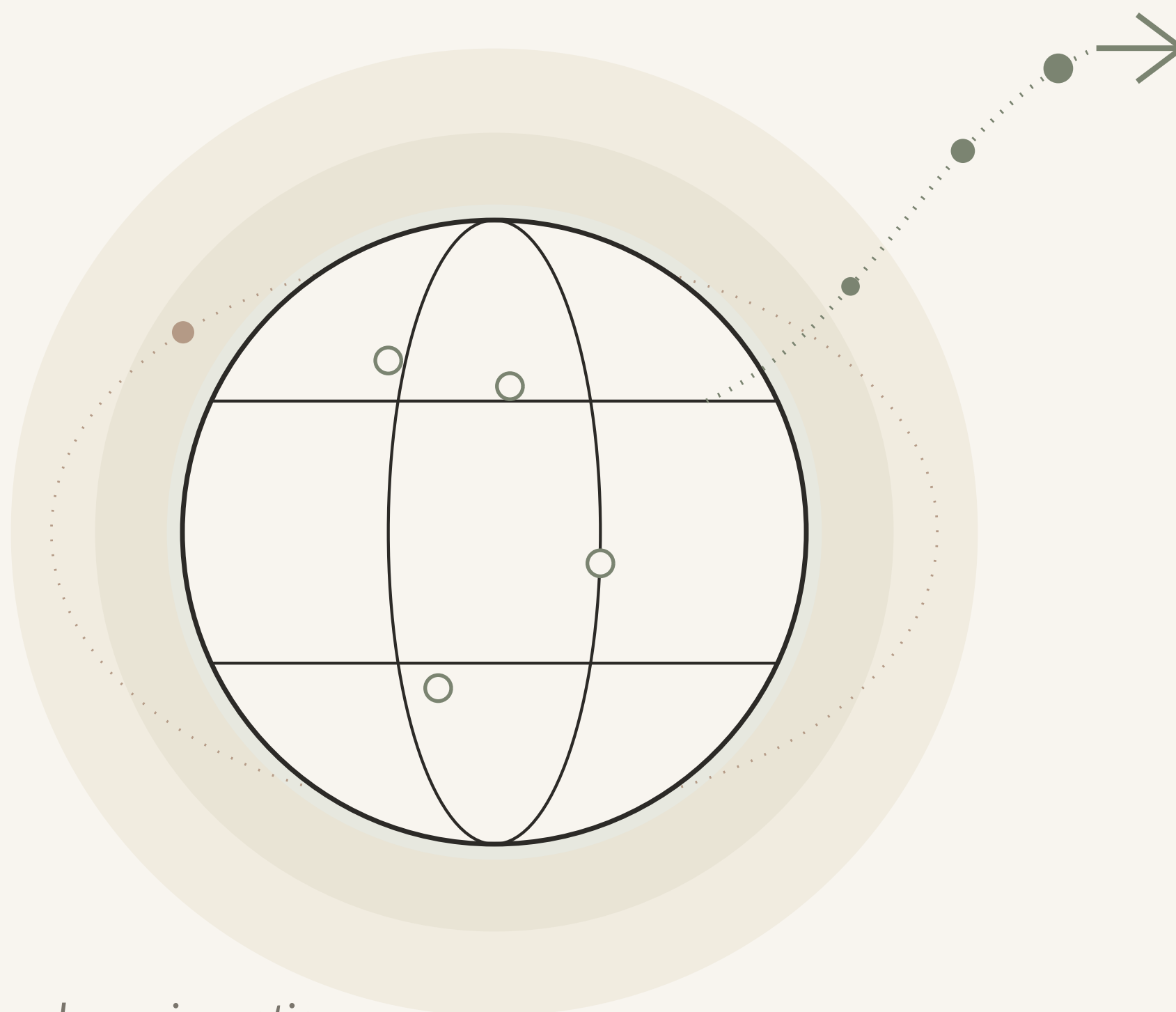




A world of evidence, always in motion.

Designing evidence for the journey, not just the milestone.

What AI, JCA and real-world data actually change about HEOR — and what they don't.

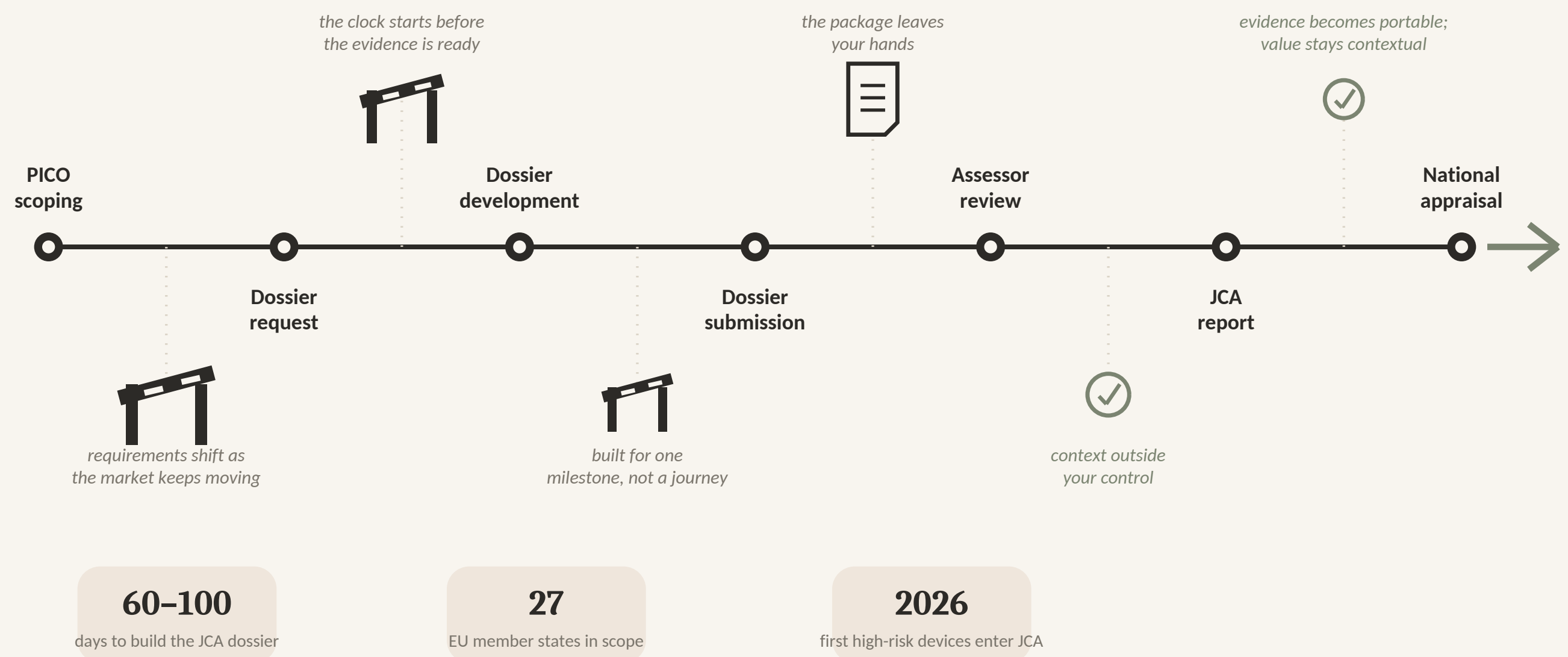




THE ROADMAP

The real submission journey — and where each argument clears a roadblock.

● MILESTONE • A REAL STEP IN THE PROCESS 🚧 ROADBLOCK • AN ASSUMPTION THIS ARTICLE CHALLENGES



Every argument in this deck removes one assumption. By the end, only the system remains.

SOURCE: EU HTA REGULATION • JOINT CLINICAL ASSESSMENT PROCESS, HTA COORDINATION GROUP



ROADBLOCK 1 • THE PREMISE

AI makes evidence faster. JCA makes it shareable. Real-world data makes it continuous. None of it answers the only question that matters.

AI

accelerates literature reviews, structures complex datasets, speeds up analysis

JCA

reduces duplication across 27 EU member states

Real-world data

lets evidence keep learning after launch

ISPOR 2026-27 TOP HEOR TRENDS

- 1 Artificial Intelligence
- 2 Real-World Evidence
- 3 Value-Based Healthcare

Hybrid AI-human workflows outperform fully automated approaches.

Evidence only creates value if it reaches the decision it was designed to support.



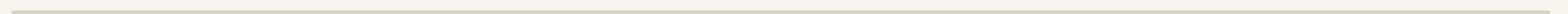
ROADBLOCK 2 • THE WRONG SHAPE

We build evidence around a milestone. The world keeps moving after we ship it.

BUILT AROUND A MILESTONE



Submission



DESIGNED AROUND A JOURNEY



Regulatory

HTA

Reimbursement

Launch

Practice

WHAT KEEPS MOVING AFTER THE SUBMISSION

Clinical practice

changes

Comparators

emerge

Patient populations

become better understood

New evidence

changes what we knew

Sometimes the most important change is that the question itself has changed.



ROADBLOCK 3 • THE OBESITY EXAMPLE

The market was not shifting categories. The category itself was being redefined.

Lifestyle issue



Chronic disease

- Who is the relevant patient?
- What is the unmet need?
- Where does treatment belong in the pathway?
- What does value mean, here?

WHAT NICE'S OWN FRAMEWORK HAD TO ABSORB

Long-term treatment effects

Discontinuation

Comorbidities

Care pathways

Resource implications

SOURCE: NICE — DISEASE-SPECIFIC REFERENCE CASE EXTENSION, OVERWEIGHT & OBESITY IN ADULTS

The task was never only to prove the treatment worked. It was to explain what a changing disease meant for the system around it.



ROADBLOCK 4 • THE US PATHWAY

Access is not one decision. And it doesn't stop at four.



FDA already signals that regulatory evidence may not be enough for coverage. CMS links coverage decisions to further evidence generation. Access is a living pathway, not four fixed doors.

Evidence does not move through healthcare in a straight line.



ROADBLOCK 5 • JCA AND NATIONAL CONTEXT

Evidence may become portable. Value stays deeply national.

UNITED KINGDOM

NICE

Weighs the decision problem, population, comparator, uncertainty and implementation — not clinical evidence alone.

SWEDEN

TLV

Follows drug utilisation and treatment effects in clinical practice, after the reimbursement decision.

DENMARK

Medicinrådet

In dialogue with the other Nordic countries on a more consistent approach to assessing new medicines.

The EU HTA framework supports a joint clinical assessment, while pricing and reimbursement decisions stay at national level.

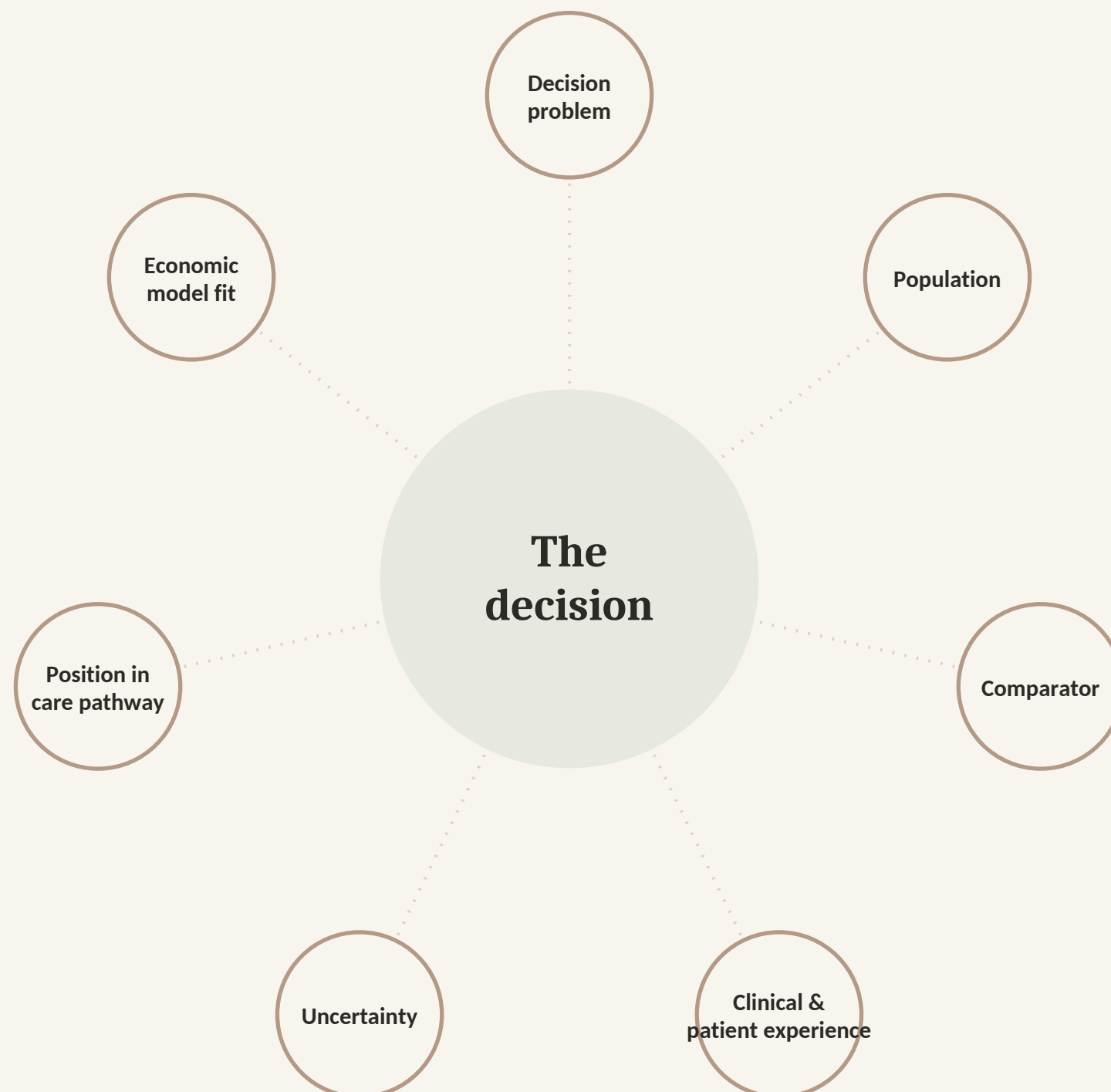
SOURCE: EUROPEAN COMMISSION — HEALTH TECHNOLOGY ASSESSMENT

JCA will not make national HEOR disappear. It will make the contextual part of HEOR matter more.



ROADBLOCK 6 • WHAT CONTEXT ADDS

A sophisticated analysis can still be the wrong analysis.



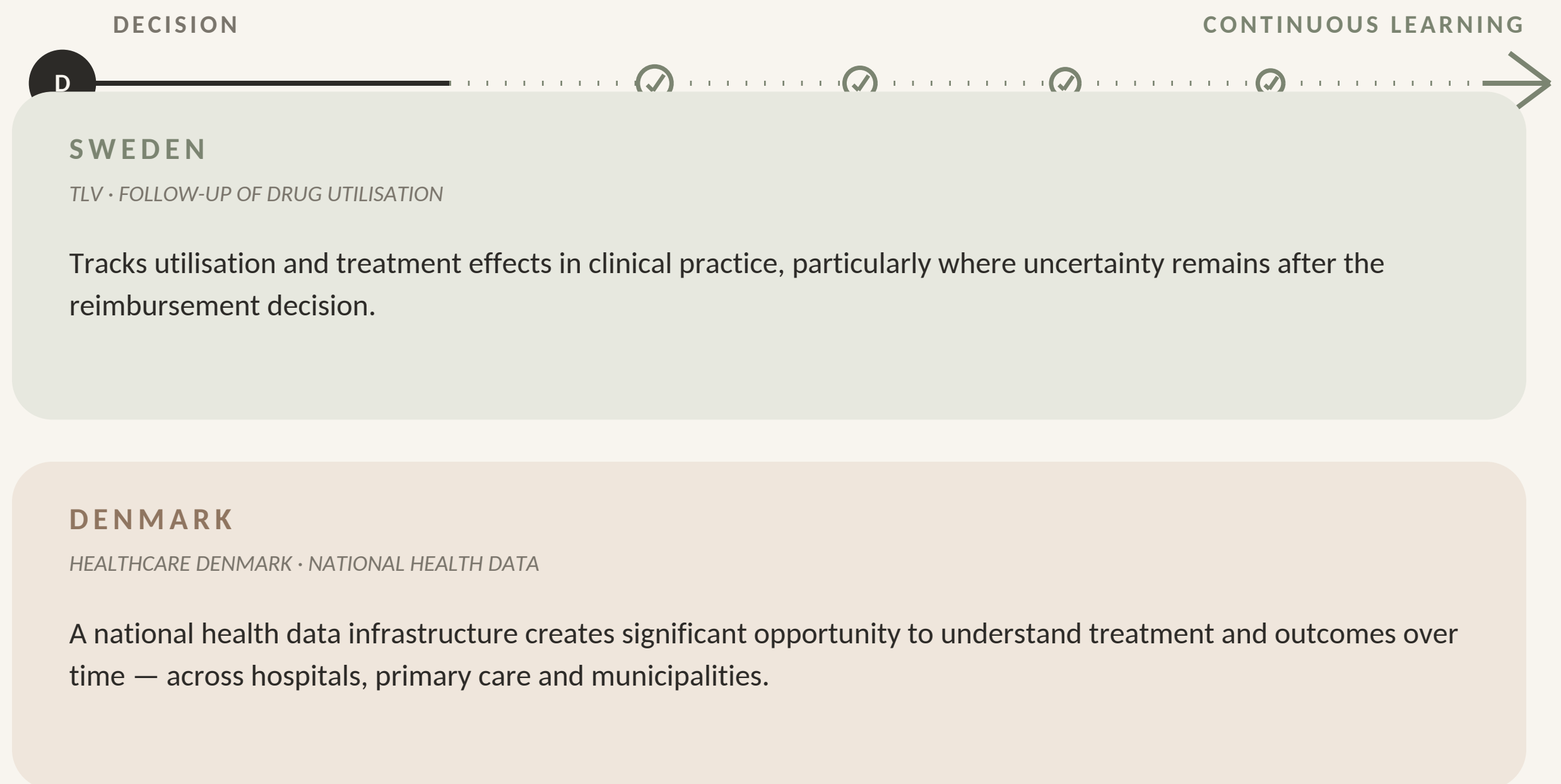
NICE'S HEALTH TECHNOLOGY EVALUATION — WHAT IT WEIGHS BEYOND CLINICAL EVIDENCE

- Where do the economic consequences land?
- Who carries the uncertainty?
- Who has the authority to act on the evidence?

A sophisticated analysis can still be the wrong analysis, if it does not answer the question that matters to the decision-maker.



The decision is not the finish line.



The opportunity is not simply more real-world evidence. It is more continuous evidence.



ROADBLOCK 8 • THE NEXT STEP

Evidence is not a deliverable. It is a system that has to keep working.



Not a choice between generic and bespoke, manual and AI-enabled, or global and local — but what can be standardised, what stays contextual, and how evidence evolves.



TO CLOSE

Evidence is not the strategy.

The strategy is understanding the journey.

CONCLUSION

We are moving from evidence built for a single decision, to evidence that stays connected to the decision throughout its lifecycle. The HEOR professional of the future is not the one who produces the most sophisticated analysis — it is the one who knows what evidence needs to exist, why it matters, and when the question itself must change.



ROADBLOCKS CLEARED



ABOUT THE AUTHOR

Jasmin Cecilie Tiedemann is a Market Access & HEOR Strategist and lawyer by training (Cand.jur., University of Copenhagen), with 14 years across Pharma and MedTech at Novo Nordisk, Coloplast and Orifarm. She is the published author of a series of articles on AI, HEOR and evidence generation.

