Amsterdam UMC
University Medical Centers

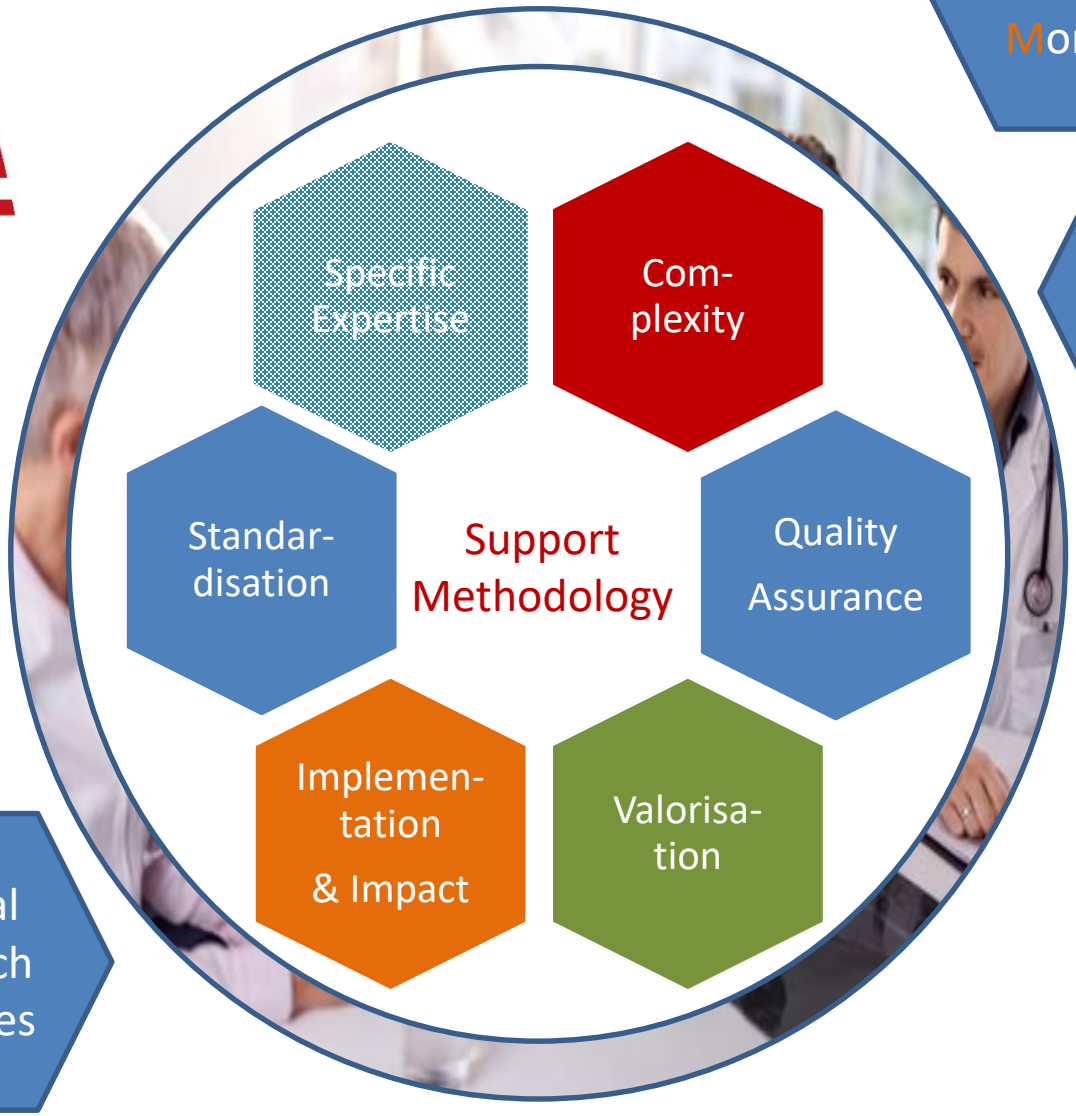
Research Support
About HTA

Sharing academic support experiences

Amsterdam UMC
Universitair Medische Centra

Research Support
CRU Clinical Methodology

INNOVATION EXCHANGE AMSTERDAM



Clinical Research Monitoring

Research Data Management

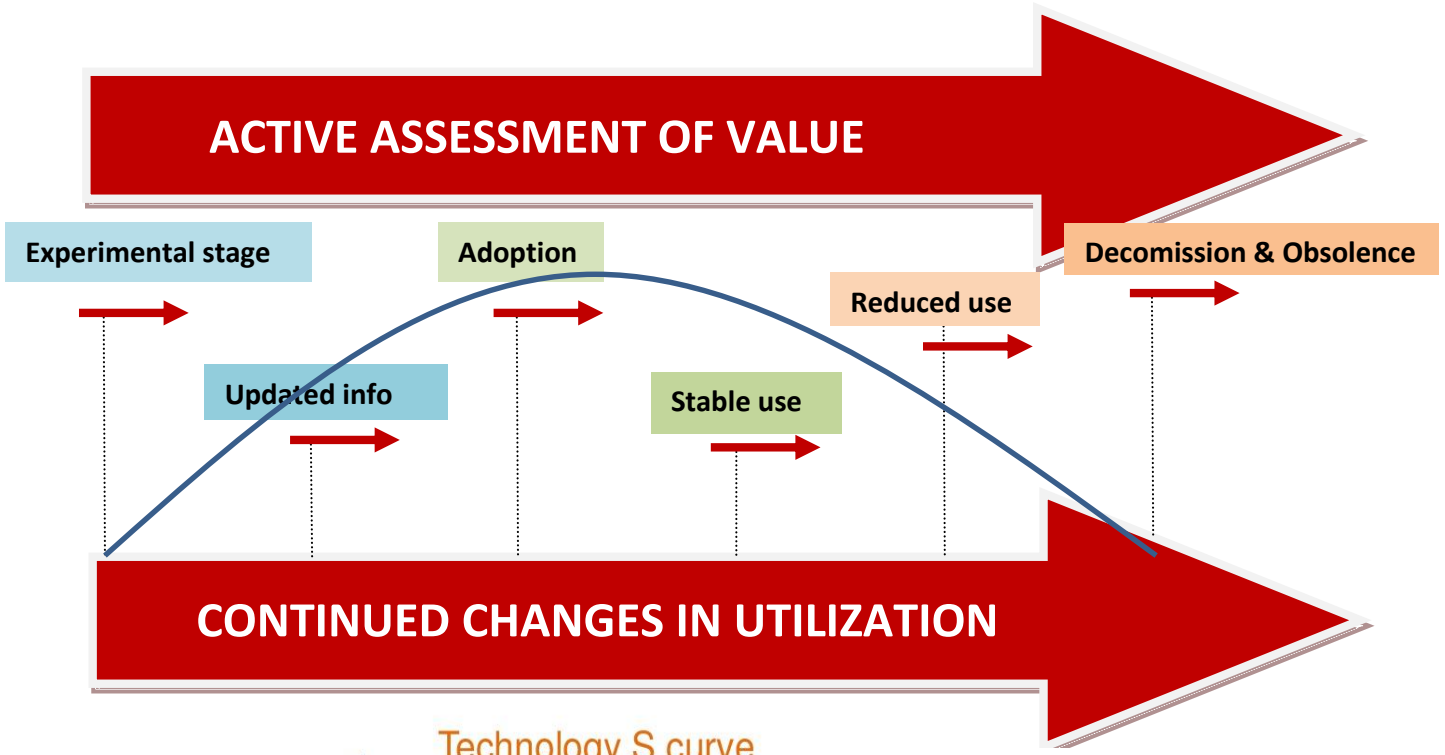
Support Statistics

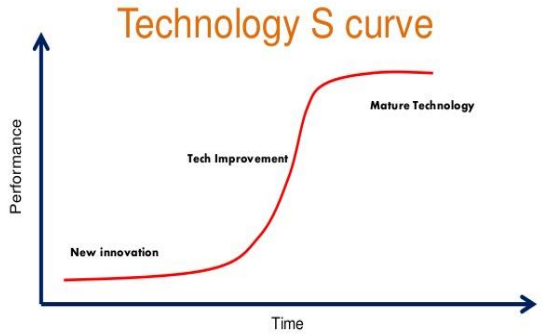
Clinical Departments & Investigators

Clinical Research Institutes

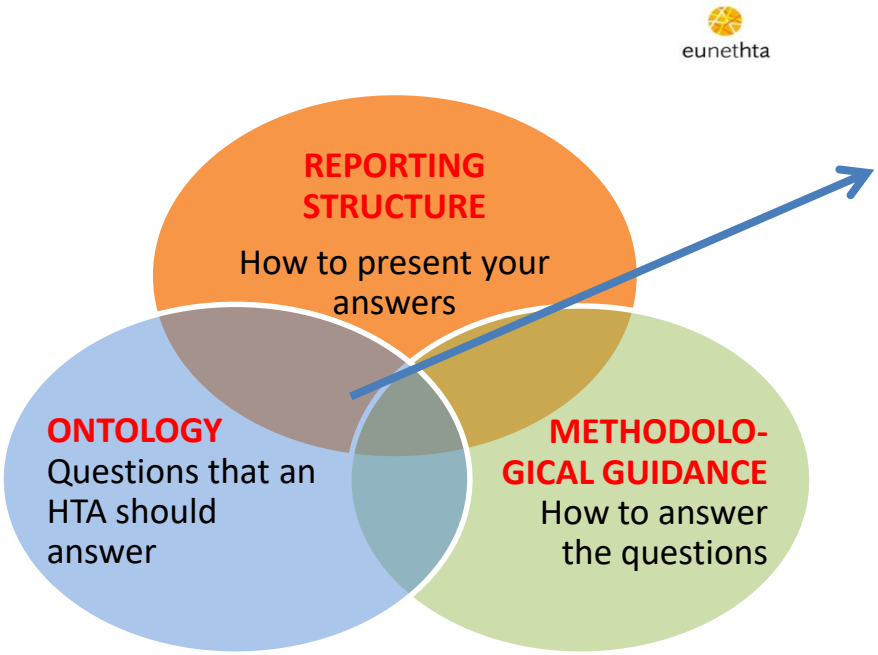
Clinical Research Unit

Innovation Life Cycle





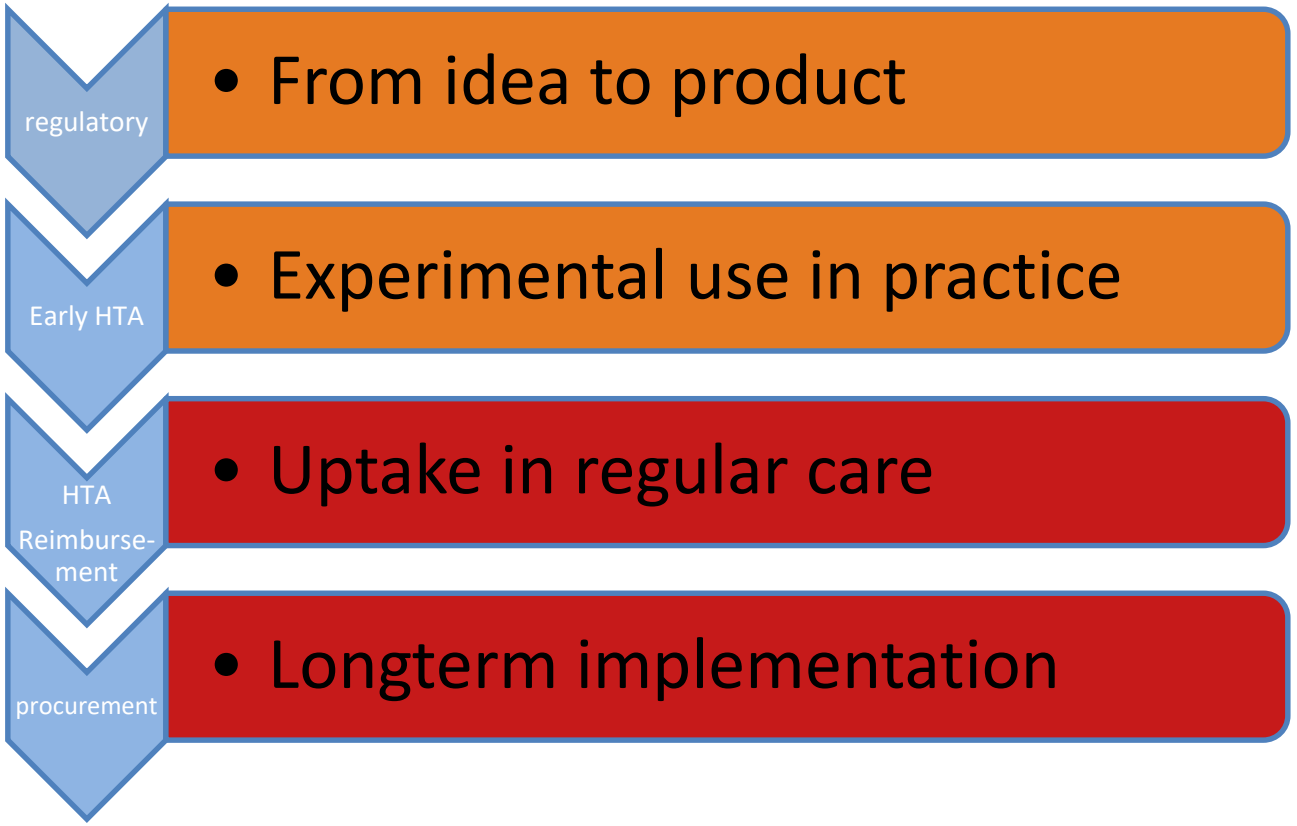
AIMS & SCOPE
HTA Core Model ®



HTA Core Model DOMAINS
1. Health problem and current use of technology
2. Description and technical characteristics
3. Safety
4. Clinical Effectiveness
5. Costs and economic evaluation
6. Ethical analysis
7. Organisational aspects
8. Social aspects
9. Legal aspects

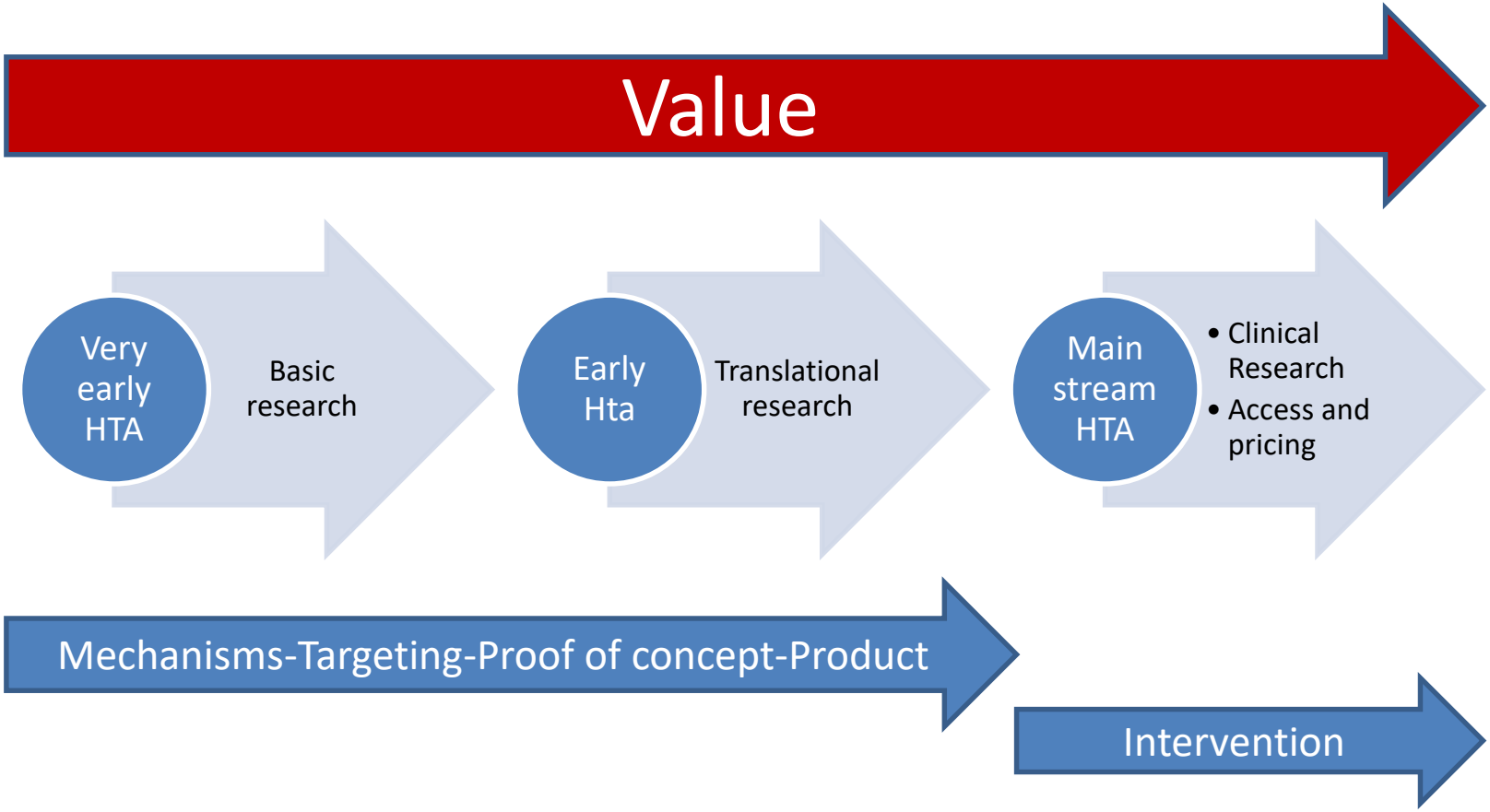
AIMS & SCOPE

complexity medical device pathways



AIMS & SCOPE

active assessment of value



Appl Health Econ Health policy 2011; 9(5): 331-347

AIMS & SCOPE
early HTA – Assessment

Perspective
- Clinical
- Patient
- Economic

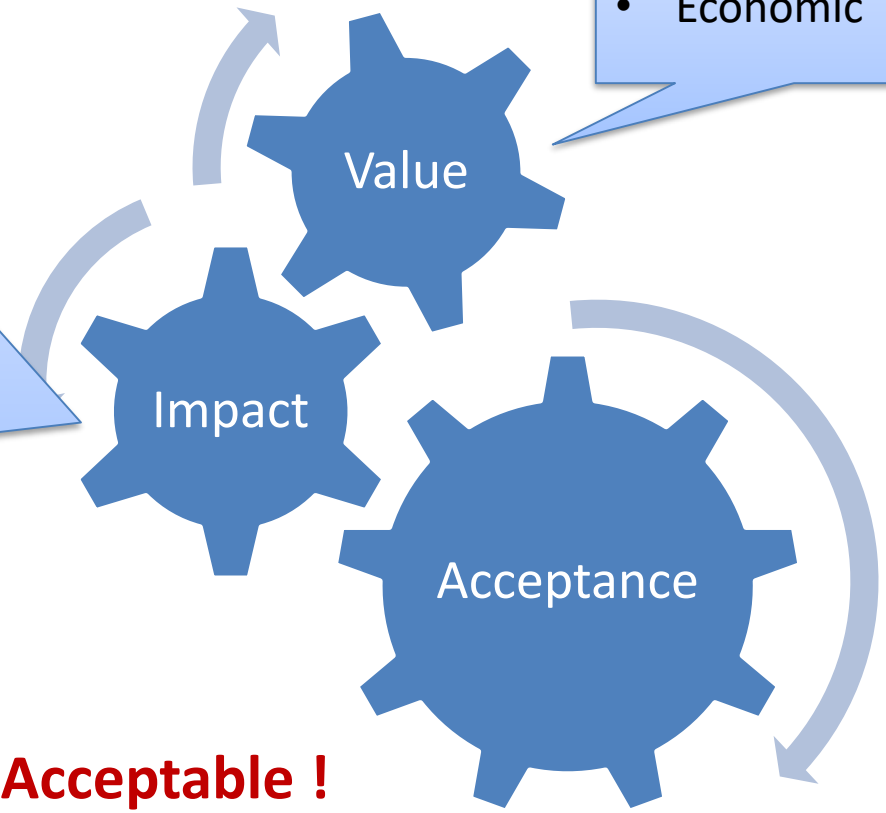
Target population

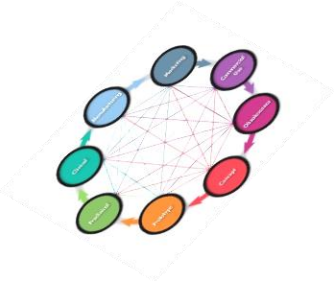
State of the art

Common practice

Health care system

Technological demands





Usefull !

Acceptable !

Applicable !

Issues to consider

- Ethical Considerations (e.g. placebo arm)
- The Device ≠ the treatment, often part of
- Primary Outcome Measure? QOL? Effectiveness? Safety?
- Learning Curve
- Patient Bias
- Doctors Bias, practice variation
- Methodology? Perspective? Medical cost approach?
- Health care system
- External Validity

To conclude

- **Avoid the one-size-fits-all approach**
  - Individualized approach due to the diversity and complexity of medical devices (N0 cut-and-paste from the Clinical trials Regulation)
  - All stakeholders together from early stage
  - Clearly define terms (e.g. clinical equivalence, efficacy, effectiveness…)

- **Safety and Effectiveness needs a balance of Pre- and Post-market data**

- **Justification for trial design should be within safety file**
  - Do the changes raise questions on effectiveness and safety?
  - Consider data on similar devices and technical testing
  - Consider burden on patient
  - Consider impact on cost / sustainability / access
  - Big Data!

- **Balance the need for Transparency and Intellectual Property Rights**
  - To innovate for patients you have to protect the Intellectual Property
  - Avoid overuse and misuse of transparency and data requests

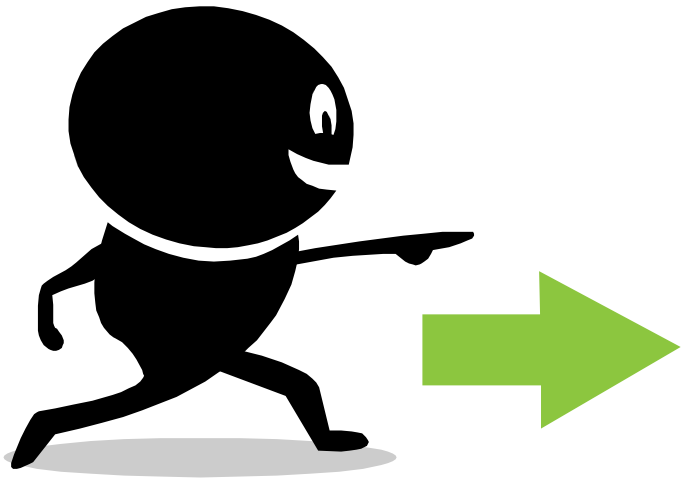
Last but not Least!

Identify the Innovation Pathway……..

- Consumer
- Health care provider
- Insurance
- Municipality
- Government

Dynamics
Business Innovation
discours

Contact



www.amc-cru.nl

Corianne De Borgie, PhD,

Head Clinical Methodology

Clinical Research Unit

cru@amc.nl

c.deborgie@amc.uva.nl