

KEY TAKEAWAYS

80%

noted the importance of **transparency and reporting** when AI is used but only 50% of these explicitly stated what should be reported

70%

stated that users are **ultimately accountable** for all outputs but only 40% of these provided detail on the level of human oversight

65%

discussed **validation** of AI algorithms and testing of outputs but only 20% of these gave recommendations for how this should be done

Recommendations to consider the rationale for using AI was identified in 35% of records:

1. Other options should be considered as AI may not be the most suitable solution

2. Multiple stakeholders should be involved in the decision to use AI

3. The need to follow a framework is itself dependent on risk

CONCLUSIONS

- Core principles are useful to align frameworks, and clear task-driven guidelines are also beneficial
- Lack of practical guidelines is a manifestation of the varied applications and fast-evolution of AI systems
- Emphasis on reporting is driven by the scientific principle of reproducibility, but this is inherently more challenging with the lack of explainability of AI algorithms
- Organisations should take a case-by-case approach in line with risk-based assessment frameworks
- Learning pathways are equally important to frameworks: they are essential to support appropriate use and integration of AI systems

INTRODUCTION

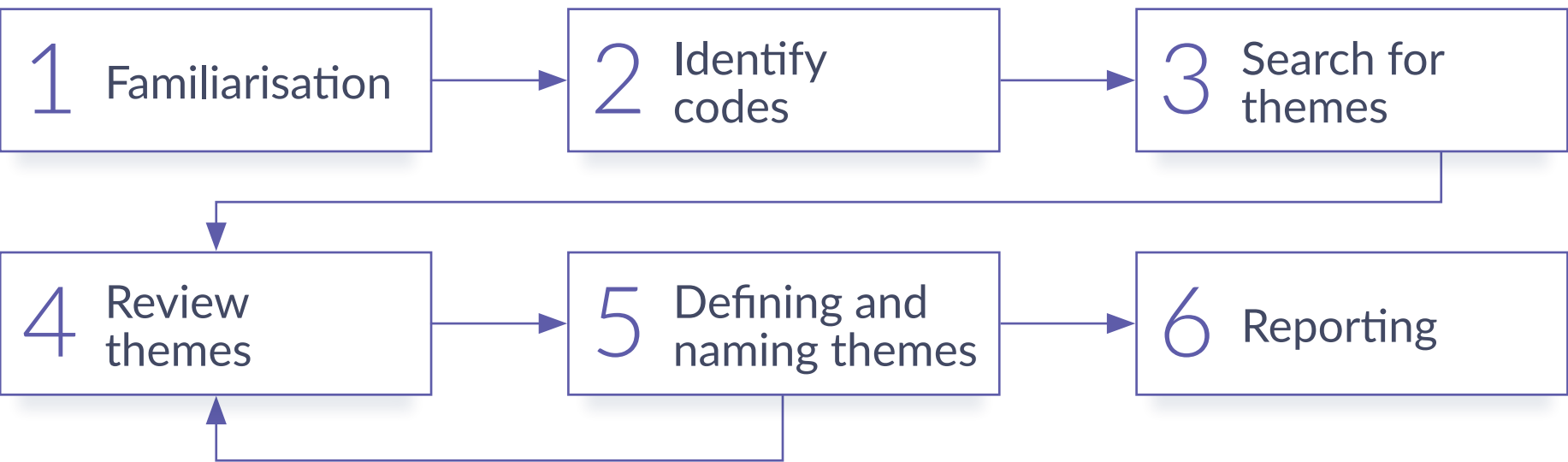
- AI is any computer system that can perform complex tasks that would typically require human intelligence, such as pattern recognition, decision-making, and problem-solving¹
- Many tasks arise from the HEOR and market access industry where AI has the potential to assist and improve on traditional methods. A few key examples include evidence review (sourcing and summarising evidence), code generation (VBA, R, Python), data analysis, and pricing strategy development

OBJECTIVES

- To understand what guidance is available on the use of AI within HEOR, and to evaluate what guidance is necessary

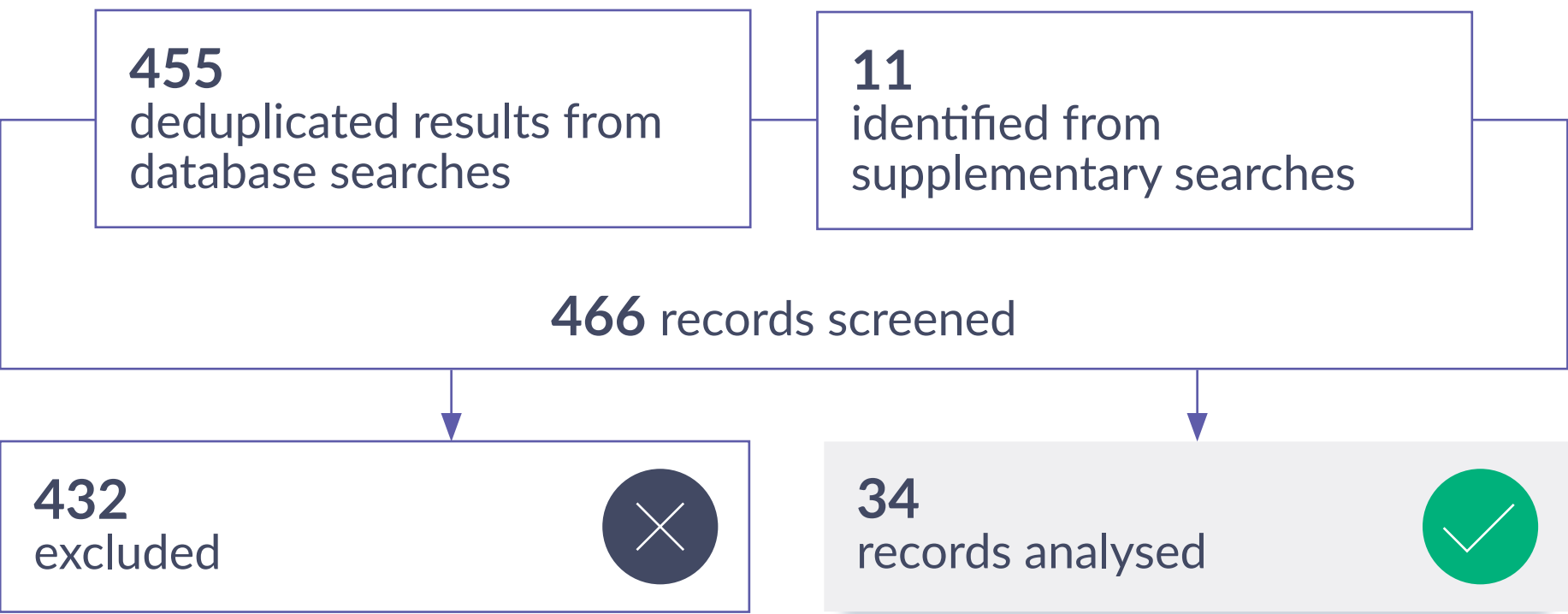
METHODS

- A targeted literature review (TLR) was conducted to find evidence of guidelines, recommendations, or critiques, of the use of the AI within HEOR and market access
- Structured searches were conducted on 26th June 2025 in MEDLINE, with supplementary searches of Semantic Scholar, WHO, FDA, EU parliament, UK gov, NICE, ISPOR, and Cochrane
- A single reviewer screened all records with a 10% validation check from a senior reviewer; enough clarity was provided in the abstracts that a second pass screen of the full text articles was not deemed necessary
- Thematic analysis was conducted on the relevant records according to Braun and Clarke guidelines²



- TLR identified 34 records (Figure 1)

Figure 1. Flow of literature



LIMITATIONS

- Not a comprehensive review. Citation lists of articles revealed several missed guidelines and frameworks.
- Heterogeneity in the objectives and methods of the articles reviewed limit the synthesis

RESULTS

- 65% records were secondary reviews or commentaries on guidelines: more theoretical than practical
- Primary frameworks/guidelines identified (35% records) included:
 - Broader guidelines with elements relevant to HEOR, e.g., EU³, UK⁴, FDA⁵, WHO⁶
 - HEOR related policies, and task-specific frameworks, e.g., NICE⁷, ISPOR⁸, RAISE⁹, Hamel¹⁰, Fleurence¹¹, Hasan¹²

Relevant themes and sub-themes, derived from 29 records, fell into two overarching categories:

1 Underlying principles
on which interactions with AI should be based

INEVITABILITY

No reviews identified blanket bans on AI use

Consensus that AI will be an agent of change

Assumption that AI will provide a/some benefit

EVOLVING LANDSCAPE

Ongoing monitoring of new systems

Responsibility to report errors/biases to developers

Need for core principles in guidance to account for this

ETHICAL AND SAFE PRACTICE

Concerns the environmental and health impacts of AI models make them unethical in this field

Data privacy and copyright issues

Issues related to systemic bias in models and training data

FRAMEWORKS

Balance needed between consistent core principles, and flexibility to adapt to changing landscape

Supplementary frameworks established according to tasks

Multi-discipline collaboration

Stakeholder engagement

2 Practical steps and considerations
to be followed in the use of AI within HEOR and MA

Accountability

Method design

Rationale

User responsibility

Foundational AI expertise

Validation

Output accuracy

Algorithms

Explainability of decisions

Sources of bias

Transparency

Lay summaries

Disclosure

Detailed reporting

Auditing

Confidence and trust

Impact of bias

Human-in-the-loop

Error reporting

Validate approach

Practical steps and considerations spanned all stages from project conceptualization through to external review

Consensus that users are accountable, with suggestion that developers are too, and an onus on users to report errors back and contribute to improved performance

The various sources of bias were a key concern

Validation needs to be specific to the use: consider the algorithm, training data, and implementation

“ no consensus on what defines a trustworthy AI, let alone how to measure it ”

Hartung.¹³

“ preservation of critical thinking abilities and ethical writing practices must be balanced with the advantages of efficiency to maintain the integrity of academic research ”

Alnaimat et al.¹⁴