

Early HTA for medical devices

from unmet needs to sustainable innovation

Mirre Scholte, PhD
Assistant professor, Radboudumc
Mirre.Scholte@radboudumc.nl

Radboudumc

Large influx of MedTech



- 500,000+ devices
- 300,000+ apps
- Every 30 seconds a new patent is filed

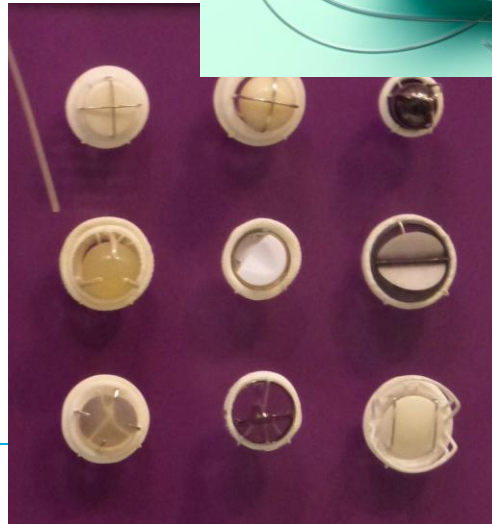
FDA device approvals 2024

- 3107 incremental improvements
- 120 novel devices
 - 35-40 high risk

1900

Radboudumc 2026

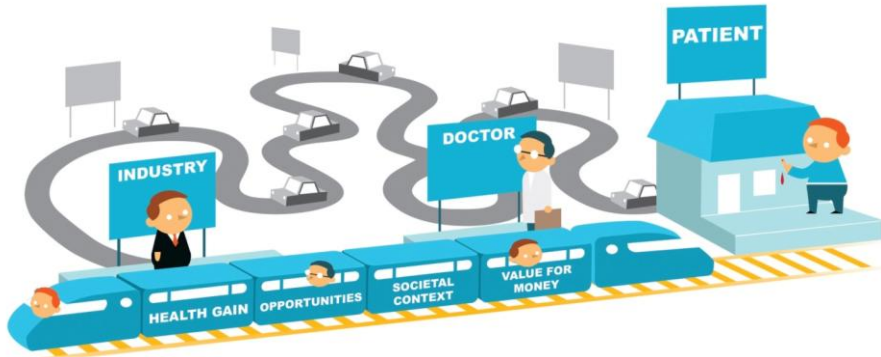
Revolutionary devices



Worst case scenario



Desired scenario



- Ideally, we aim for innovations that:
- Have added value
- Are affordable
- Are in line with the needs of patients and the healthcare system

How can we achieve that?



Only invest in the stars

Early HTA



- Systematically explore under what circumstances an innovation meets those needs
- Focus is on decisions in the further development of the technology
- Need for adaptations to the technology
- What studies to conduct
- What might the costs be and is that societally acceptable
- The earlier the better!

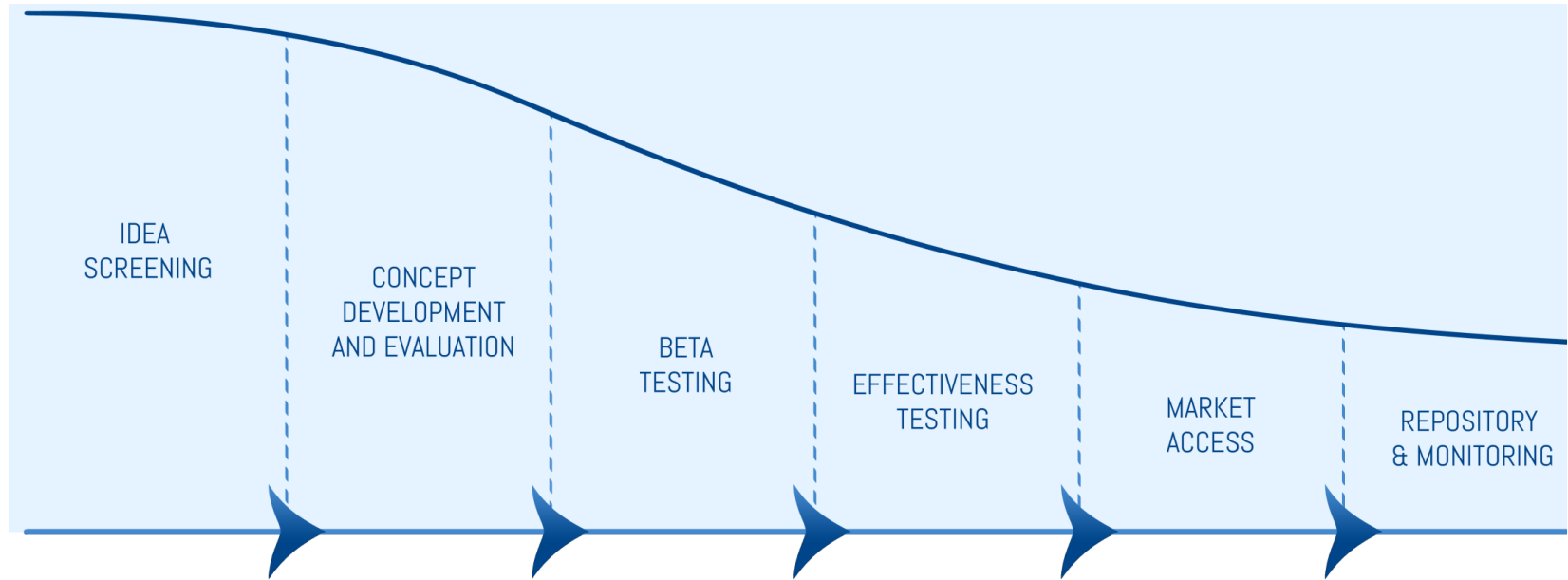
What is (early) HTA?

A multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle.

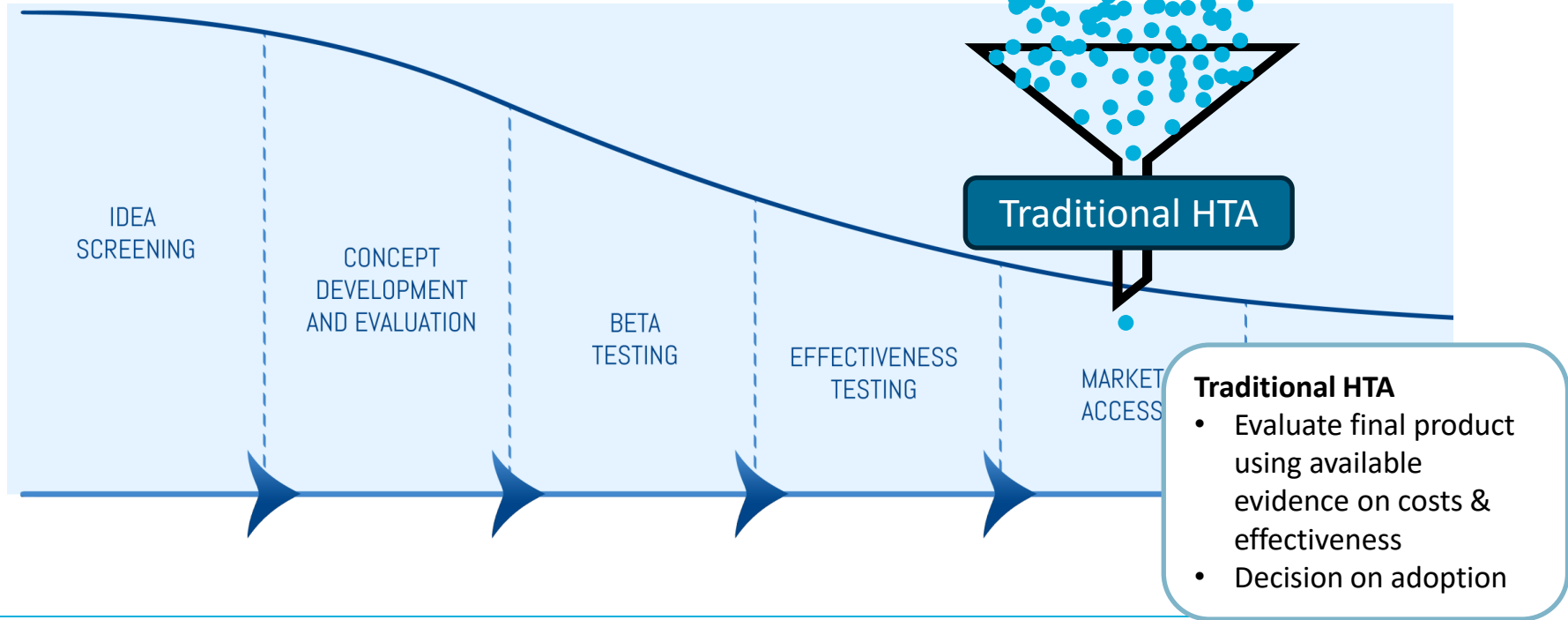
Early HTA

A HTA conducted to inform decisions about subsequent development, research and/or investment by explicitly evaluating the potential value of a conceptual or actual health technology.

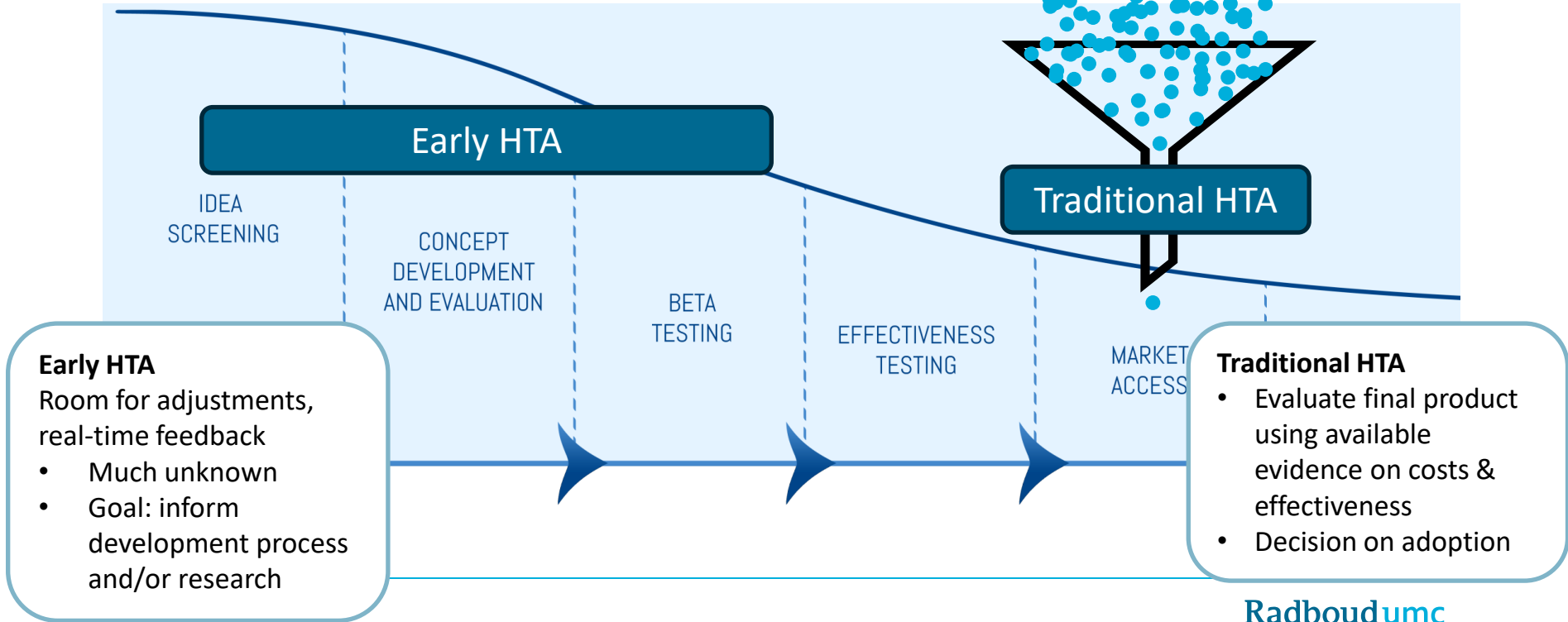
Innovation lifecycle



Lifecycle HTA



Lifecycle HTA



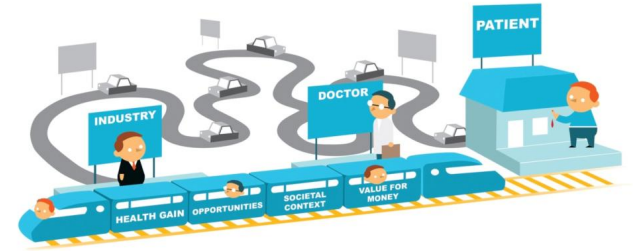
For whom is early HTA?



Innovator

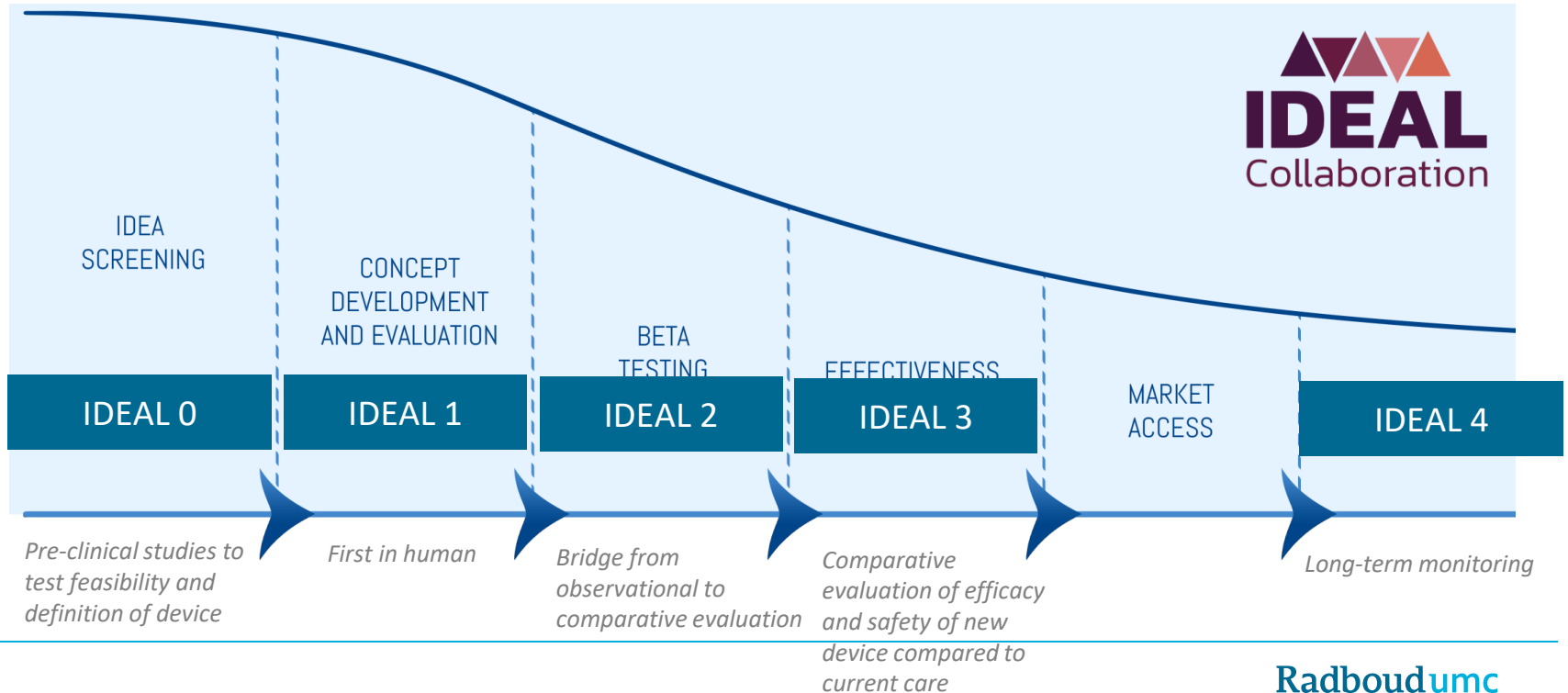


Healthcare provider
Hospital

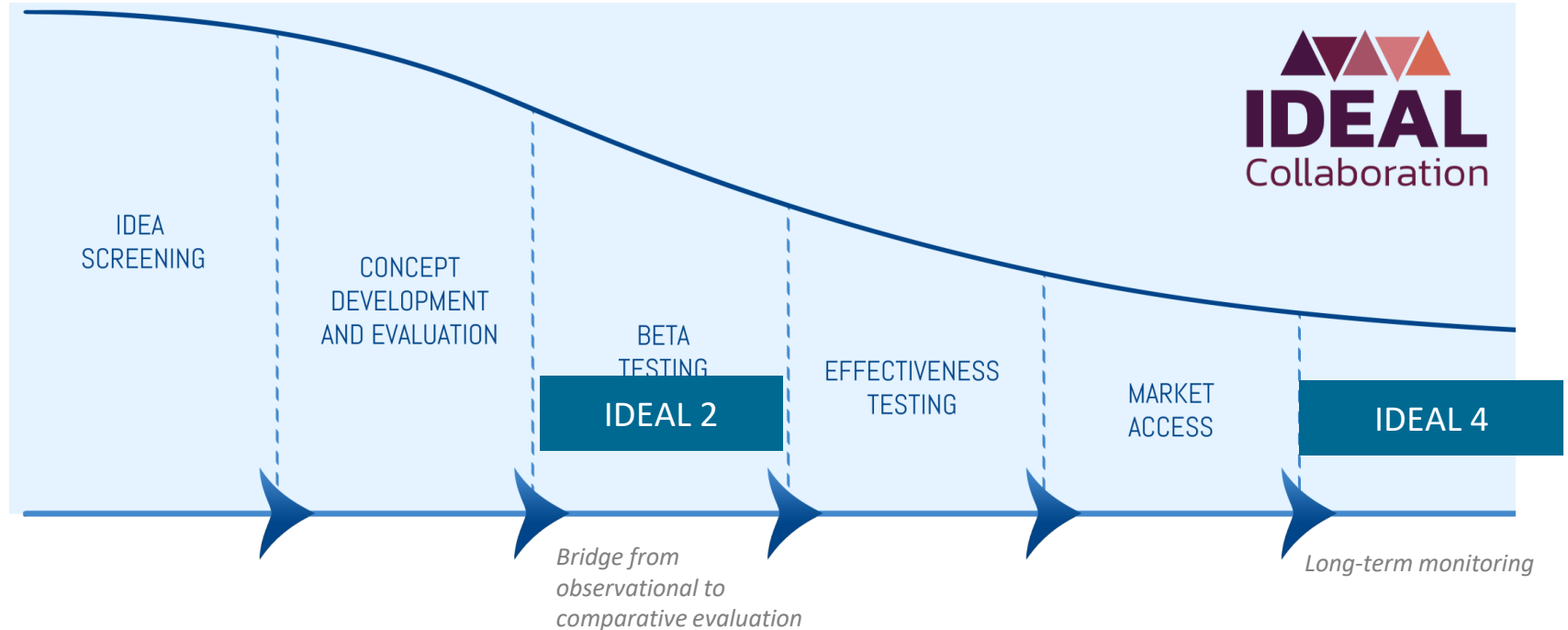


Society

High risk device research



Low risk device research



High risk device research

Problem exploration

Assessment

Anticipation & optimisation

IDEAL 0

IDEAL 1

IDEAL 2

IDEAL 3

IDEAL 4

Pre-clinical studies to test feasibility and definition of procedure

First in human

Bridge from observational to comparative evaluation

Comparative evaluation of efficacy and safety of new procedure compared to current care

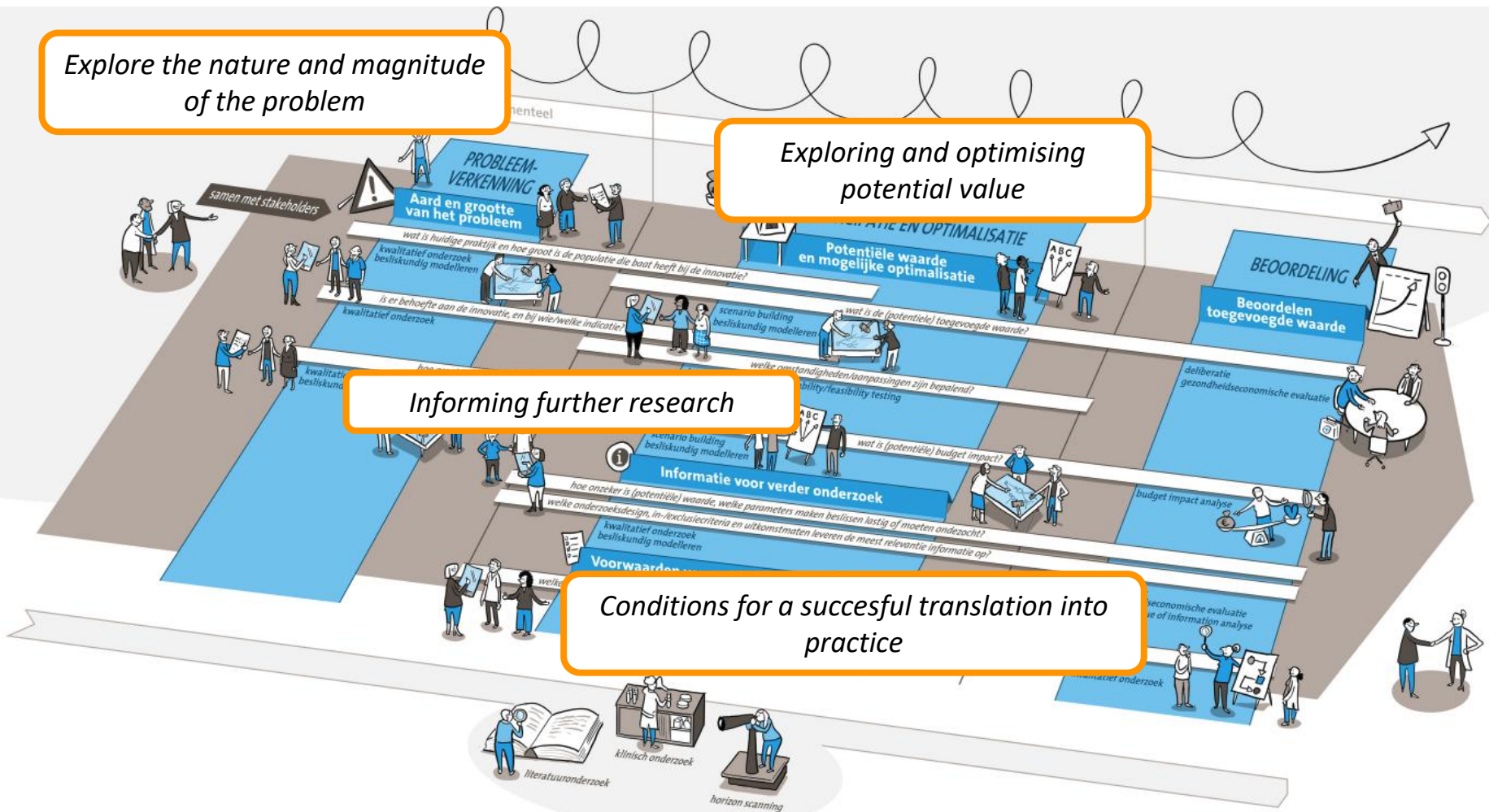
Long-term monitoring

Explore the nature and magnitude of the problem

Exploring and optimising potential value

Informing further research

Conditions for a succesful translation into practice



The early HTA toolbox

Evidence synthesis



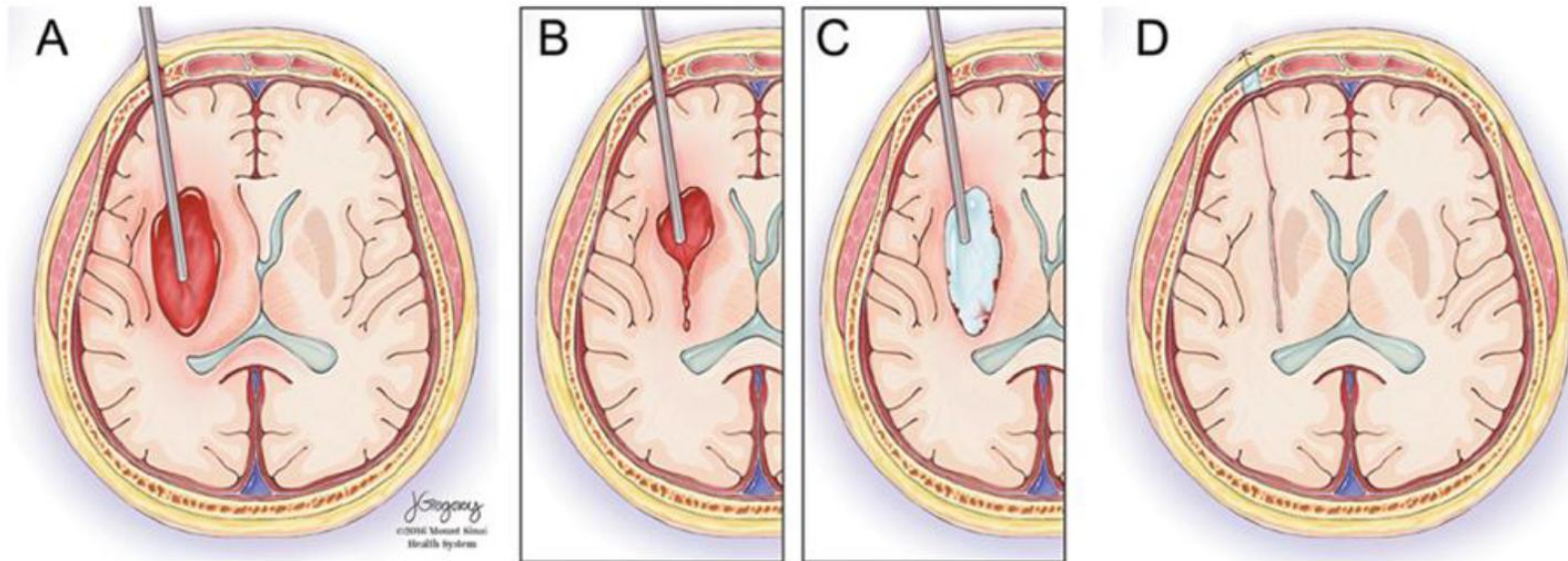
Stakeholder involvement



Decision analytical modelling



Example: minimally invasive surgery for ICH



Early HTA results

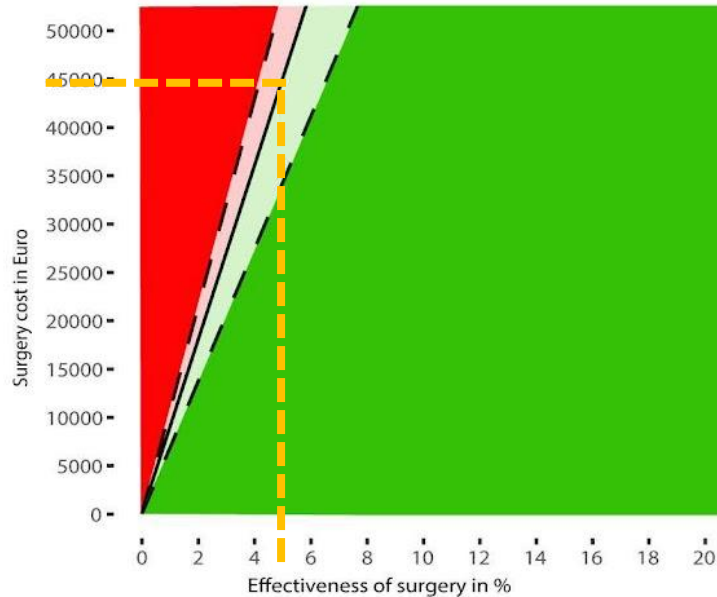


The sooner surgery starts after ICH, the more effective the operation is



Psychological wellbeing is very important
Deferred informed consent is feasible
Burden on informal caregivers is large, include in further research

Early HTA results



- Cost-effective at low effectiveness thresholds
- In patients with a poorer prognosis, surgery must demonstrate greater clinical effectiveness to remain cost-effective
- The frequency and impact of complications require further investigation



Inform trial

- Surgery within 8 hours of symptom onset
- Deferred informed consent
- Extra questionnaires for psychological wellbeing and burden on informal caregivers
- Very bad cases of ICH are excluded, as more effectiveness is needed here



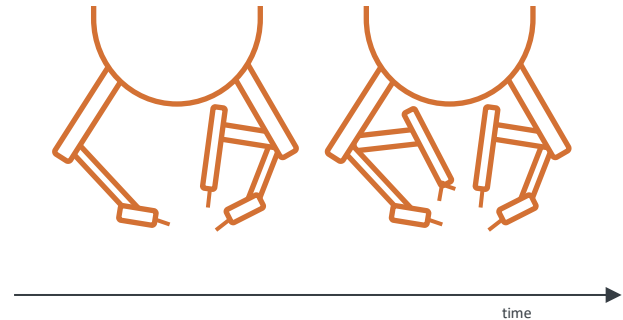
MedTech and early HTA



Specific challenges in medical devices

- Changes in devices over time
 - What adaptations may have added value?
 - Lifecycle HTA: Iterative approaches can evaluate the impact of these changes

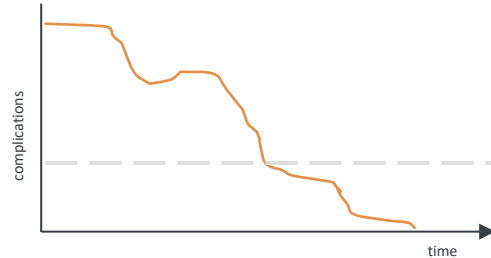
Incremental innovation



Specific challenges in medical devices

- Changes in effectiveness and safety over time
- When is it good enough?
- Lifecycle HTA: Iterative approaches can evaluate the impact of these changes

Learning curve



Specific challenges in MedTech

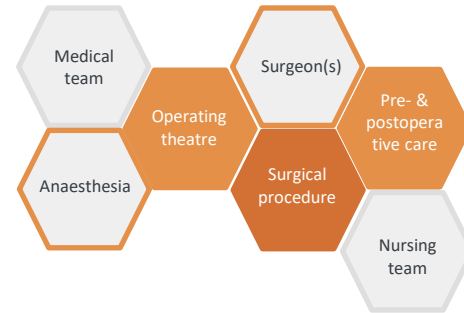
- Medical devices are user products
 - Interaction with their environment
 - Implementation is important
- More uncertainty about added value
- Determine minimal quality for cost-effectiveness in an early stage



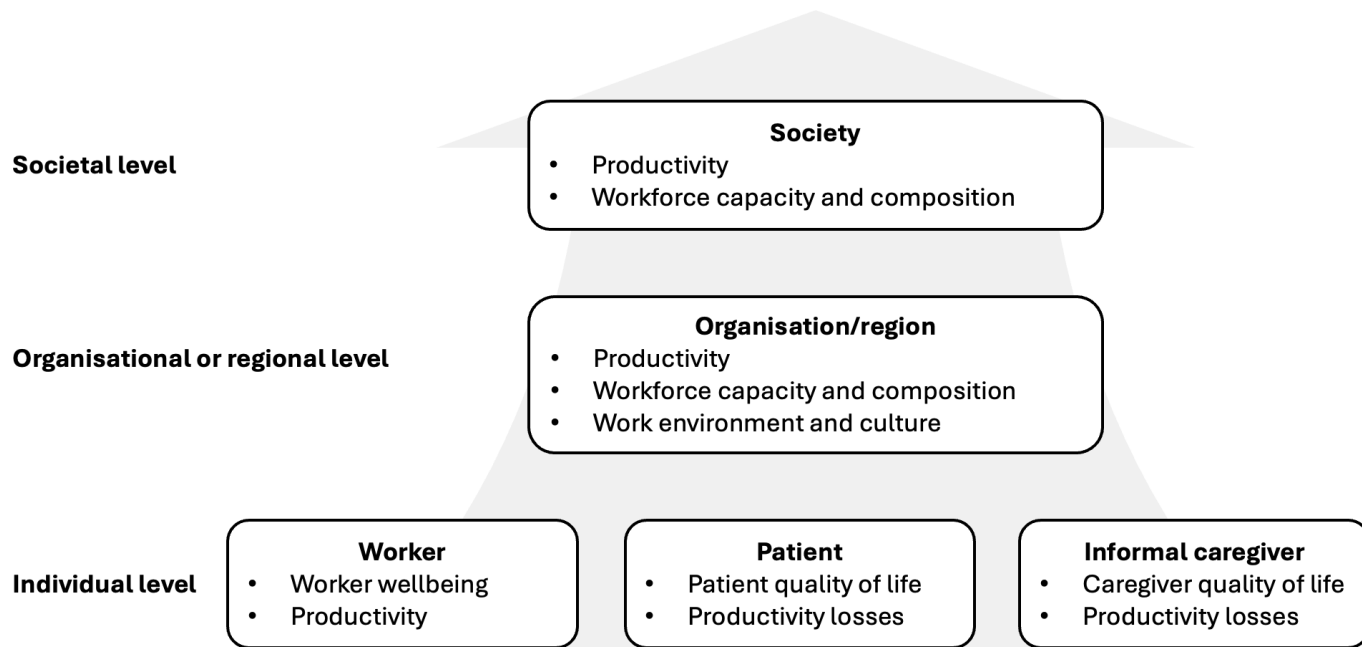
Specific challenges in MedTech

- Interaction with healthcare professionals
 - Interaction with environment
- What factors cause uncertainty and can be controlled?
- Measure impact on labour

Organisational impact



Impact on labour



Impact on labour

Worker

- Worker wellbeing
- Productivity

Please send me an email if you want to join our Delphi study on this framework!

- Productivity
 - Amount of tasks
 - Time spent
- Worker wellbeing
 - Autonomy
 - Competence
 - Relatedness
 - Meaningful work
 - Emotional, physical and cognitive impact

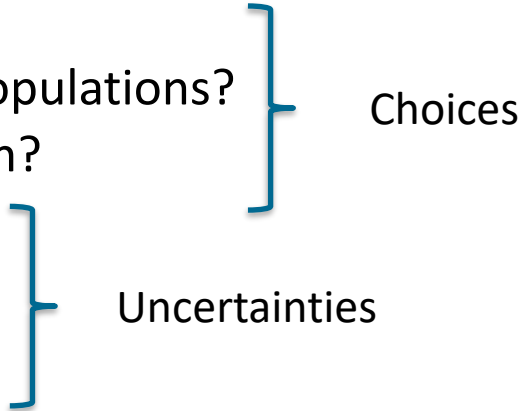
Challenges in early HTA for MedTech

“From unmet needs towards sustainable innovation”

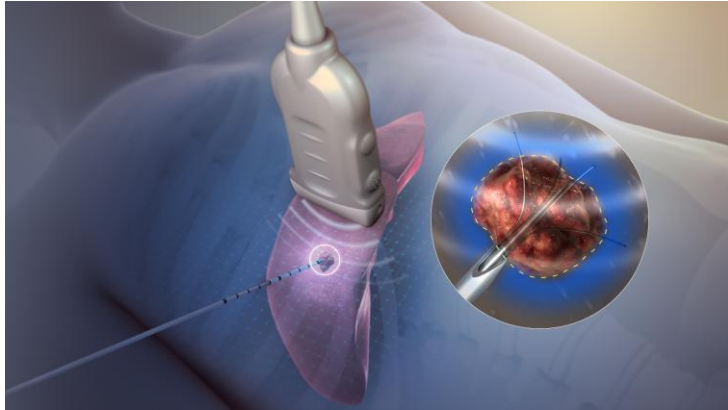
- Broadening the assessment
- Dealing with multi-indication devices
- Counter the tech push
- One size fits all?



Broadening the assessment

- In early development stages we explore uncertainty, but often forget to explore critical choices
 - Which disease?
 - Which patient populations?
 - Which innovation?
 - Effectiveness?
 - Risks?
 - Costs?
 - Start early!
 - Explicitly incorporating choices enhances the agency of HTA
- 
- The diagram consists of two blue brackets. The first bracket is on the right side, grouping the items 'Which disease?', 'Which patient populations?', and 'Which innovation?' under the label 'Choices'. The second bracket is on the left side, grouping the items 'Effectiveness?', 'Risks?', and 'Costs?' under the label 'Uncertainties'.

Dealing with multi-indication devices



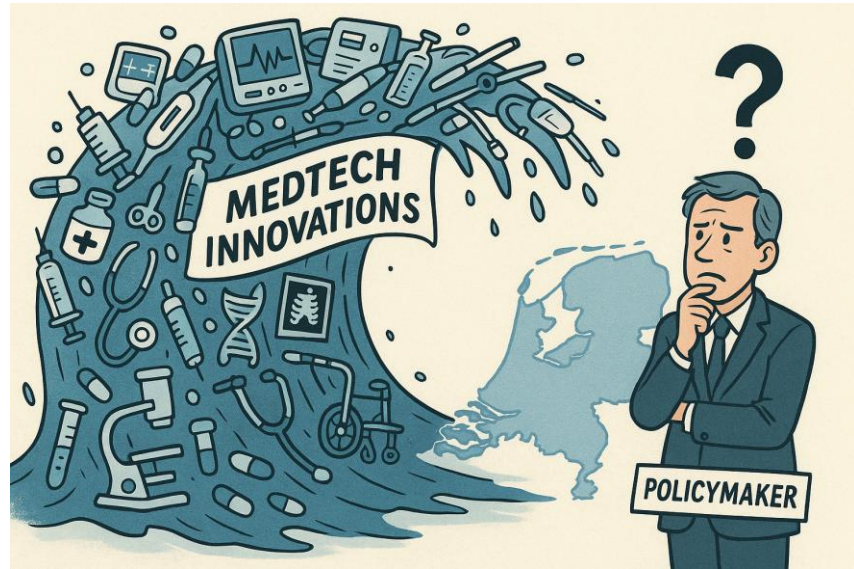
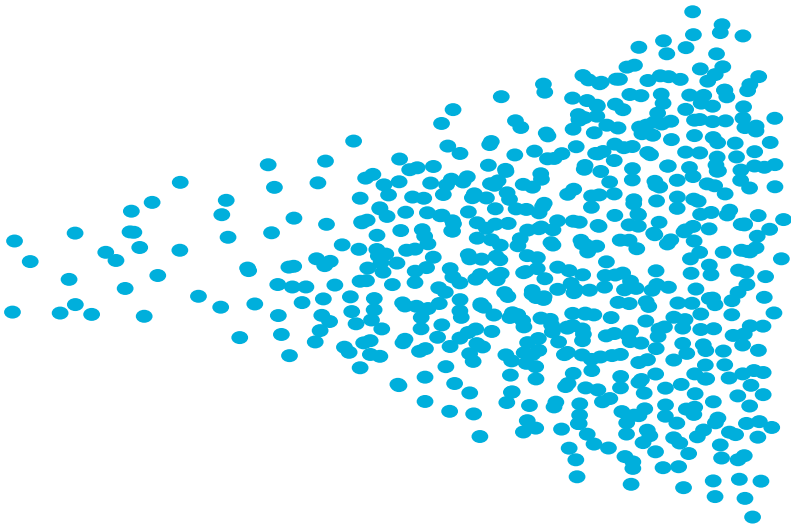
Harrison.ai chest X-ray (CXR) is a comprehensive AI solution for chest X-rays that detects up to 124 findings in under 20 seconds, boosting emergent and incidental capture while surfacing urgent cases for review first – all within the workflow you're used to.

→ Gradual increase in indications, can we steer the direction with early HTA?

→ Evaluate consequences for 124 findings?

Counter the tech push

- Solution in search for a problem

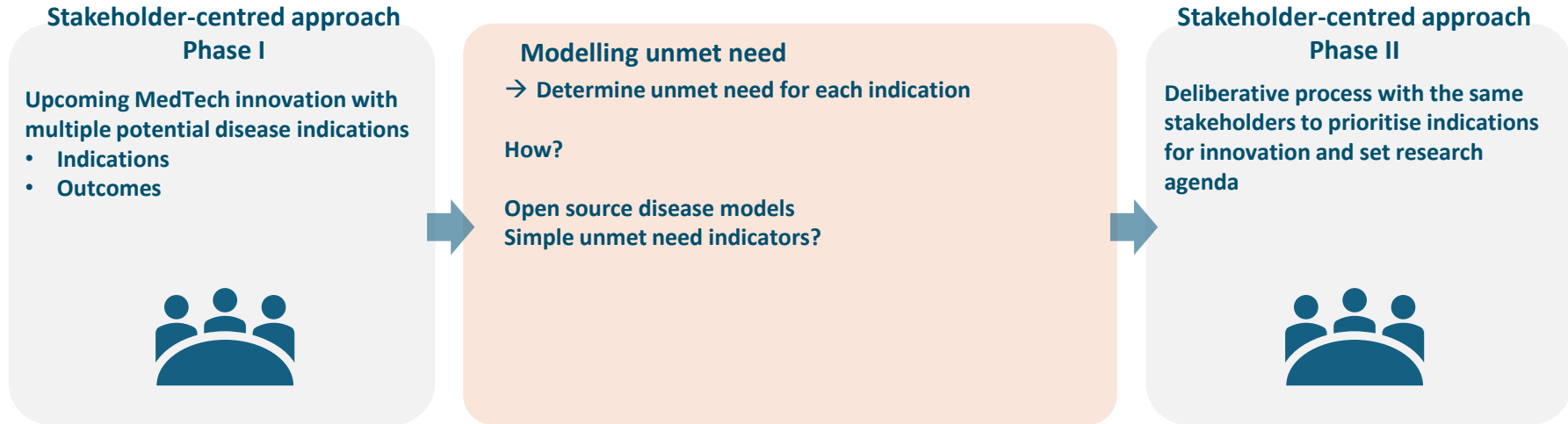


Counter the tech push

- Towards needs driven innovation
- Priority setting → indications with largest unmet need
- New methods that keep up with the pace of innovation

Facilitate needs driven innovation

Combine fast, scoping HTA exercises with key stakeholder involvement



One size fits all?

IDEAL 0

Pre-clinical studies to test feasibility and definition of procedure

IDEAL 1

First in human

IDEAL 2

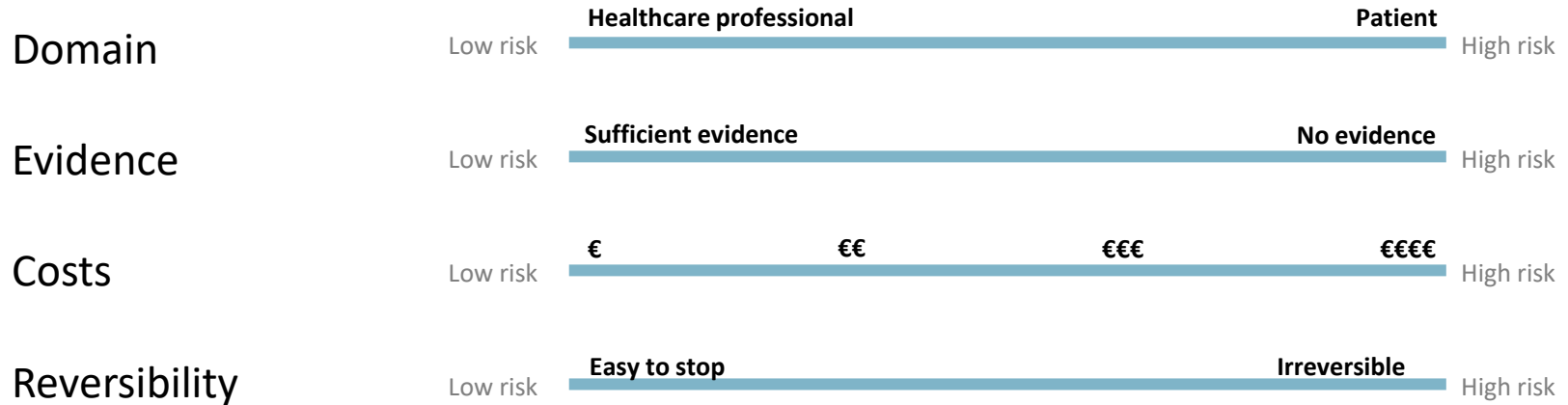
Bridge from observational to comparative evaluation

IDEAL 3

Comparative evaluation of efficacy and safety of new procedure compared to current care



Risk assessment



- ...
- The higher the risk, more elaborate assessment needed
 - Need guidelines that link risk classification to research, adoption and reimbursement

To conclude...

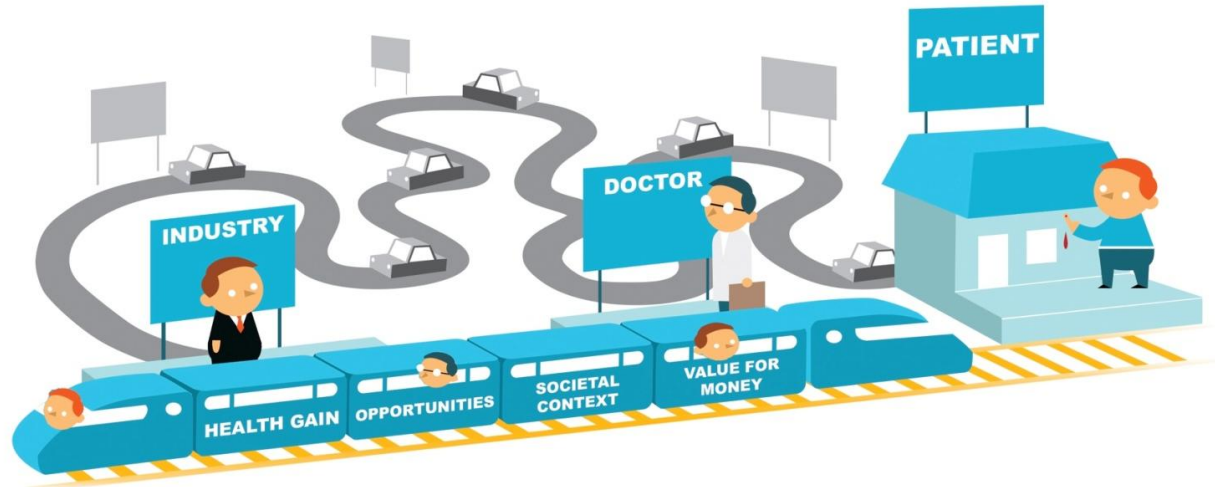
- Early HTA useful to evaluate the promises of MedTech in an early stage, and explore the circumstances for added value
- Can deal with specific challenges for MedTech

BUT

We need to work towards sustainable MedTech system

- Broadening the assessments
- Facilitate needs-driven innovation
- Fast, flexible methods that can deal with multi-indication devices
- Unified risk based evaluation, adoption and reimbursement criteria

Thank you!



It is never too early to evaluate a technology