Responsible AI in HTA - Introducing the NICE AI Methods for Evidence Framework

ISPOR Europe 2026

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NICE National Institute for Health and Care Excellence®

Explore the framework while you wait for the session to start

https://www.nice.org.uk/corporate/ecd20

The global context for AI governance and implementation

Mitch Higashi

ISPOR

From: Can AI support dossier development?
To: Will stakeholders *trust* what AI generates?

TRUST

Consistency

A common structure and vocabulary across products, updates, and jurisdictions.

Decision-Grade AI

Traceability

Every material claim can be followed back to its source evidence.

Human judgment

Scientific interpretation and final accountability remain human responsibilities.

Trend methodology: Following publication of the ISPOR Europe 2026 program, ISPOR analyzed the publicly available text of ~70 session abstracts and >2,000 poster abstracts using LLM-assisted thematic clustering. Building on two years of tracking AI-related content, three themes appear new or nascent.

1. Consistency - AI Governance and Trust

Core question: What makes AI-generated evidence acceptable to HTA agencies, payers, and decision-makers?

Why it matters

This cluster signals growing demand for:

- AI governance frameworks
- Validation services
- Auditability solutions
- Compliance consulting
- Decision-grade AI standards

SIGNAL: AI trust infrastructure may become an entirely new HEOR services category.

2. Traceability - AI Standardization

Core question: What common standards and infrastructure are needed for AI-enabled HEOR to scale?

Why it matters

As AI-generated analyses become more common, stakeholders are beginning to focus on:

- Standard model components
- Reproducibility
- Shared libraries
- Methodological consistency
- Validation frameworks

SIGNAL: Future value may shift toward platforms and reusable infrastructure rather than individual projects.

3. Human Judgement - Building the AI-Ready Workforce

Core question: How must HEOR professionals evolve to work effectively alongside AI?

Why it matters

Organizations increasingly require:

- AI training
- Competency development
- Organizational change management
- Workforce transformation programs

SIGNAL: AI adoption may drive substantial spending on capability-building before it drives software spending.

The NICE AI Methods for Evidence Framework

Raphael Sonabend-Friend

NICE

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Scope

Principles-based living framework with updates aligned to evolving use cases.

In scope

Principles and best-practice guidance for evidence activities.

Out of scope

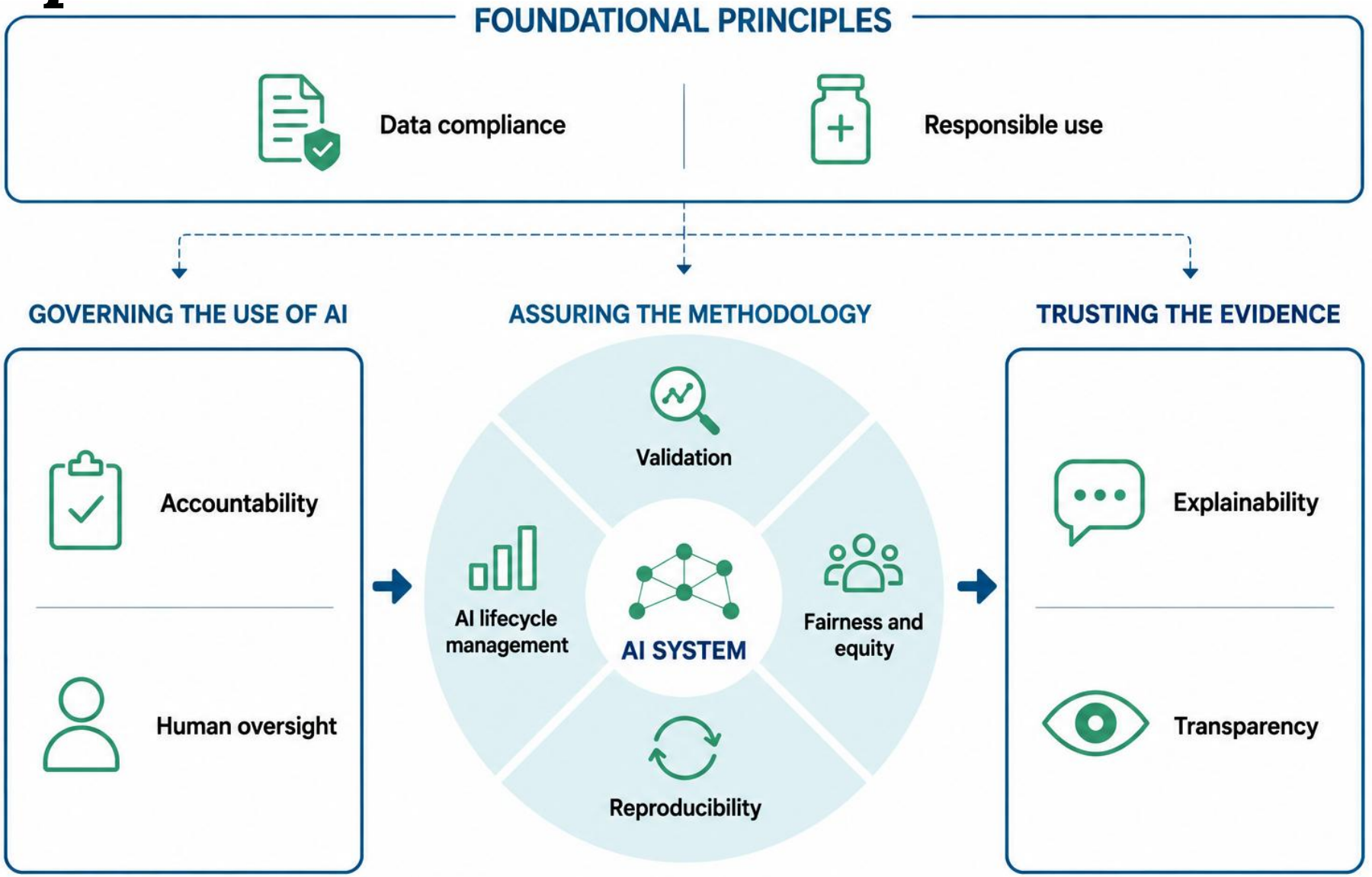
- AI-enabled health technologies
- NICE business processes
- Appraisal of specific AI tools
- Regulation

Intended users

All involved, directly or indirectly, in an evidence submission to NICE.

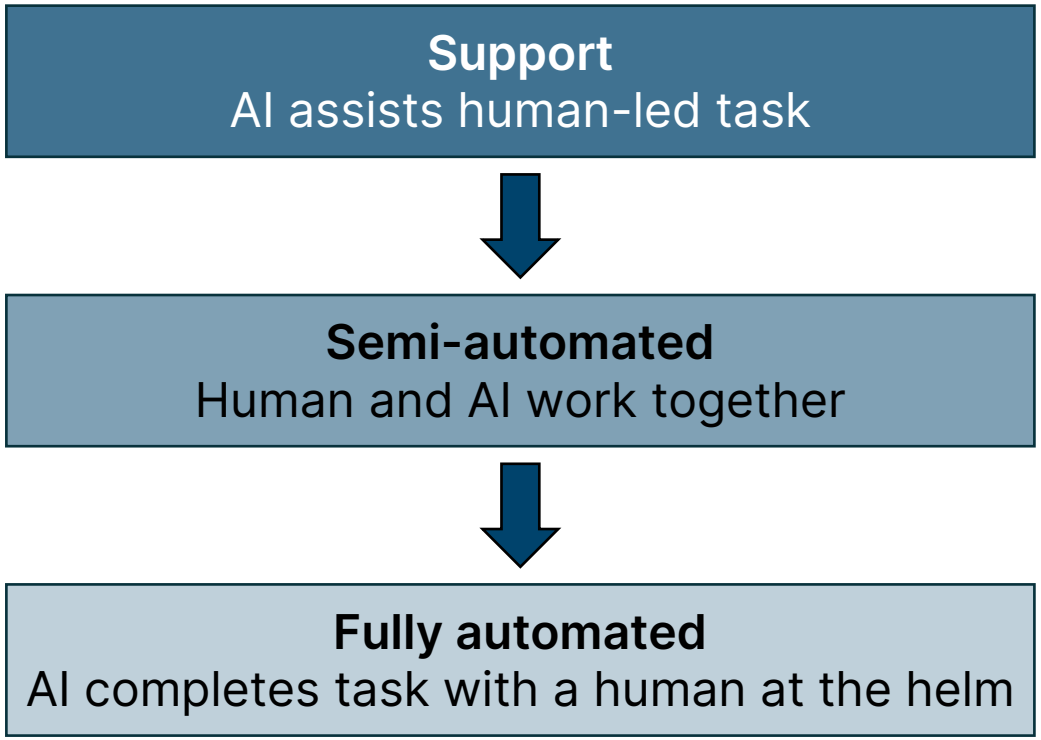
Overview
Scope
Introduction to AI in NICE decision making
Principles for using AI in evidence activities
AI methods for primary evidence generation
AI methods for evidence synthesis
AI methods for health economic evaluation
AI methods for technical documents
How the framework was developed
Acknowledgments
Appendix: A glossary of main terms used in the AI framework

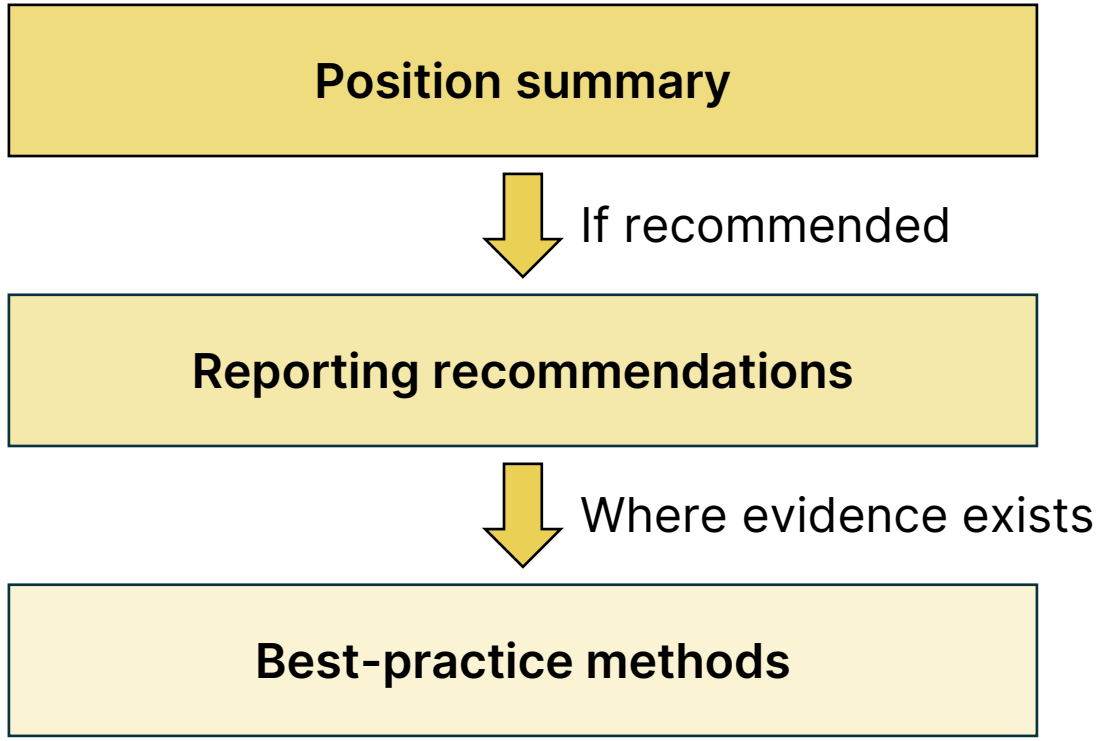
Principles



NICE

Proportionate guidance





NICE

AI declaration checklist

Purpose

Make AI use visible and reviewable

- Declare AI use across the submission.
- Show AI contributions, risk, biases, controls.
- Support interpretation, scrutiny, reproducibility and audit.
- Developed iteratively through the HTA Lab AI submission pilot.

Application

#1-2 **Map every use of AI**

List all uses and specify risk and influence.

With material risk or influence

#3-21 **Detailed reporting**

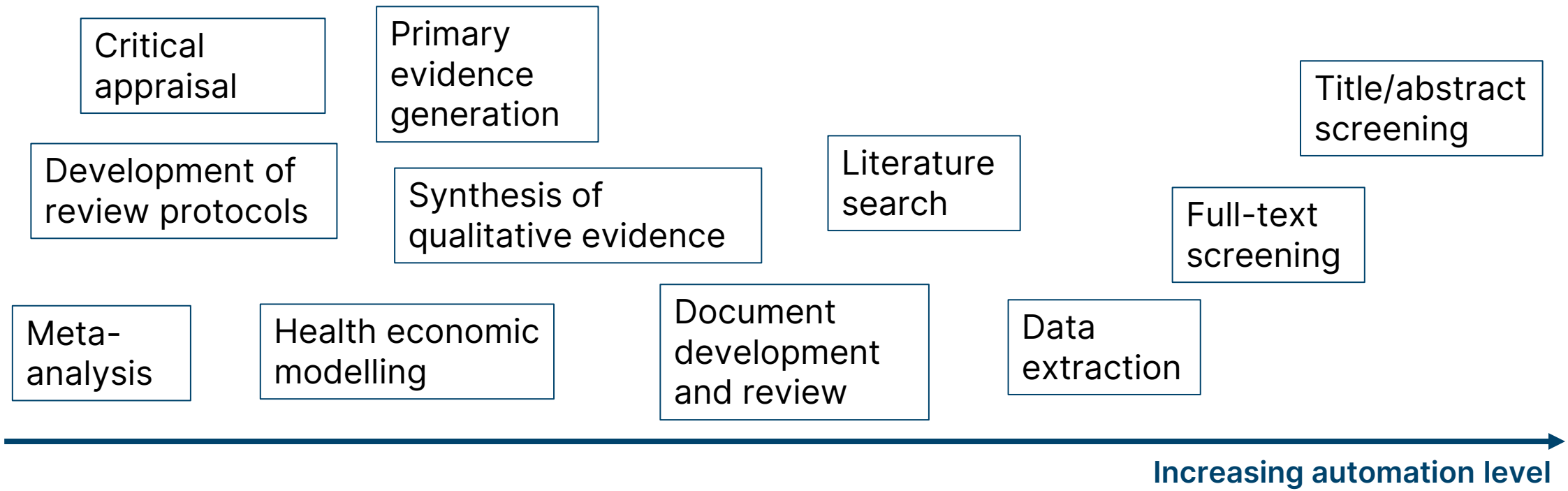
Explain and justify AI use, including inputs, outputs and human oversight.

Alignment

Supports framework reporting

- Mirrors principles and terminology.
- Translates principles into reporting checks.
- Supports consistent, proportionate scrutiny across submissions and critiques.

Currently included use cases



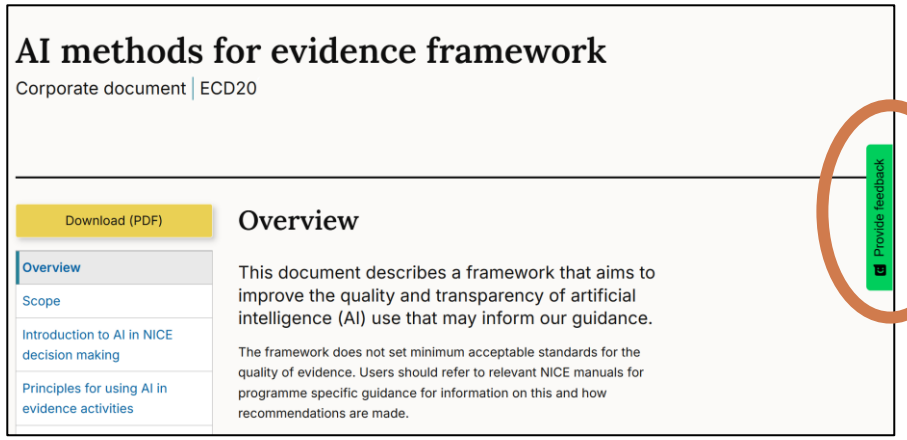
Disclaimer: Positions are illustrative and do not necessarily reflect recommended automation level. All use cases may be updated in future versions to change recommendations and/or level of detail.

Next steps

1. Do you agree with the guidance?
2. Does the framework correctly balance innovation and safety?
3. Is the framework clear and practical to implement?

You Are Here

ISPOR draft launch → Public feedback → v1 launch



https://www.nice.org.uk/corporate/ecd20

Publish → Prioritise → Draft → Review

Bristol Myers Squibb®

Reflection on the NICE AI Framework

Sven Klijn, Bristol Myers Squibb

Disclosure

Sven Klijn is employed by, and owns stock in, Bristol Myers Squibb.

The opinions expressed in this presentation and on the following slides are those of the presenter and do not necessarily represent formal positions of Bristol Myers Squibb.

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Framework provides clarity on expectations



Different levels of guidance

Use case guidance ranges from limited holding statements, to position summaries, to best-practice guidance

Shows where evidence is still developing in a young field



What good looks like

Ten principles across foundational, governance, assurance and trustworthiness domains

Helpful for anyone building AI tools in the HTA space



What to report

The AI Declaration checklist, with full detail reserved for use cases with material influence or risk

Helpful for manufacturers preparing evidence packages

Reporting effort should be proportional to risk & influence

2

Items for every AI use

#1 AI use map
Where was AI used?

#2 Influence
Does the AI use have a material risk or influence on the evidence submission?

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Items for uses with material risk or influence
Material influence includes outputs "(i) directly used as evidence, (ii) used to generate or transform data later analysed, (iii) used for complex tasks typically performed by an expert […]"

Responsible use	Transparency (4)	Explainability
Human oversight (2)	Validation (2)	Reproducibility (3)
Accountability (2)	Lifecycle management	Fairness and equity
Data compliance	Reporting completeness	

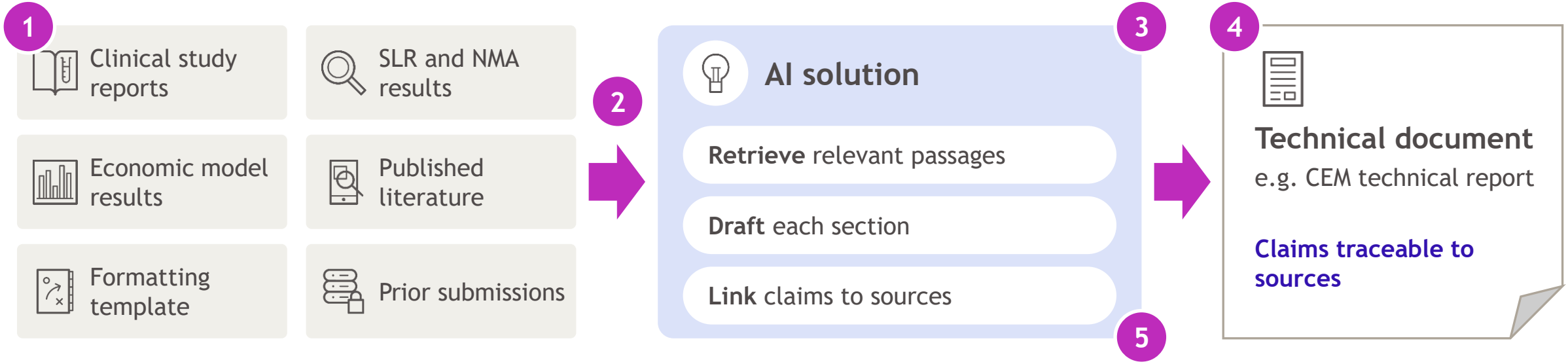
Influence × Consequence = **Model risk**

FDA draft guidance (Jan 2025)
Credibility evidence scales with model risk

Case study: technical document generation

What the NICE AI Framework asks for

- Expert review of all AI outputs
- Outputs linked to verbatim quotes or sources
- Reviewer expertise, role and responsibilities stated
- Proportionate oversight: in-the-loop or at-the-helm



1. Curate permitted sources
2. Select input data
3. Iterate with the AI
4. Review and verify output
5. At the helm of the process

Each working model has its own points of attention



In-house

Validation: evidence that tools are fit for purpose

Accountability: clear roles across different stakeholders

Auditability: logging and versioning by design

Lifecycle management: re-validation on change

Hybrid

Validation: interaction between company data and external AI tool

Accountability: clear boundaries between platform integrity and generated outputs

Auditability: access to model version, settings, input and output logs

Lifecycle management: notice of platform changes

Outsourced

Validation: evidence that tools are fit for purpose

Accountability: vendor roles and responsible handover

Auditability: where and how AI was used

Human oversight: vendor reviewer expertise



Company is accountable for evidence submissions, irrespective of the working model

Conclusion

Summary

- Clear expectations for AI use in evidence generation
- Proportionate reporting based on the risk and influence of each AI use

Next steps

- Continued refinement as the evidence base matures
- Guidance that extends to agentic AI workflows
- Broad stakeholder input to shape future updates

Panel discussion



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NICE Committee Chair



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Audience discussion

How can we achieve greater consistency in AI governance while supporting innovation and access to technologies?

Audience discussion

What are the biggest barriers to implementing

AI solutions in evidence activities?

Audience discussion

What are the biggest barriers to implementing standardised principles across AI solutions?

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Thank you

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