

Ennov AI Roadmap Introduction

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10:30am - 11:30am	The Confluence of Change - The Strategic and Tactical Impact of AI Steve Gens
11:30am - 12:00pm	Ennov AI Roadmap Introduction François Guély
12:00pm - 1:30pm	Lunch Break



Agenda

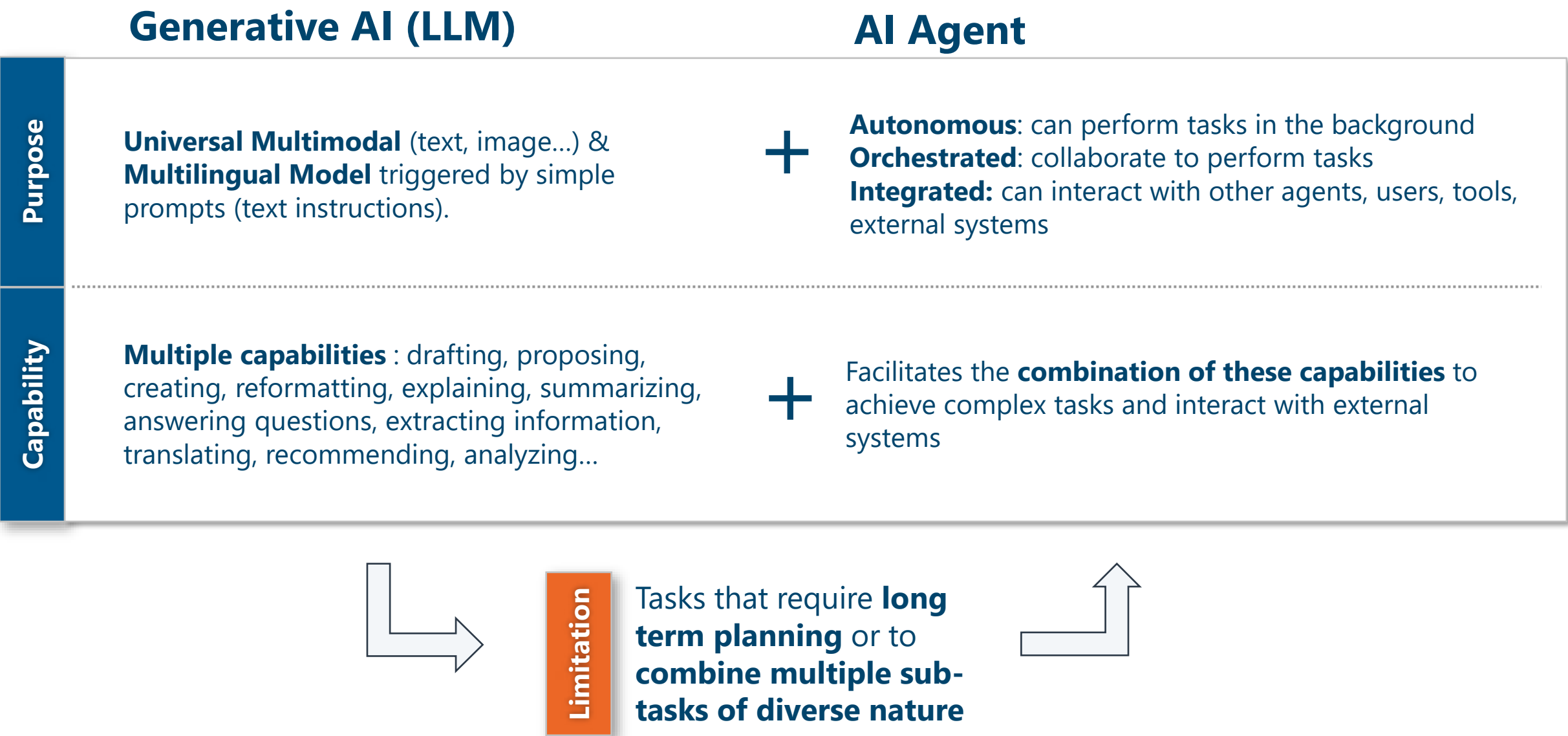
1 Agentic AI

2 Ennov's Agentic AI Vision

3 Ennov AI architecture

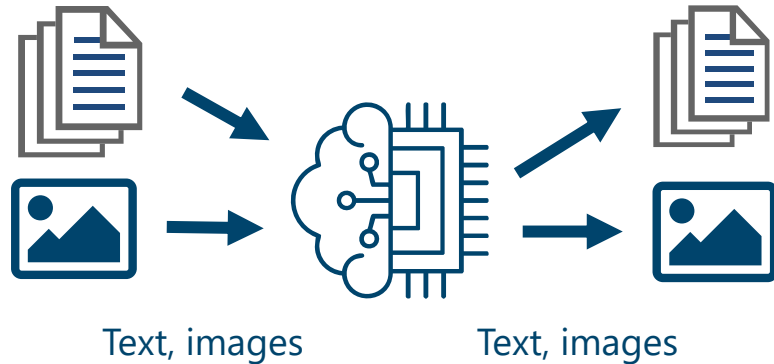
4 AI Roadmap

What Is Agentic AI?



LLMs V.S. AI Agents

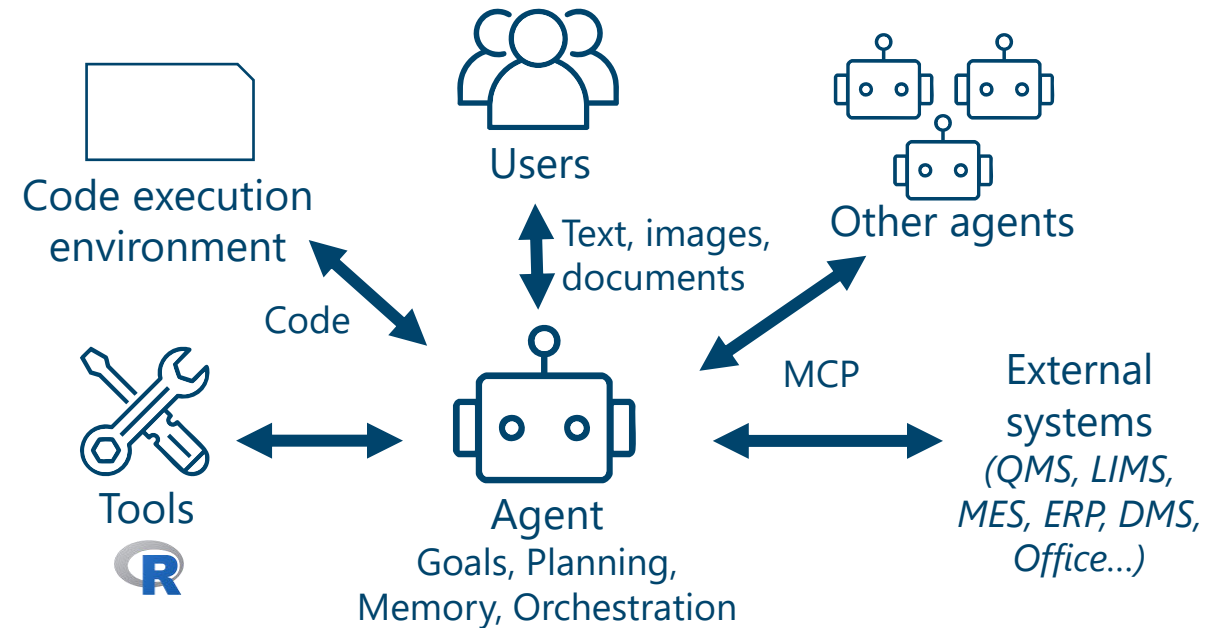
- › **LLMs** (GPT...) generate outputs based on inputs and instructions (prompts)



Limitations

- › Hallucinations
- › Lack of integration
- › Limited planning ability
- › Difficult to take into account multiple aspects of a goal at the same time

- › **AI Agents** (each specialized for one task) collaborate to achieve a goal under an orchestrating agent



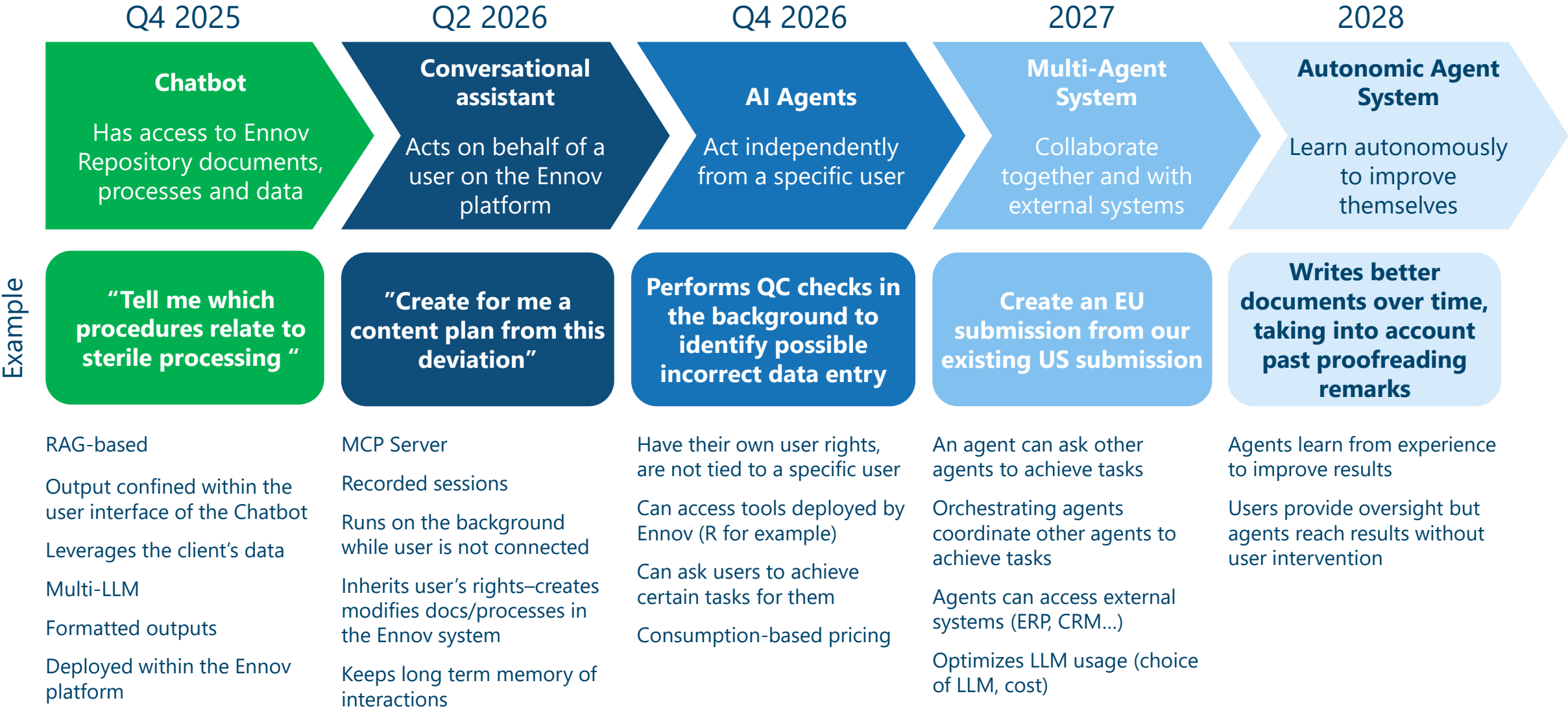
Benefits

- › Multi-system orchestration
- › Handling regulatory context
- › Better traceability (agent interaction trail) & explainability

5-Year AI Vision

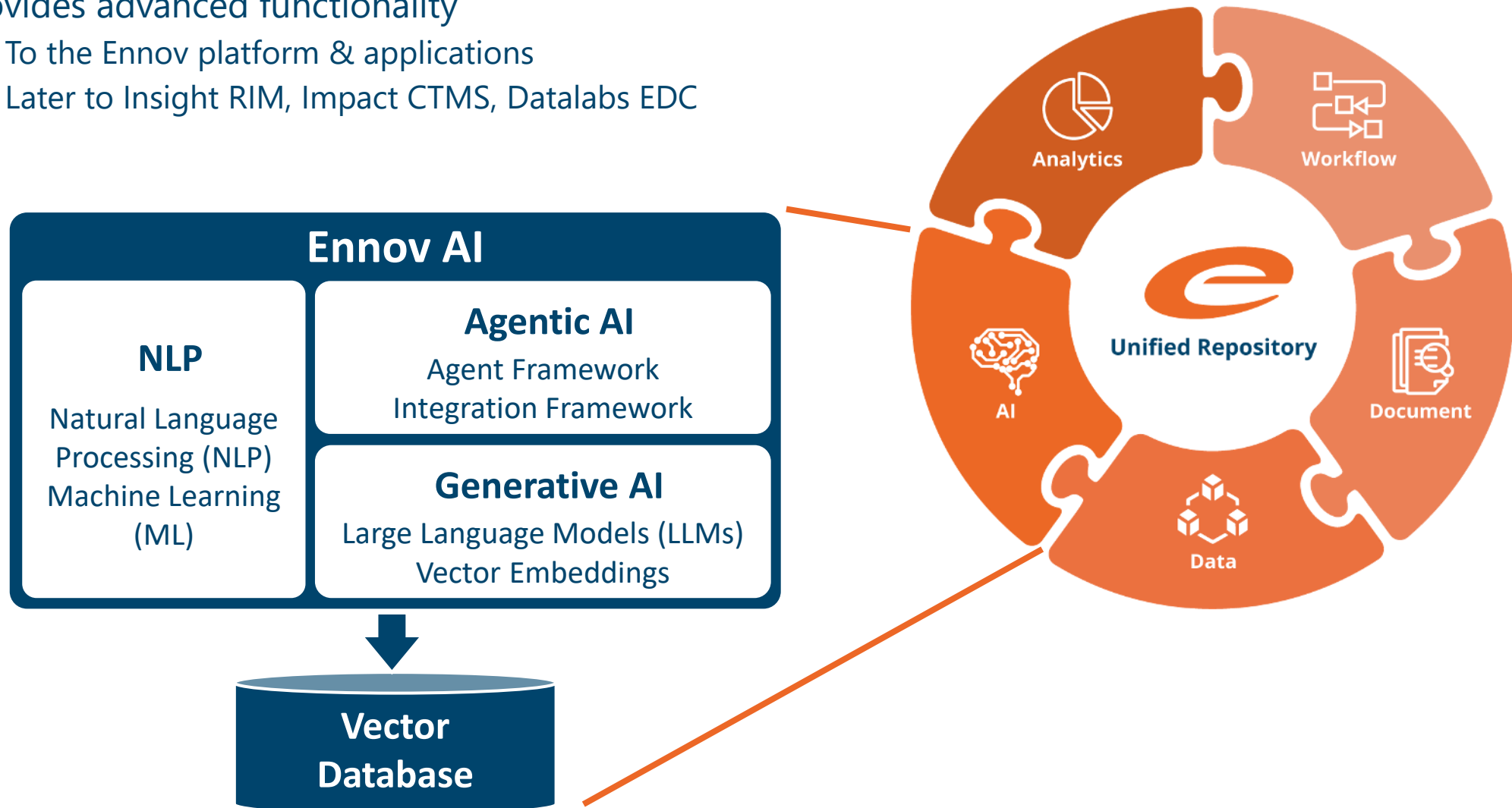
- › Agentic AI will strongly impact how Life Science companies develop & market products
 - › Agents will progressively achieve goals autonomously, humans being there for oversight
 - › Agents will collaborate together and with users
 - › Agents will access company & external systems, as well as specialized tools
-
- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none">› Ennov preconfigured agents will accelerate numerous practical use cases in Regulatory, Quality, PV, Clinical...<ul style="list-style-type: none">› Document drafting, proofreading & rewriting› Acceleration of workflows› Helping take better decisions› Data monitoring to ensure coherence... | <ul style="list-style-type: none">› Ennov clients will configure agents for specific needs thanks to an easy-to-use agent configuration interface<ul style="list-style-type: none">› Automating procedures› Managing data› Producing insights... |
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Ennov's Agentic AI Technology Steps



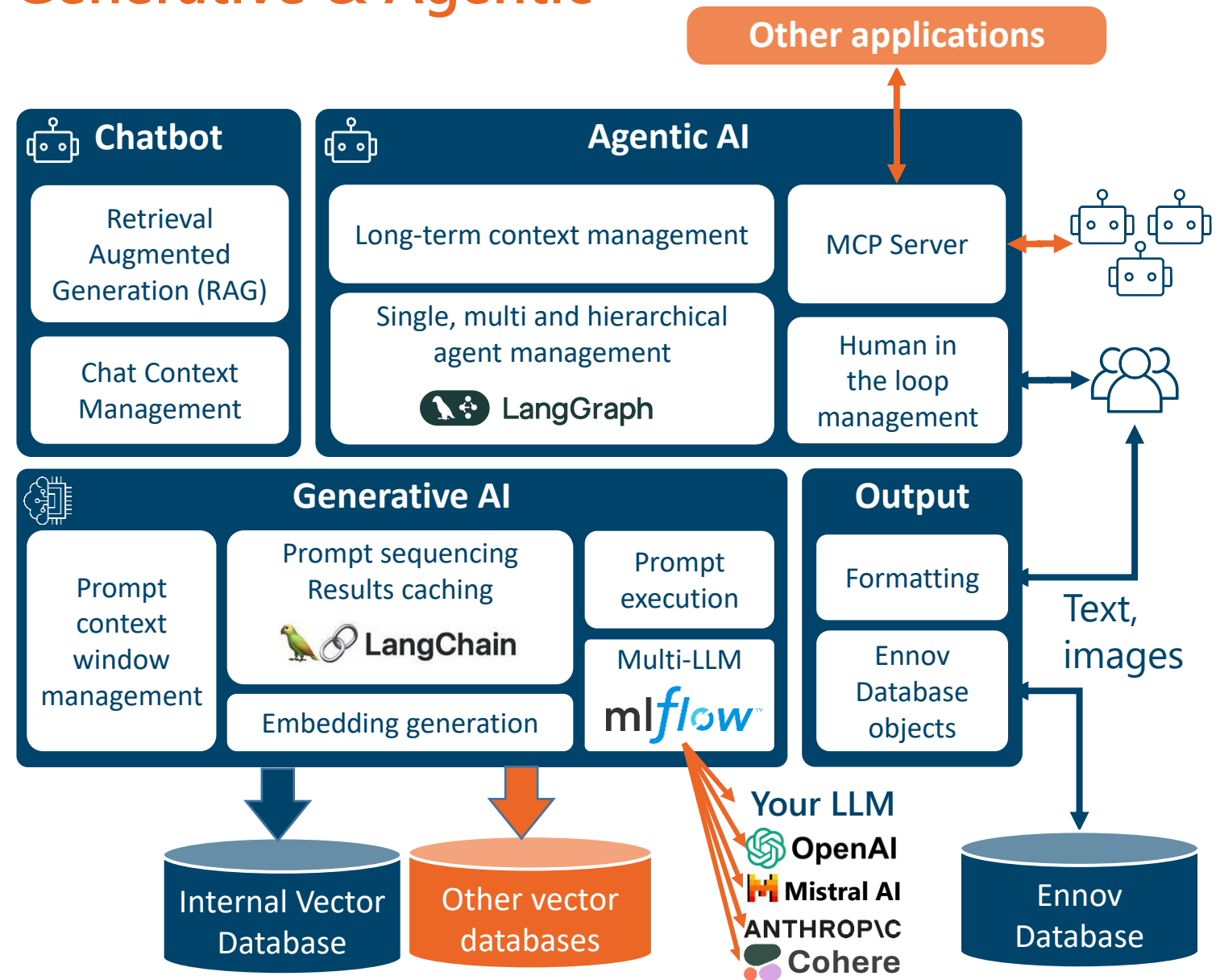
Ennov AI: NLP / Generative AI / Agentic AI

- › Provides advanced functionality
 - › To the Ennov platform & applications
 - › Later to Insight RIM, Impact CTMS, Datalabs EDC



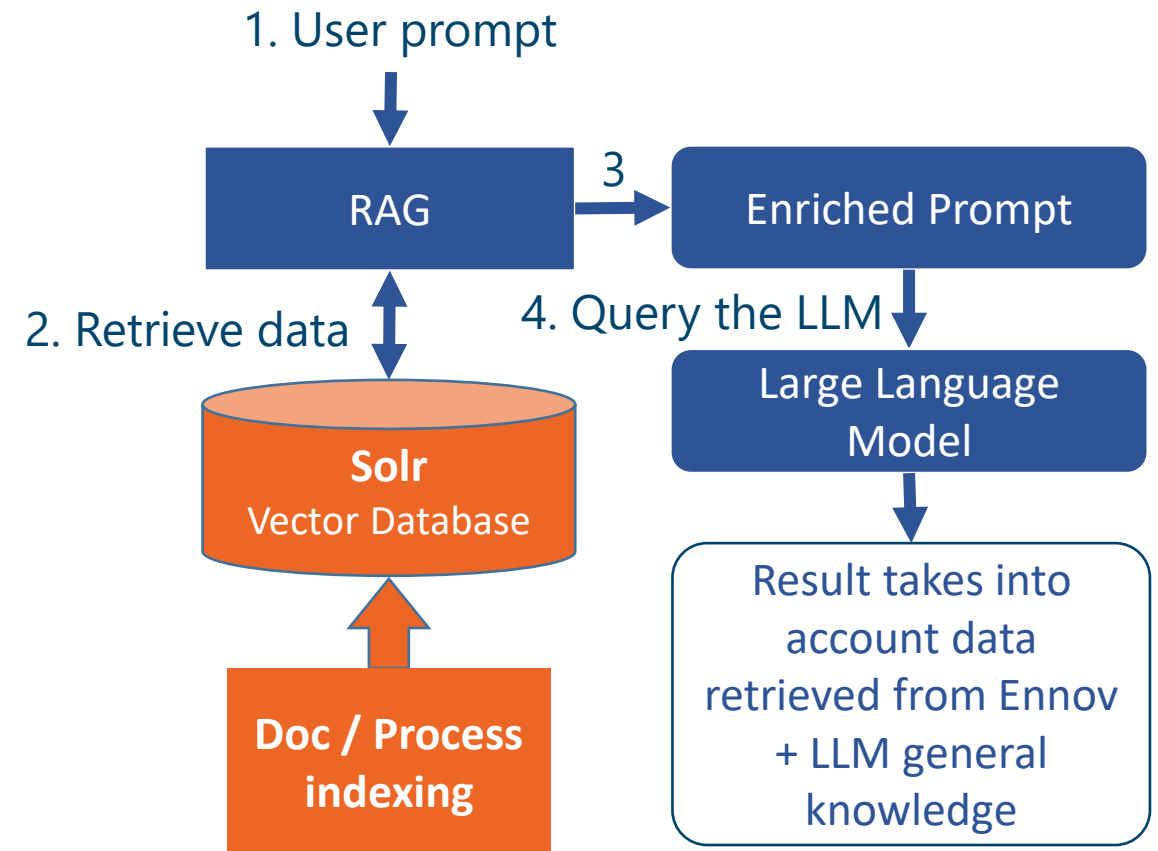
Ennov AI Architecture – Generative & Agentic

- › Deployed within the Ennov platform
 - › Works on cloud and on-premise deployments
 - › Calls external LLMs (cloud or self hosted)
- › Numerous use cases
 - › Questionnaire generation
 - › Automatic expense intake
 - › Assisted deviation management
 - › Answer to Agency Letters
 - › Draft document generation
 - › Data coherence analysis (metadata versus documents)
 - › Regulatory Intelligence Chatbot...



AI Chatbot – With RAG* (Ennov 11.0)

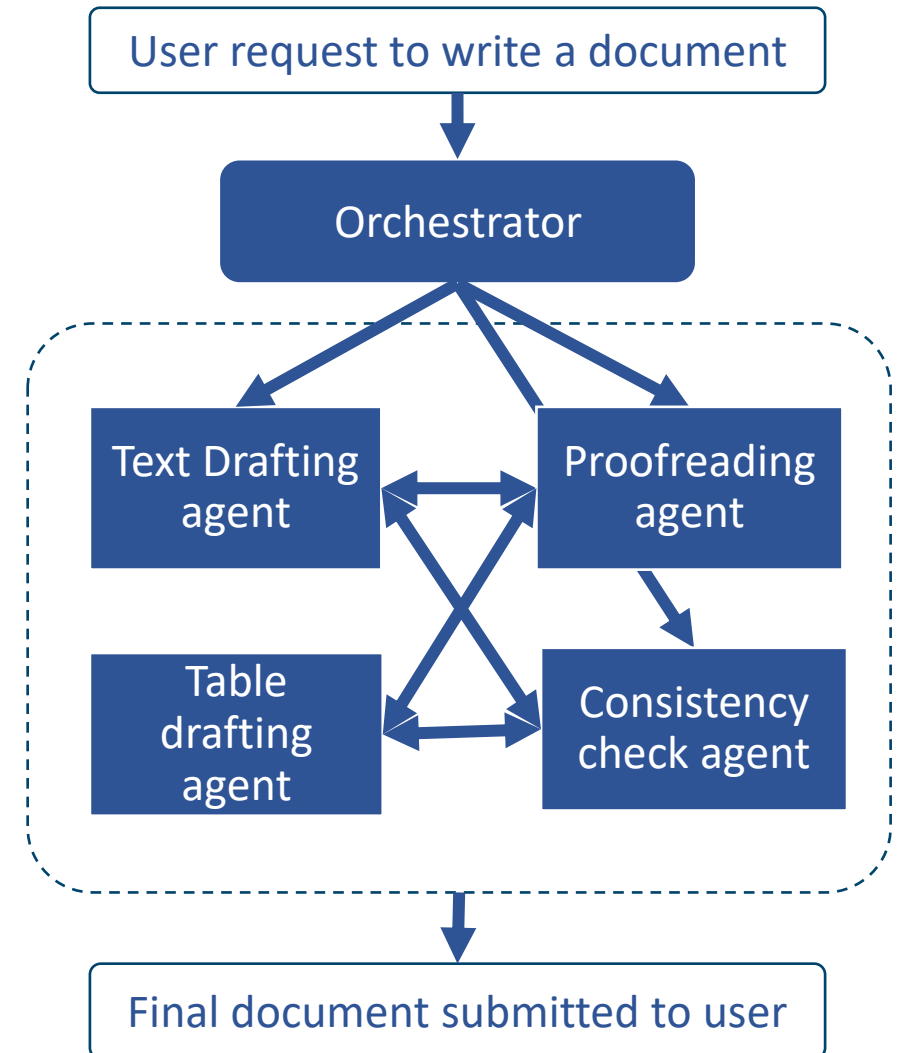
- › AI Chatbot
 - › Conversational mode
 - › Queries Ennov data, using Retrieval Augmented Generation (RAG)
 - › Combines LLM knowledge & capabilities with the data from your Ennov Database
- › Benefits
 - › Uses **your data** (documents, processes, data objects) to
 - › Search information for you
 - › Generate content
 - › Synthesize, analyze...
 - › Always up to date data



*RAG: Retrieval Augmented Generation

Multi-Agent AI Framework (Ennov 11.x)

- › Autonomous AI agents
 - › Performs specialized tasks
 - › Message / trigger other agents
 - › Are coordinated by an orchestration agent
 - › Are configurable
 - › Can interact with external systems (MCP)
 - › Can interact with users
 - › Can use external tools (e.g. R)
- › Benefits
 - › **Split complex tasks into smaller tasks** manageable by LLM prompts
 - › Perform advanced tasks automatically



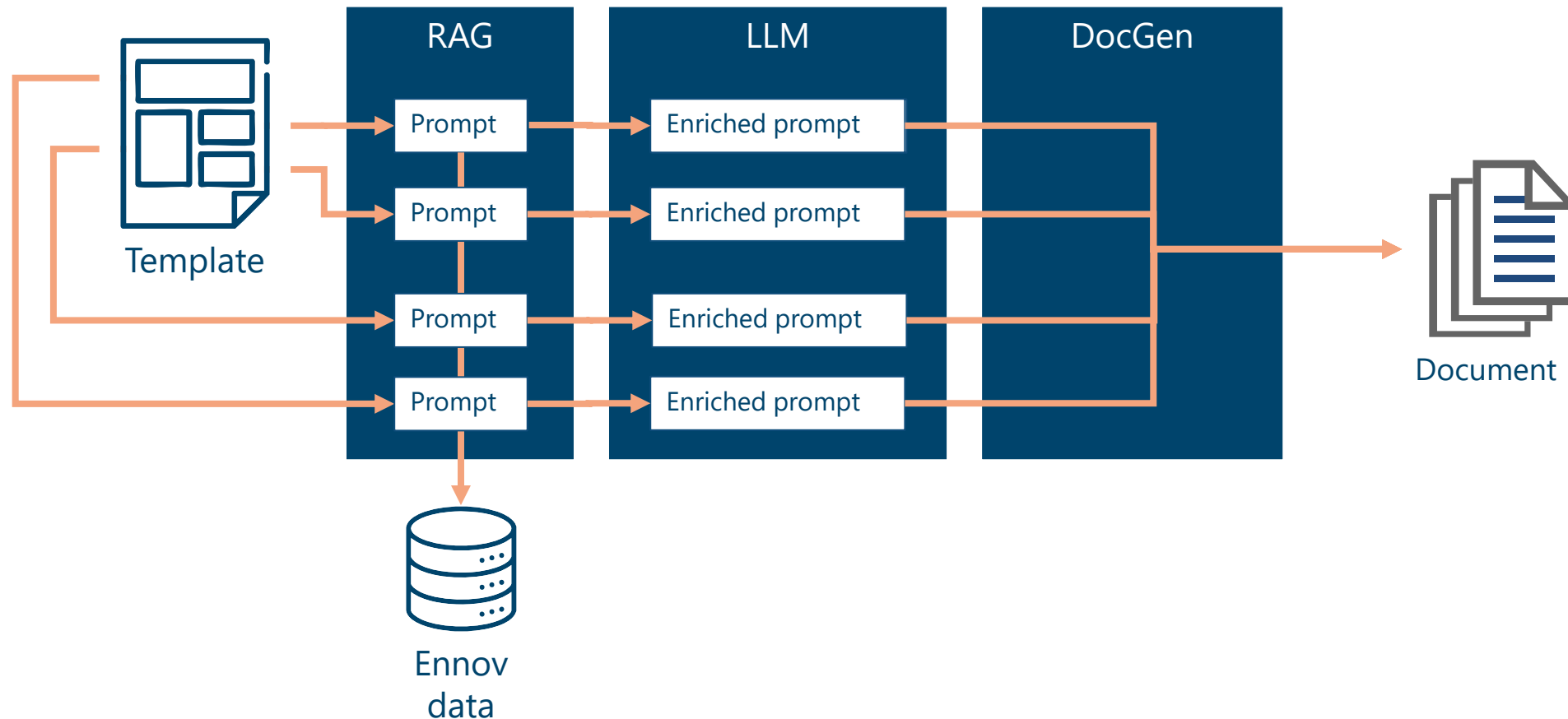


Ennov AI Roadmap

	April 2025	October 2025	April 2026	September 2026
Ennov Platform	Document summary & translation	Chatbot (RAG based)	Conversational Assistant MCP Server Prompt Library	Ennov Autonomic Agents Document Co-Author Microsoft Graph connector
Quality	MCQ generation for Ennov Training	Multi-doc MCQ generation	Co-Investigator	AI Training Tutor Co-Trainer
Regulatory	eCTD automatic classification Questions & commitments extraction from HA letters		HA answer draft generation Regulatory intelligence chatbot (FDA content)	Regulatory document generation template library ePI generation*
Clinical	eTMF document classification		Auto-coding for EDC	Patient visit transcription & CRF automatic entry* Clinical document generation template library
Event	Expense automatic intake			
PV	Automatic CV case entry	Automatic PV case entry	Duplicate case detection	Auto-assessment of cause-effect relationship

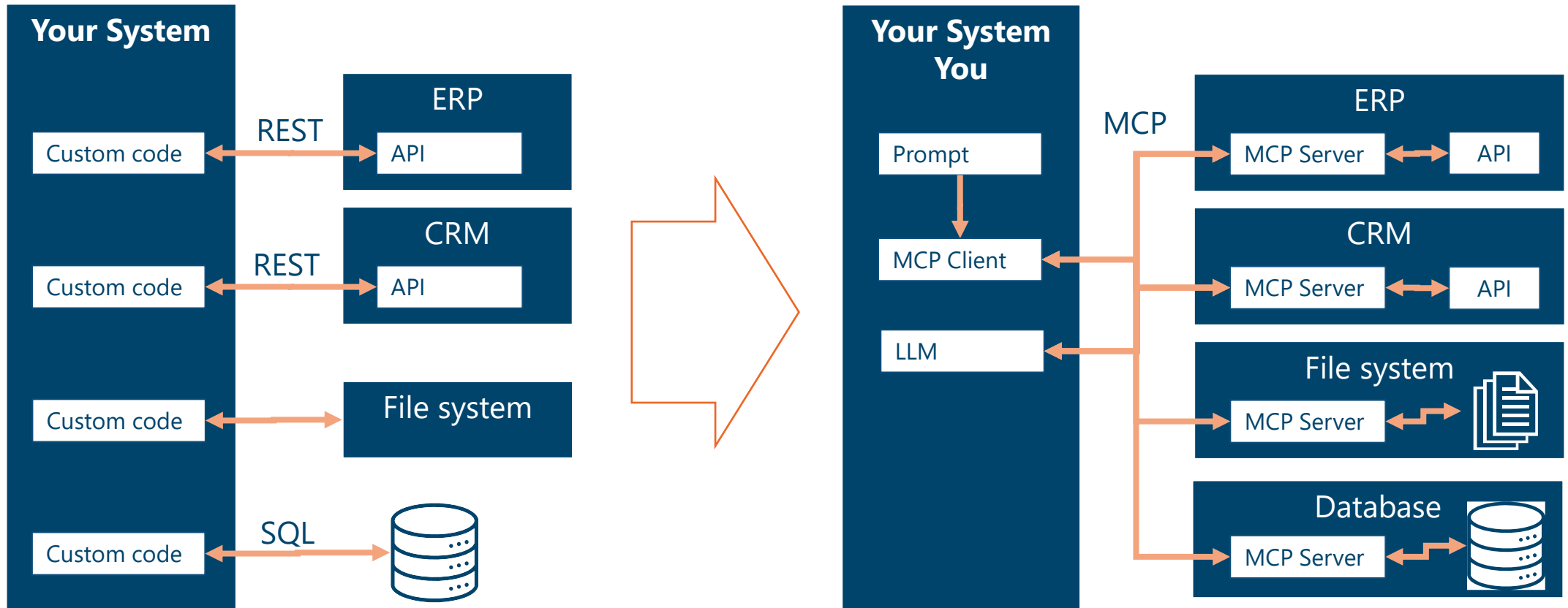
Template-Based Document Generation

- › Generating documents with generative AI while complying with a pre-defined document structure & template



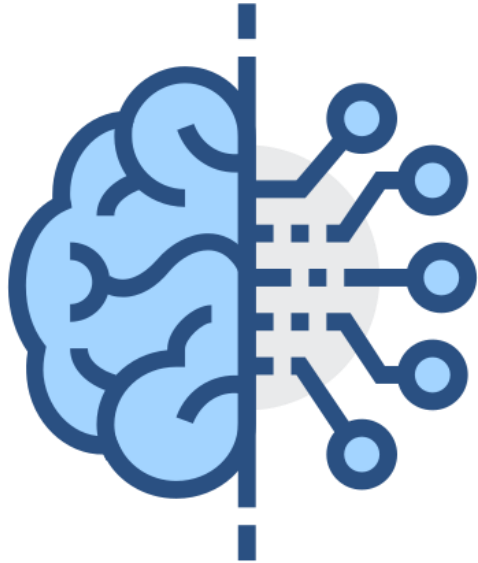
Why MCP (Model Context Protocol)?

- › What if you or your system could connect to other systems without programming the interactions with their API or datasources every time ?



What about “solving” integration ?

Ennov AI License



- › Per user
- › Gives access to all AI based use cases throughout the platform
 - › NLP-based & Generative AI-based
 - › Spend once, use many times
- › All inclusive and predictable: No additional cost for the LLM workloads
- › Could evolve in 2026 based on usage

Ennov AI Implements Trustworthiness Principles



Transparency

The user interface makes it clear when an input is AI generated.



Bias and Accuracy

“Human in the loop” helps avoid this risk
(AI does not submit content to authorities)



Privacy, Security, Intellectual property

Supported LLMs

- Do not use client data for training
- Encrypt data in transit & at rest

You can use privately deployed LLMs



Governance, compliance

Traceability (CFR21 part 11)

Supported LLMs embrace non-discrimination

EU AI Act compliant

Thank you for your attention!

