# Acceptance of Artificial Intelligence in Evidence and Dossier Development by Global HTA Agencies

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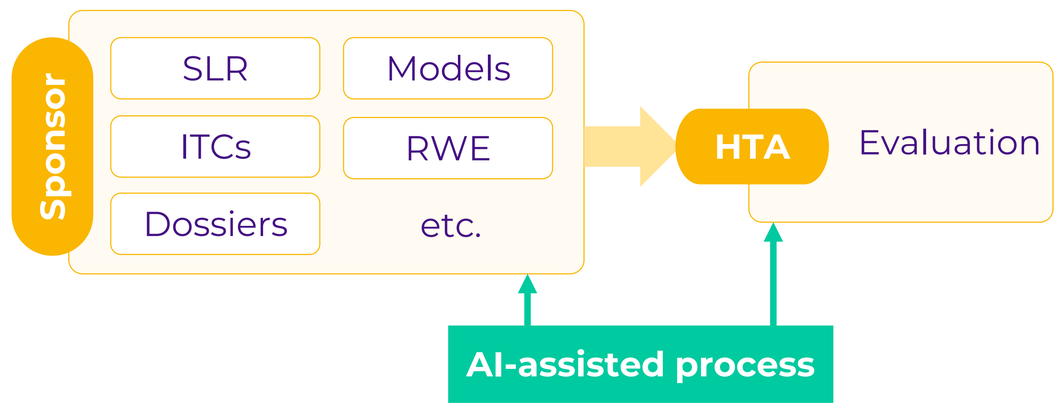
HTA18

## Background and objective

- Artificial Intelligence (AI) has the potential to reshape Health Technology Assessment (HTA) by streamlining and expediting evidence generation processes, dossier development and technology assessment[1,2] (**Figure 1**).
- EU Joint Clinical Assessment underscores the need for robust and timely evidence generation. AI-driven solutions may help companies respond to growing evidence demands by accelerating evidence generation activities.
- However, concerns around the "Black box" nature of some AI models, risks of bias and inaccuracies, lack of transparency, and data privacy highlight the need for cautious, responsible adoption of AI in HTA.[1,3,4]
- This study investigates the extent to which HTA agencies have issued guidance related to the use of AI in HTA submissions.

**Figure 1. Potential uses of AI in evidence and HTA**




## Methods

- Targeted searches were conducted for publicly available documents – such as policy papers, position statements, or other materials – issued by HTA agencies that provide guidance on the use of AI in HTA submissions.
- The searches covered ten key markets: UK, Germany, France, Italy, Spain, Sweden, Netherlands, Canada, Australia, and US. Agency websites and official publications were reviewed as of August 2025 to determine the presence and nature of any such guidance.

## Results

- Position statements addressing the use of AI in HTA submissions have been published by two agencies: NICE (UK) in 2024 followed by CDA (Canada) which published its own adapted version of NICE's statement in 2025 (**Table 1**).
- No AI-specific HTA guidance was identified for the other countries reviewed (**Table 1**).
- However, some agencies, such as HAS, have been actively exploring AI applications internally, developing frameworks for evaluation of AI digital tools and monitoring impact of AI on HTA processes.

**Table 1. Guidelines on use of AI in evidence generation and HTA dossier development**

| Country | HTA body | Availability of guidance on AI in HTA | | | Guidance details and other comments |
|---|---|---|---|---|---|
| | | Y/N | Date | Type | |
| **United Kingdom** | **NICE** | ✓ | **August 2024** | Position statement | Position statement sets out expectations for using AI in HTA evidence generation:<br>• Used only when it adds clear value, with full transparency, justification, and human oversight[4]<br>• Submissions must disclose AI use, align with ethical and legal standards, and apply established frameworks[4]<br>• Early engagement with NICE encouraged[4] |
| **Canada** | **CDA** | ✓ | **April 2025** | Position statement | • Adapted NICE AI guidance tailored to fit into Canada's HTA and regulatory environment[5] |
| **Australia** | **PBAC** | ✗ | | | Not available |
| **United States** | **ICER** | ✗ | | | Not available |
| **Spain** | **AEMPS** | ✗ | | | Not available |
| **Italy** | **AIFA** | ✗ | Not available | | • Regulatory guidelines for clinical trials involving AI/ML methods published in 2021[6] |
| **Germany** | **IQWiG** | ✗ | Not available | | • IQWiG's General Methods allow ML for study selection and search strategy development[7] |
| **France** | **HAS** | ✗ | Not available | | • In 2025 HAS reaffirmed its role in evaluating health technologies developed using AI tools, digital medical devices and telemonitoring systems; it is planned to create a "framework of trust" for use of professional AI digital tools[8]<br>• HAS monitors new challenges raised by AI that may impact HTA process and expressed readiness to provide guidance on its expectations for companies submitting dossiers prepared with help from AI systems[8]<br>• HAS is also exploring AI tools to support internal literature reviews[9] |
| **Sweden** | **TLV** | ✗ | | | Not available |
| **Netherlands** | **ZIN** | ✗ | | | Not available |

**Key:** ✓ Available ✗ Unavailable

## Discussion

- Although AI has significant potential in evidence generation processes, such as systematic literature reviews, accelerated RWE synthesis, and health economic modelling, enabling more efficient responses to growing evidence needs (e.g. multiple PICOs), its actual use in HTA dossiers is not well documented and is likely underreported.
- Development of guidance on AI use in HTA remains in its infancy: only two HTA agencies (NICE [UK] and CDA [Canada]) have published brief position statements on AI use in HTA.
- However, the situation may change rapidly. For example, HAS (France) recently expressed awareness of the need to provide relevant guidance for companies willing to submit AI-assisted dossiers.[9]
- In parallel, regulatory bodies such as the EMA[10] and FDA[11] have released or drafted documents on the use of AI in the medicinal product lifecycle – soon, HTA bodies will need to adapt their frameworks to the growing AI-supported evidence base.
- Development of AI acceptance in HTA will likely mirror integration process of real-world evidence – initially met with caution, it has gradually gained credibility and acceptance as standards, methodologies and frameworks matured.[12]

## Conclusions

- AI is gradually entering the HTA domain, with NICE and CDA providing early direction.
- Continued cross-stakeholder collaboration on development and harmonisation of HTA-specific frameworks supported by pilot projects, hybrid AI-human approaches, and reviewer training, will be essential to support broader acceptance and consistent integration of AI into HTA dossiers.

## References

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## Abbreviations

AEMPS, Spanish Agency of Medicines and Medical Devices (Agencia Española de Medicamentos y Productos Sanitarios); AI, artificial intelligence; AIFA, Italian Medicines Agency (Agenzia Italiana del Farmaco); CDA, Canadian Drug Agency; ECG, electrocardiogram; EMA, European Medicines Agency; EU, European Union; FDA, Food and Drug Administration; HAS, French National Authority for Health (Haute Autorité de Santé); HTA, health technology assessment; ICER, Institute for Clinical and Economic Review; IQWiG, Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen); LLMs, large language models; ML, machine learning; NICE, National Institute for Health and Care Excellence; NLP, natural language processing; PBAC, Pharmaceutical Benefits Advisory Committee; PICO, population, intervention, comparator, outcome; RWE, real-world evidence; TLV, Swedish Dental and Pharmaceutical Benefits Agency (Tandvårds- och läkemedelsförmånsverket); UK, United Kingdom; US, United States; ZIN, National Health Care Institute, Netherlands (Zorginstituut Nederland)

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