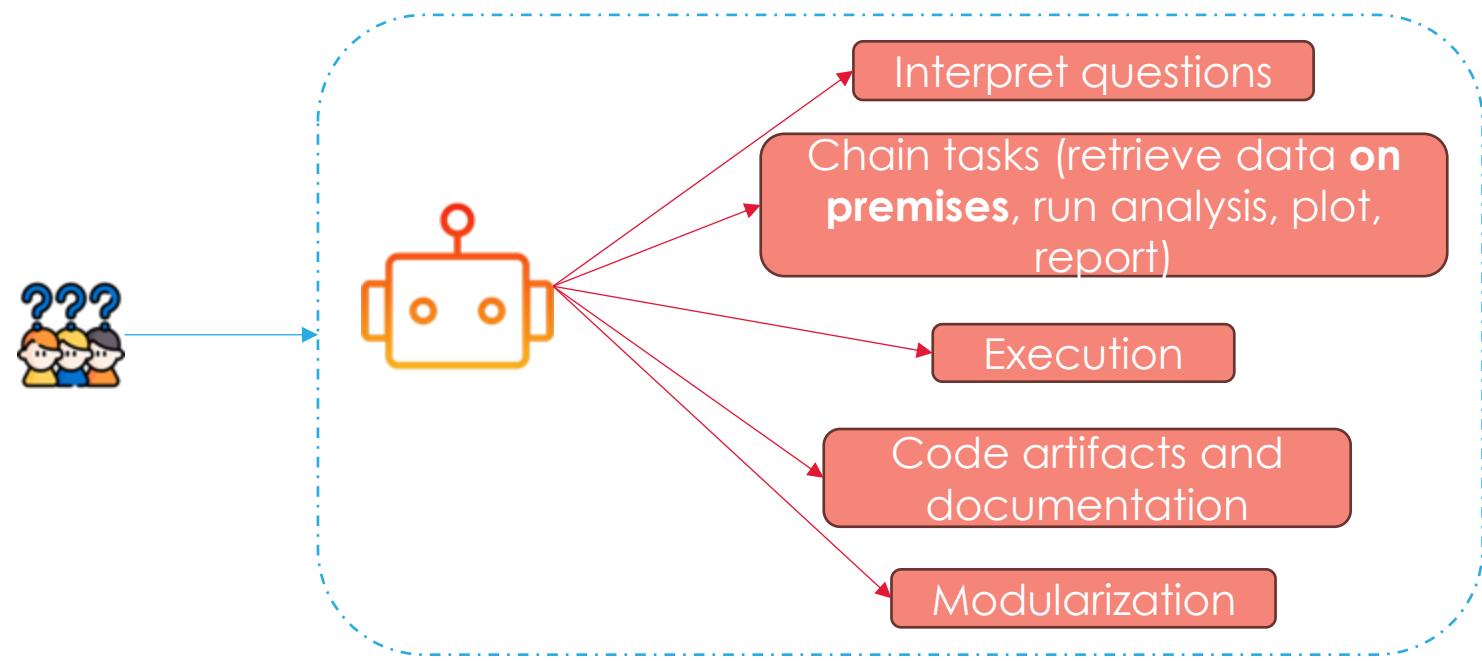
Isolated, embedded

+

human instructions and executions

AI Agents: autonomous systems that integrate and execute workflows

- Understands analysis requests in natural language
- Retrieves relevant datasets locally and runs scripts automatically
- Produces traceable outputs within minutes
- Modules and Adaptability



End-to-end pipelines in minutes

+

Human governance

moderna

AI agent to streamline data analysis: architecture overview



Database preparation

- Automated dataset annotation
- Database creation with semantic labels



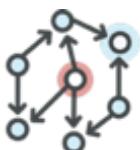
Multi-LLM orchestration

- Question interpretation & classification
- Database query and records retrieval
- Analysis & visualization
- Result interpretation



Integration with R/Python

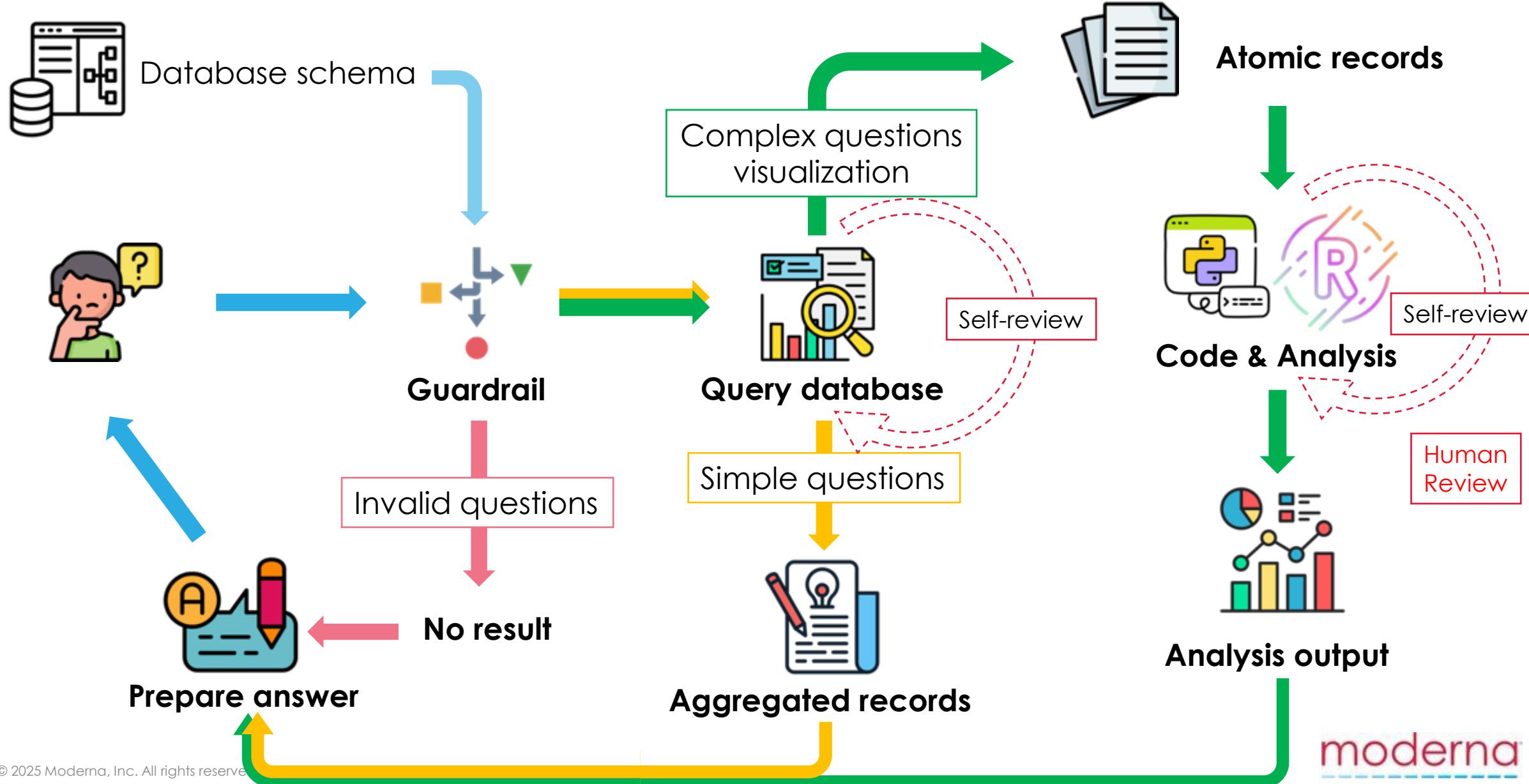
- Alignment with standard workflows
- Trackability & reproducibility



LangGraph + API Key

- Task chain and workflow definition
- Modularity for plug-and-play

AI agent can answer questions with varying complexity



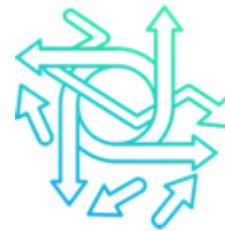
Accelerating clinical insights: from days to minutes

Q: In study X, is progression free survival associated with treatment and age group?

Days:



- ✓ Programmer
- ✓ Data analyst
- ✓ Biostatistician
- ✓ Clinical...



- ? Population flag
- ? Source data
- ? Statistical models
- ? Plot...

Minutes:



Demo

moderna

Demo

Clinical Data Analytical Tool (Internal Preview)

Piloted by *Statistical Innovations and Data Analytics*. This tool aims to assist clinical data analysts in generating database queries and performing data analyses using natural language prompts. It leverages a combination of LLMs, a graph-based workflow engine, and a clinical research database to facilitate efficient data exploration and analysis.

> How it works

> Tips

Select study:

mRNA-9999-Oncology-DEMO1 mRNA-9999-Oncology-DEMO2

For available fields, please refer to the interactive graph database schema to the right.

Analysis (if applicable) language:

Python

Good for exploratory analysis

R

Good for statistical modeling

Analysis code will be generated in the selected language.

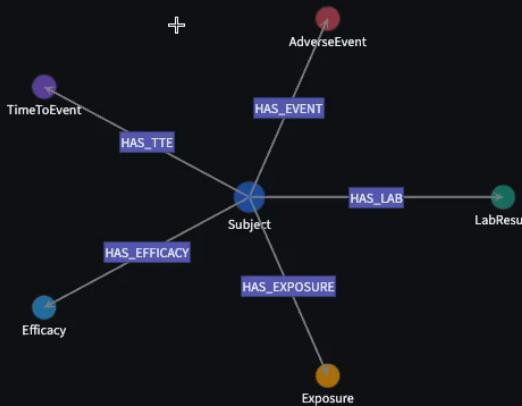
Start New Chat and Clear History

Chat History

Ask me something about the study...

Context information:

Graph Database Schema for Clinical Data



Future work

Scalability



- Improve automation in database preparation for various source data
- Workflow optimization for robust and reproducible analysis
- Unit test, engineer optimization with Digital team

Compliance



- Data governance, compliance, Validation and Audit Tails
- Standardization of code adherent to company policy
- Human in the loop on every steps

Adaptability



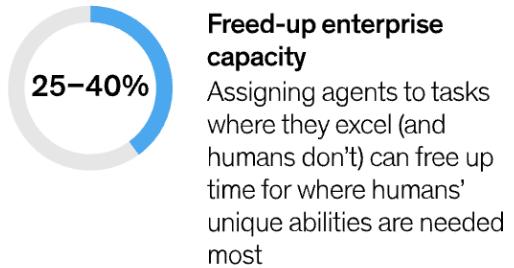
- Continue modularization to expand adaptability
- Integrating latest tools and approaches e.g. MCP , Claude code SDK
- Feedbacks from Users and RL/Fine Tune with local model

Thank you

Work will transform



Roles will change

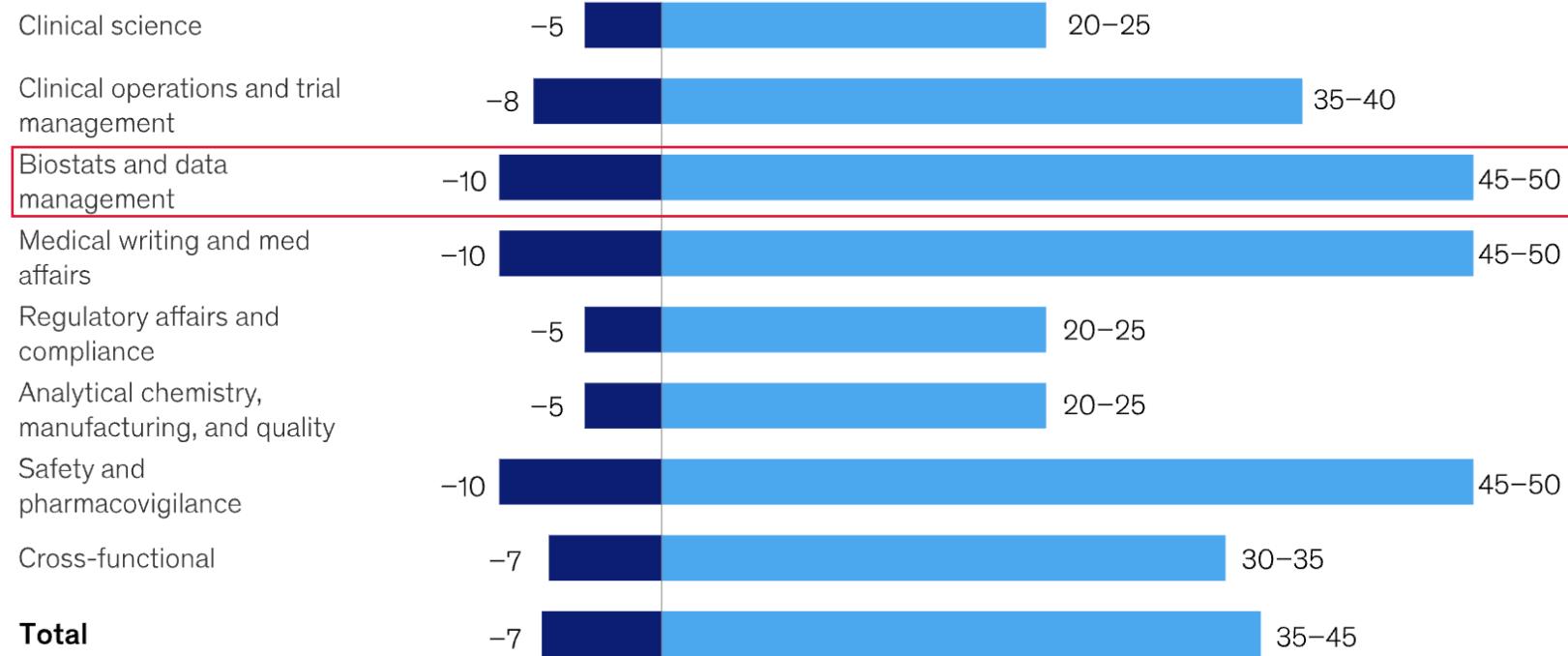


Health data science draw benefits from agent deployment

Work hours shifted by agentic workforce, % of function capacity

■ Incremental time spent on agents ■ Time savings from agents

Function



CDISC standardization

Statistical programming & analysis

TFL reporting

Data integration & management

...