



Using AI Agents to Optimize the EU HTA Process

An industry perspective

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Disclaimer

I am an employee of F. Hoffmann-La Roche Ltd. The views and opinions expressed in this presentation are solely those of the presenter and do not necessarily reflect the official policy or position of F. Hoffmann-La Roche Ltd. This presentation is provided for educational and informational purposes only.

Back in 2020 ...



copy and
paste
delays

late nights

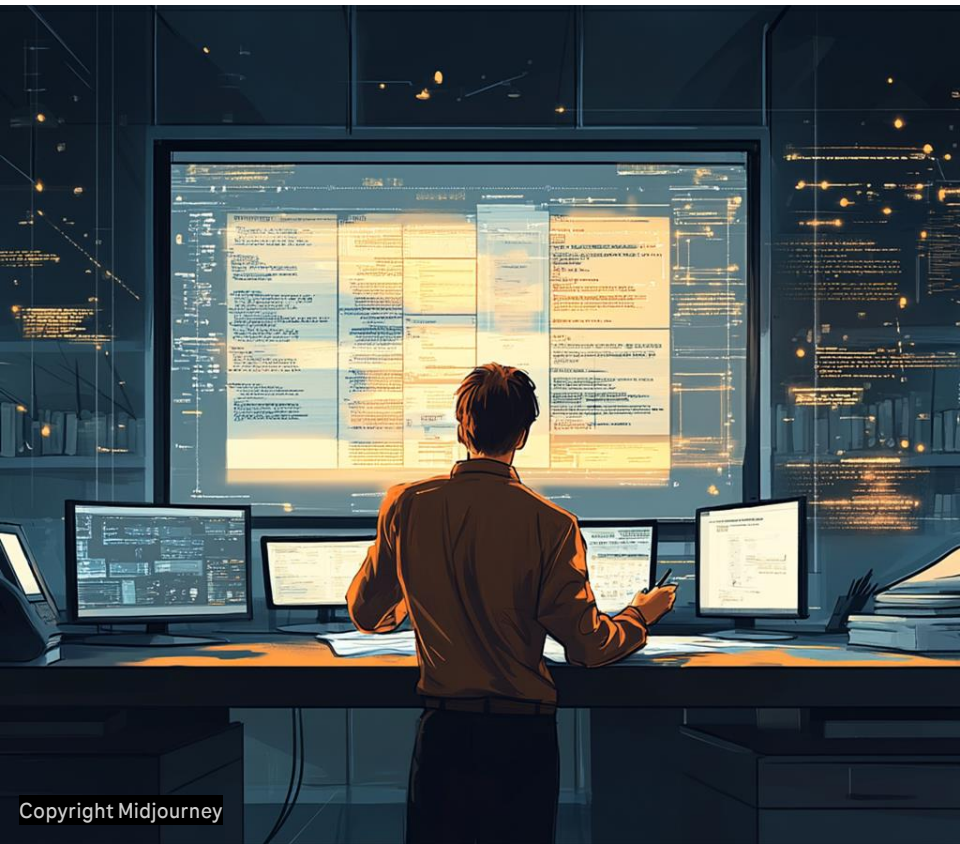
information
overload

outdated searches

human errors

multiple
applications

We are now exploring ...



AI algorithms

process
transformation

speed &
accuracy

AI agents

HTA submission

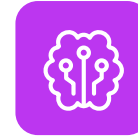
AI is a key enabler for the future of HTA



Health technology assessment (HTA) is becoming increasingly complex, especially given the latest European Commission legislation on joint clinical assessments



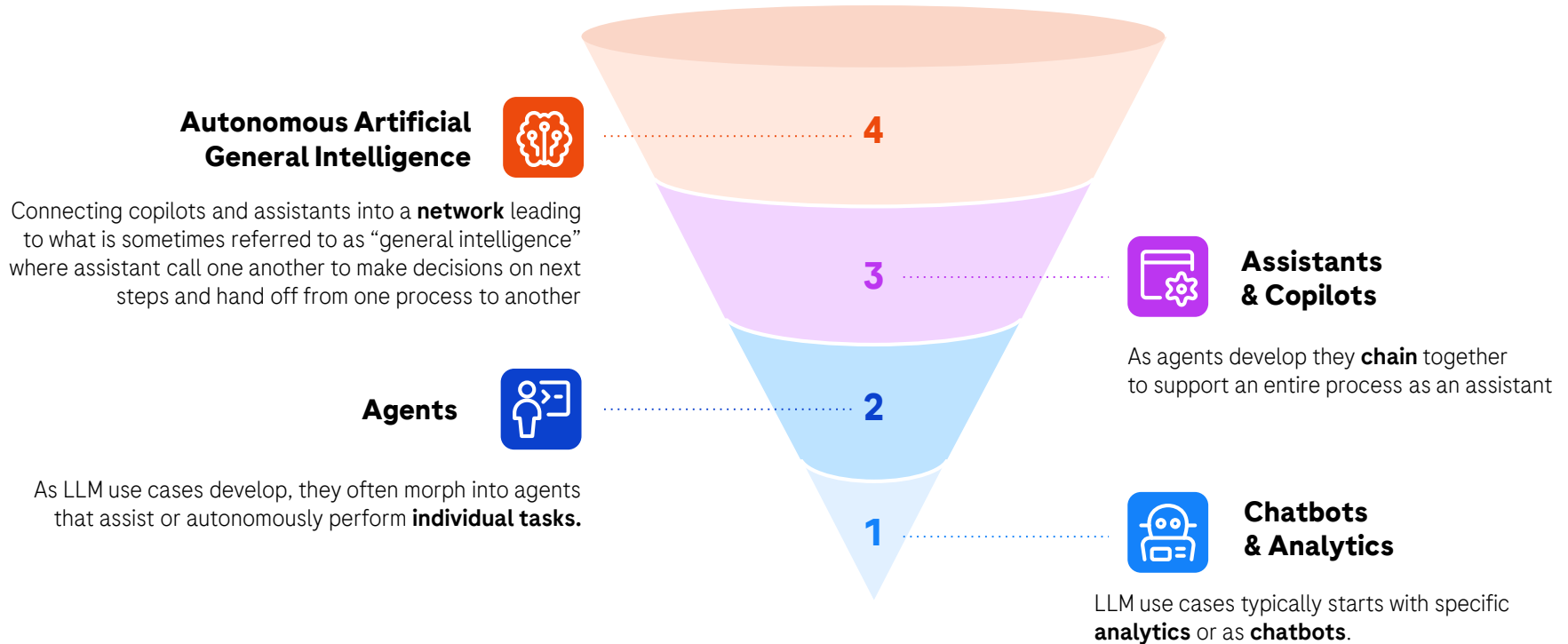
HTA processes generally involve the evaluation of massive volumes of data to assess the clinical and economic value of health technologies.



Leveraging AI agents can speed up the process of systematic reviews, meta-analyses, dossier preparation

Evolution of autonomous AI agents development

Changing together GenAI may occasionally spiral upwards in capabilities



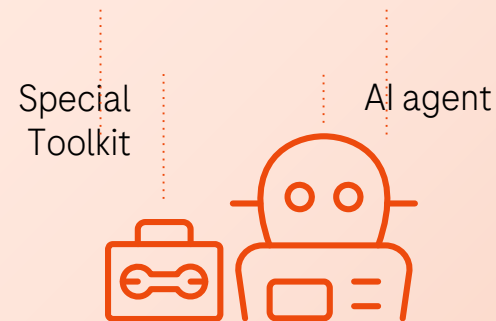
What are AI agents?

Definition:

Autonomous software systems that perform specific tasks using AI and ML algorithms that operate with minimal human intervention and generate actionable insights.

Key features:

1. **Autonomy:** Independent execution of tasks without constant human supervision.
2. **Learning:** Improved performance over time by learning from past data and decisions.
3. **Natural language processing:** Rapid understanding, interpretation, and analysis of human language in documents and databases.
4. **Decision-Making:** Ability to make informed decisions, offer recommendations, predictions, or direct actions based on the task at hand.
5. **Task Automation:** Automation of repetitive and data-intensive processes, such as data extraction, literature review, or evidence synthesis.

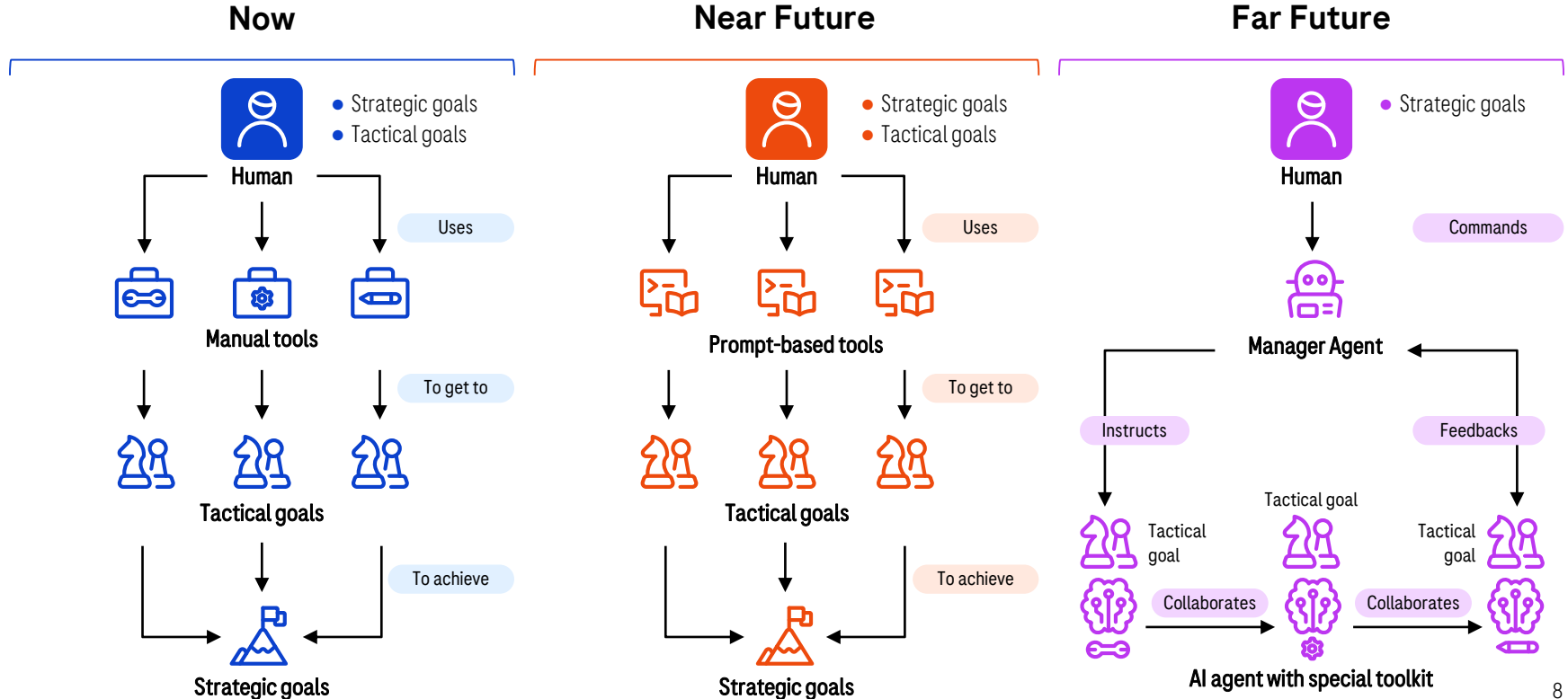


Agent attributes:

- Personality
- Tactical goal
- Background knowledge
- Tasks
- Reflection
- Memory (short- & long-term)

Accelerating the HTA preparation process

From “Doer” to “Information manager”



AI agents in systematic reviews



Prepare protocol



Run searches in multiple electronic literature DBs

- List of titles & abstracts
- API integration to eLibraries



Review of abstracts/Records

- List of eligible & ineligible titles & abstracts (.xlsx)
- Automation of review, deduplication



Download eligible full-texts

- Full-texts of eligible titles and abstracts (PDF)
- API to eLibraries



Review eligible full-texts

- List of eligible and ineligible full-texts (.docx & PRISMA diagram)
- Automation of review



Extract data from eligible full-text articles

- Data points (.xlsx)
- Text mining



Dissemination of the research findings



Slide deck preparation

- Visual summaries of findings



Report writing

- Summaries of findings, bibliographies and associated full-texts



Synthesis of data

- Qualitative and quantitative analysis report elements



Risk of bias/quality assessment


- Summaries of assessment and scoring, and report elements



Citation-chasing

- List of titles & abstracts and eligible full-texts



What AI agents for systematic reviews could look like

	 Agent manager and manager tasks
<p>Create goal for the agent manager e.g., write a protocol for the following clinical [systematic] literature review</p>	<ol style="list-style-type: none"> 1. Agent manager asks clarifying questions 2. Agent manager activates Agent 1.
<p>Challenge Technical considerations for setting up agents</p>	<p>Hard coded prompts initially for the manager agents to learn from</p>

Multiple generative AI algorithms may be required as they all perform better at some tasks than others

What AI agents for systematic reviews could look like




Protocol creation

 Agent 1 Specialization: Text summary and generation	 Agent 2 Specialization: Search strategy design
<ol style="list-style-type: none"> 1. Searches the web/uses data sources like semantic scholar and identifies references relevant to the topic 2. Writes the Introduction and Methods sections of the literature review protocol, including eligibility criteria, information sources, study selection, etc. 3. Decides which sources will be searched 4. Cites text and provides links to cited sources 	<ol style="list-style-type: none"> 1. Prepares keywords to be used to design a search strategy 2. Uses the keywords to create the first version of search strategies for querying various sources, e.g. MEDLINE, Embase, etc
Challenge	Authentication of agents, including their manager

Multiple generative AI algorithms may be required as they all perform better at some tasks than others

What AI agents for systematic reviews could look like



Study identification

 Agent 3 Specialization: Search strategy implementation	 Agent 4 Specialization: Task Management	 Agent 5 Specialization: Screening and record classification
<ol style="list-style-type: none"> 1. Implements the searches designed by Agent 2. 2. Retrieves the hits, yields, and adds the retrieved records to a literature review queue. 3. Tracks clearly which record is identified from which source 	<ol style="list-style-type: none"> 1. Moves records from the queue backlog and removes duplicates 	<ol style="list-style-type: none"> 1. Reviews each unique record and determines whether it should be included based on the eligibility criteria 2. Assigns inclusion or exclusion status, as well as reason for exclusion highlighting record sections 3. Moves records to the full-text retrieval queue)
Challenge Authentication of agents, including their manager	Authentication of agents, including their manager	

Multiple generative AI algorithms may be required as they all perform better at some tasks than others

What AI agents for systematic reviews could look like

Study identification

 Agent 4 Specialization: Task Management	 Agent 5 Specialization: Screening and record classification
<ol style="list-style-type: none"> 1. Retrieves full-texts and assigns it to the relevant title and abstract record 	<ol style="list-style-type: none"> 1. Reviews the full-texts of each included title and abstract and determines whether it should be included based on the eligibility criteria 2. Assigns inclusion or exclusion status, as well as reason for exclusion highlighting paper sections 3. Conducts citation chasing 4. Moves records to the data extraction queue
<div style="background-color: #800080; color: white; padding: 2px; display: inline-block;">Challenge</div> Authentication of agents, including their manager	Compliance with deploying machine learning algorithms on publishers' materials

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What AI agents for systematic reviews could look like

Analysis and Reporting



Agent 6

Specialization: **Data extraction (clinical)**

1. Extracts data based on pre-determined fields in the protocol, linking extracted data to the relevant section of the full-text paper including their appendices and related papers
2. Moves records to the quality assessment and risk of bias queue

Challenge

Compliance with deploying machine learning algorithms on publishers' materials



Agent 7

Specialization: **Quality assessment and risk of bias**



1. Extracts data based on pre-determined quality assessment and risk of bias elements listed in the protocol, linking extracted data to the relevant section of the full-text paper including their appendices and related papers
2. Moves records to the report writing queue

Compliance with deploying machine learning algorithms on publishers' materials

Multiple generative AI algorithms may be required as they all perform better at some tasks than others

What AI agents for systematic reviews could look like



Analysis and Reporting

 Agent 8 Specialization: Table and chart/plots creation	 Agent 1 Specialization: Text summary and generation
<ol style="list-style-type: none"> 1. Reviews the extracted data and determines how the data should be presented 2. Constructs tables, charts or plots as needed based on extracted data 3. Moves records further down the report writing queue 	<ol style="list-style-type: none"> 1. Prepares first drafts of texts accompanying each table, chart or plot using qualitative synthesis. 2. Writes the other sections of the report e.g. Background, Methods, Results, Discussion and Conclusions 3. Cites text and provides links to cited sources 4. Prepares appendices 5. Moves draft report to quality assurance queue
Challenge	Reliability and consistency of historical data and reporting

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What AI agents for systematic reviews could look like

Analysis and Reporting

 Agent 9 Specialization: Quality assurance	 Agent Manager Specialization: Oversight and task evaluation
<ol style="list-style-type: none"> 1. Reviews draft report for accuracy and cross-checks that content meets the goals set for the agent manager 2. Prepares a QC report for human user 3. Moves draft report to agent manager queue 	<ol style="list-style-type: none"> 1. Collates and assembles draft document and key output for each step using historical documents as a reference. 2. Prepares QC checklist flagging potential areas requiring human review and updates QC report for human user 3. Notifies user about status of all deliverables
Challenge Reliability and consistency of historical data and reporting	Reliability and consistency of historical data and reporting

Multiple generative AI algorithms may be required as they all perform better at some tasks than others

There is a clear benefit to implementing AI agents for HTA documentation preparation but...



Humans are still needed in the loop

Hybrid systems that combine human oversight with AI-driven automation can ensure content accuracy and quality while maintaining efficiency



Legal dilemmas and licensing of data sources and full-text papers from data vendors



Data privacy and GDPR compliance



Caution is required with introducing AI agents

Trust and transparency in the behaviour of the agents are key to success



Authentication of users for various platforms that serve the AI agents and their interoperability with existing HTA tools and processes.



Resistance to AI adoption and trust challenges

Why AI agents matter for the industry



Faster market access

AI agents can significantly speed up the time it takes to get new treatments assessed and approved. This will allow companies to bring innovations to market faster, improving patient outcomes.



Improved accuracy and consistency

AI agents can reduce human error, ensuring that HTA documentation are precise and replicable. This is crucial in a regulated environment where accuracy is paramount.



Enhanced resource efficiency

AI agents can handle large volumes of data quickly, freeing up human resources for higher-level strategic tasks, enabling teams to focus on result interpretation and informed business decision-making.

Conclusions



Efficiency and accuracy

AI agents can improve efficiency by automating routine tasks, making processes like literature reviews and data analyses faster and more precise.



Competitive advantage for pharma

Early adopters of AI agents will benefit from faster market access as the EU HTA process matures, setting themselves up for future success.



The future of HTA in the pharmaceutical industry is AI-driven

Adopting AI agents now will ensure your company stays ahead in an increasingly data-driven, heavily-regulated environment.

Explore AI in your HTA processes today.

Doing now what patients need next