

Ennov Al Roadmap Introduction

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October 16th 2025

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





Agenda

Agentic Al

2 Ennov's Agentic Al Vision

3 Ennov Al architecture

4 Al Roadmap



Generative AI (LLM)

Al Agent

Universal Multimodal (text, image...) & Multilingual Model triggered by simple prompts (text instructions).

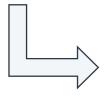


Autonomous: can perform tasks in the background
Orchestrated: collaborate to perform tasks
Integrated: can interact with other agents, users, tools,
external systems

Multiple capabilities: drafting, proposing, creating, reformatting, explaining, summarizing, answering questions, extracting information, translating, recommending, analyzing...



Facilitates the **combination of these capabilities** to achieve complex tasks and interact with external systems



Limitation

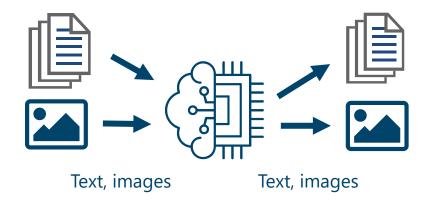
Tasks that require long term planning or to combine multiple subtasks of diverse nature





LLMs V.S. Al Agents

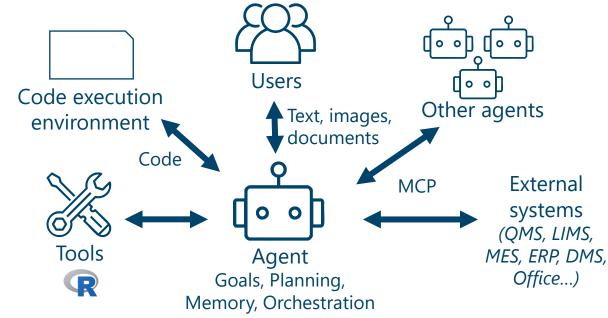
> **LLMs** (GPT...) generate outputs based on inputs and instructions (prompts)



Limitations

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

Al 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 Al 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

- Ennov preconfigured agents will accelerate numerous practical use cases in Regulatory, Quality, PV, Clinical...
 - Document drafting, proofreading & rewriting
 - Acceleration of workflows
 - Helping take better decisions
 - Data monitoring to ensure coherence...

- Ennov clients will configure agents for specific needs thanks to an easy-to-use agent configuration interface
 - Automating procedures
 - Managing data
 - Producing insights...



Ennov's Agentic Al Technology Steps

Q4 2025

Q2 2026

Q4 2026

2027

2028

Chatbot

Has access to Ennov Repository documents, processes and data **Conversational** assistant

Acts on behalf of a user on the Ennov platform

Al Agents

Act independently from a specific user

Multi-Agent System

Collaborate together and with external systems

Autonomic Agent System

to improve themselves

"Tell me which procedures relate to sterile processing "

"Create for me a content plan from this deviation"

Performs QC checks in the background to identify possible incorrect data entry

Create an EU submission from our existing US submission

Writes better documents over time, taking into account past proofreading remarks

RAG-based

Output confined within the user interface of the Chatbot

Leverages the client's data

Multi-LLM

Formatted outputs

Deployed within the Ennov platform

MCP Server

Recorded sessions

Runs on the background while user is not connected

Inherits user's rights–creates modifies docs/processes in the Ennov system

Keeps long term memory of interactions

Have their own user rights, are not tied to a specific user

Can access tools deployed by Ennov (R for example)

Can ask users to achieve certain tasks for them

Consumption-based pricing

An agent can ask other agents to achieve tasks

Orchestrating agents coordinate other agents to achieve tasks

Agents can access external systems (ERP, CRM...)

Optimizes LLM usage (choice of LLM, cost)

Agents learn from experience to improve results

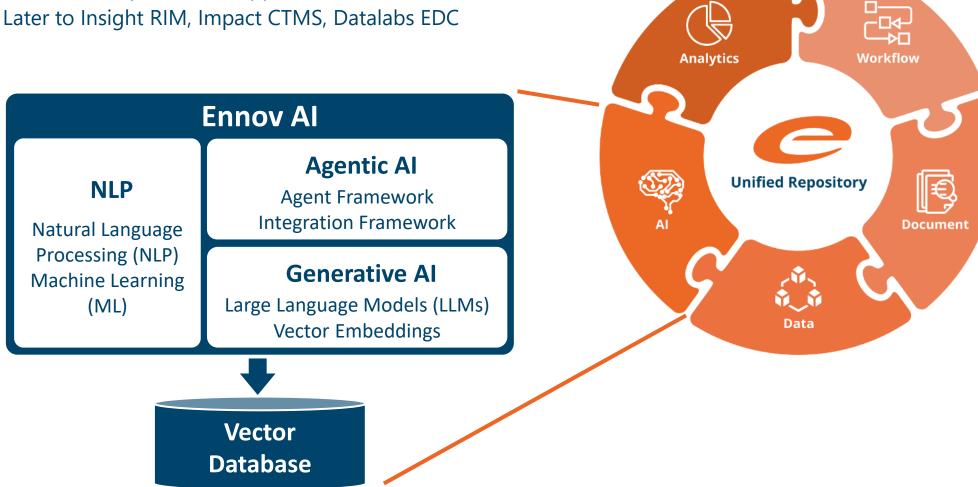
Users provide oversight but agents reach results without user intervention



Ennov AI: NLP / Generative AI / Agentic AI

Provides advanced functionality

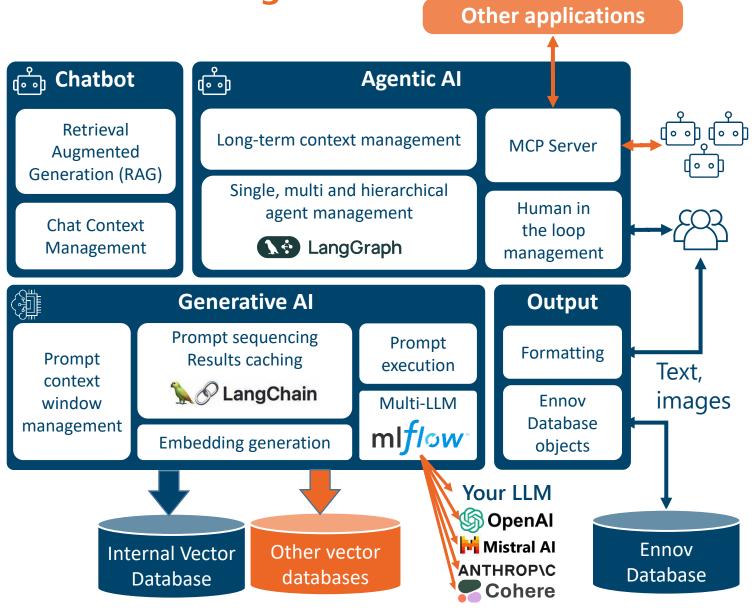
To the Ennov platform & applications





Ennov Al 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...





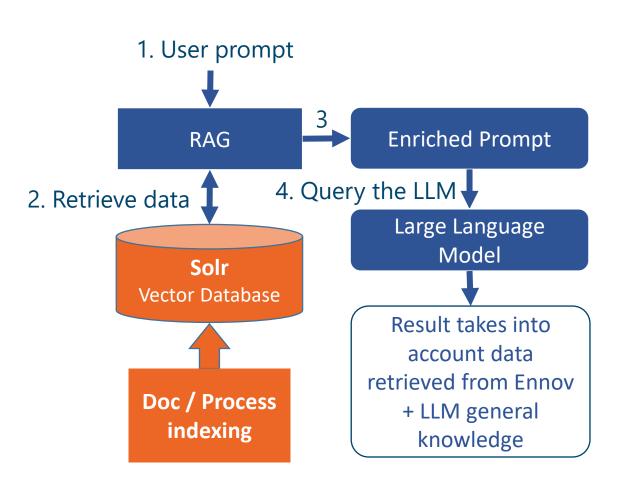
Al Chatbot – With RAG* (Ennov 11.0)

Al 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
 - Synthetize, analyze...
- Always up to date data

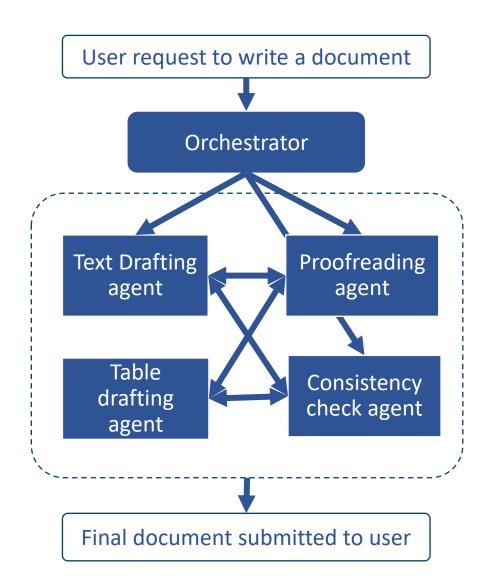


*RAG: Retrieval Augmented Generation



Multi-Agent Al Framework (Ennov 11.x)

- Autonomous Al 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





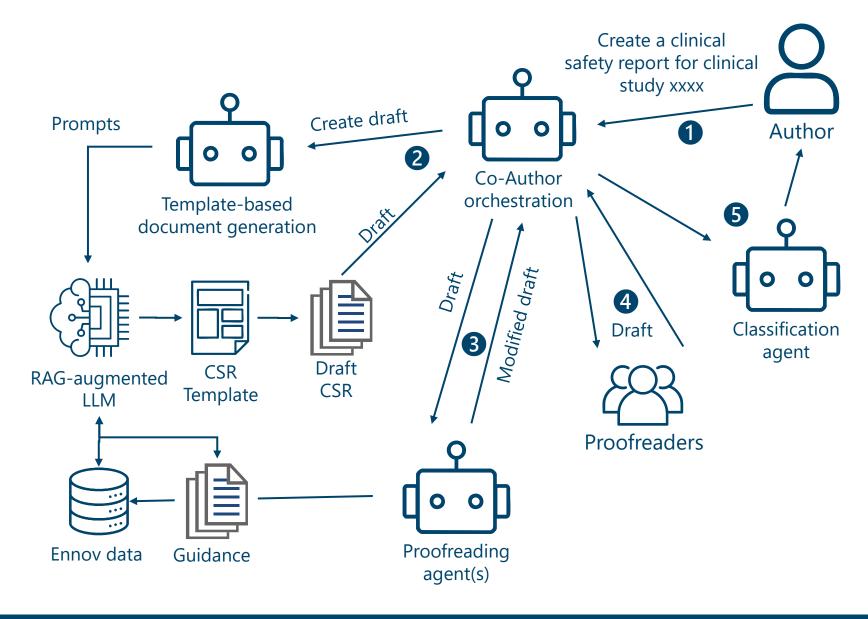


Ennov AI Roadmap

_	April 2025	October 2025	April 2026	September 2026
Ennov Platform	Document summary & translation		Conversational Assistant	Ennov Autonomic Agents
		Chatbot (RAG based)	MCP Server	Document Co-Author
			Prompt Library	Microsoft Graph connector
Quality	MCQ generation for Ennov Training	Multi-doc MCQ generation	Co-Investigator	Al Training Tutor
				Co-Trainer
Regulatory	eCTD automatic classification		HA answer draft generation	Regulatory document
	Questions &		Regulatory intelligence	generation template library
	commitments extraction from HA letters		chatbot (FDA content)	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

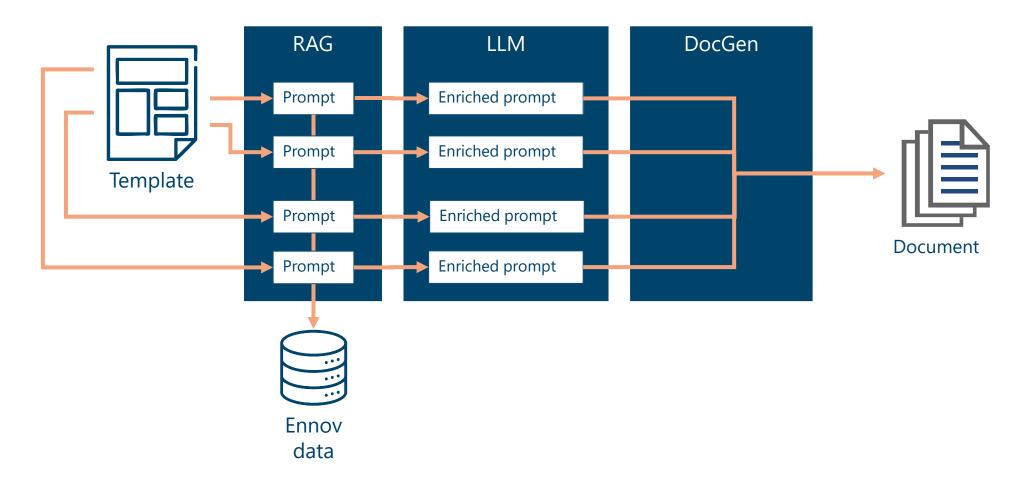
Document Co-Author

- Drafting
 - Template based document generation
 - Prompts linked to document template & refer guidance
- Proofreading
 - Style
 - **Errors**
 - Internal coherence
 - Coherence with guidance & other documents
- Document classification
 - Metadata auto-filling
 - Recipient suggestion
 - > Title creation



Template-Based Document Generation

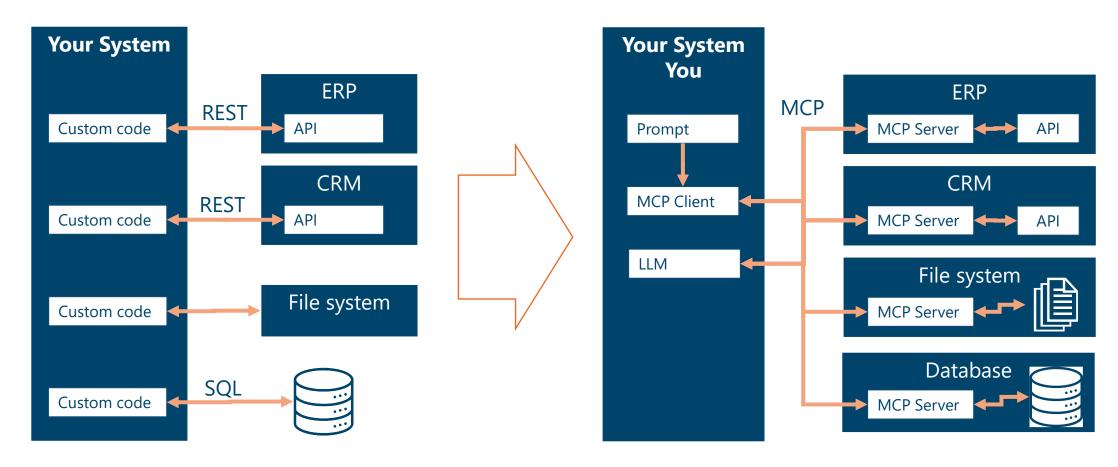
Generating documents with generative AI while complying with a predefined document structure & template





Why MCP (Model Context Protocol)?

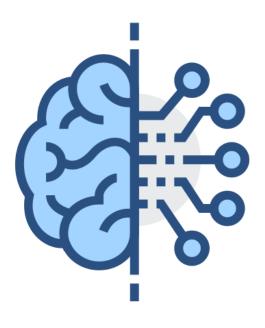
What if you or your system could connect to other systems without programming the interactions with their API or datasources every time?



What about "solving" integration?



Ennov Al 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 Algenerated.



Bias and Accuracy

"Human in the loop" helps avoid this risk
(Al 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 Al Act compliant





Thank you for your attention!

