



INSTITUTE OF
HEALTH ECONOMICS
ALBERTA CANADA

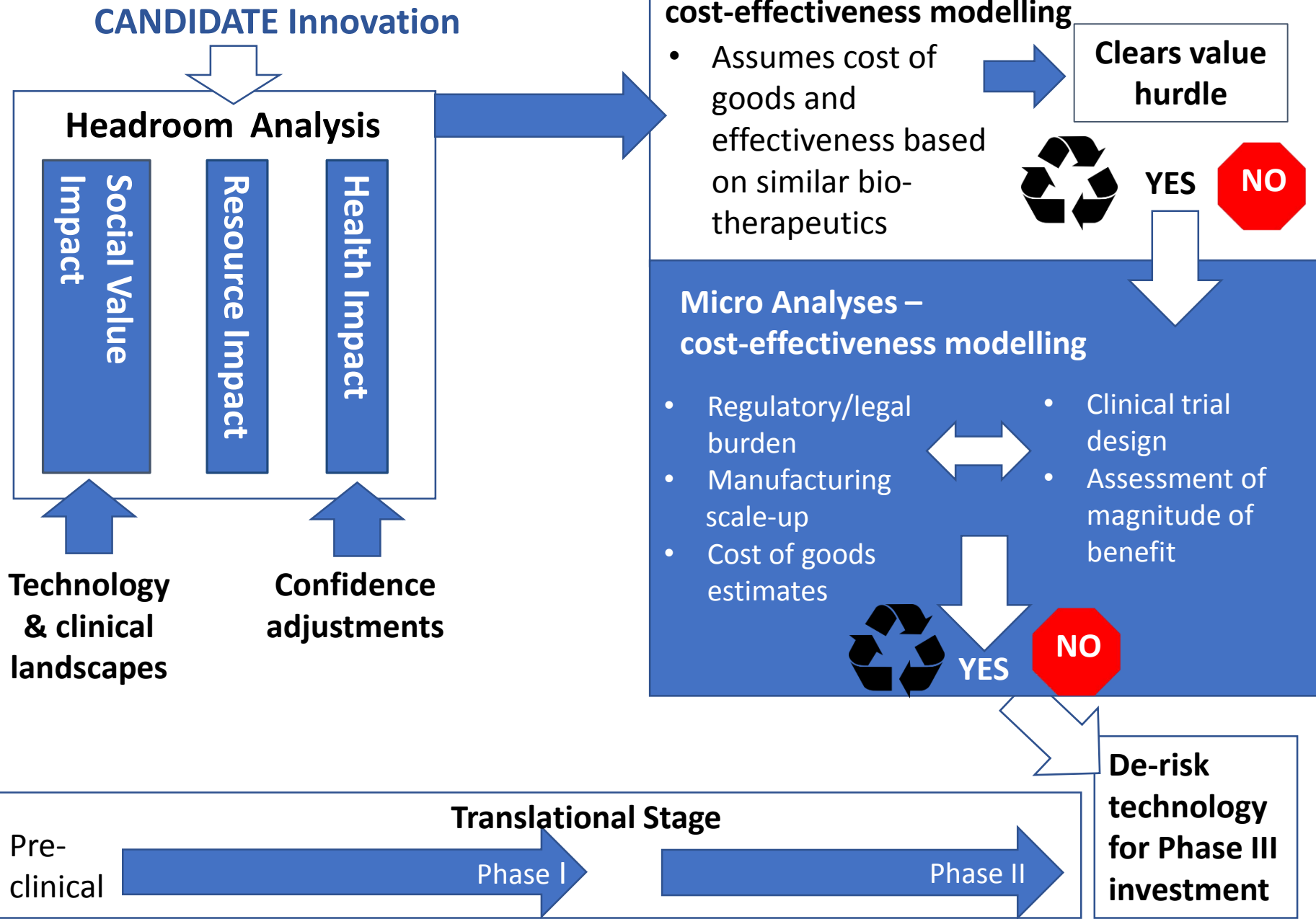
IHE Health Technology Innovation Platform

IHE HTIP Health Economics Educational Workshop

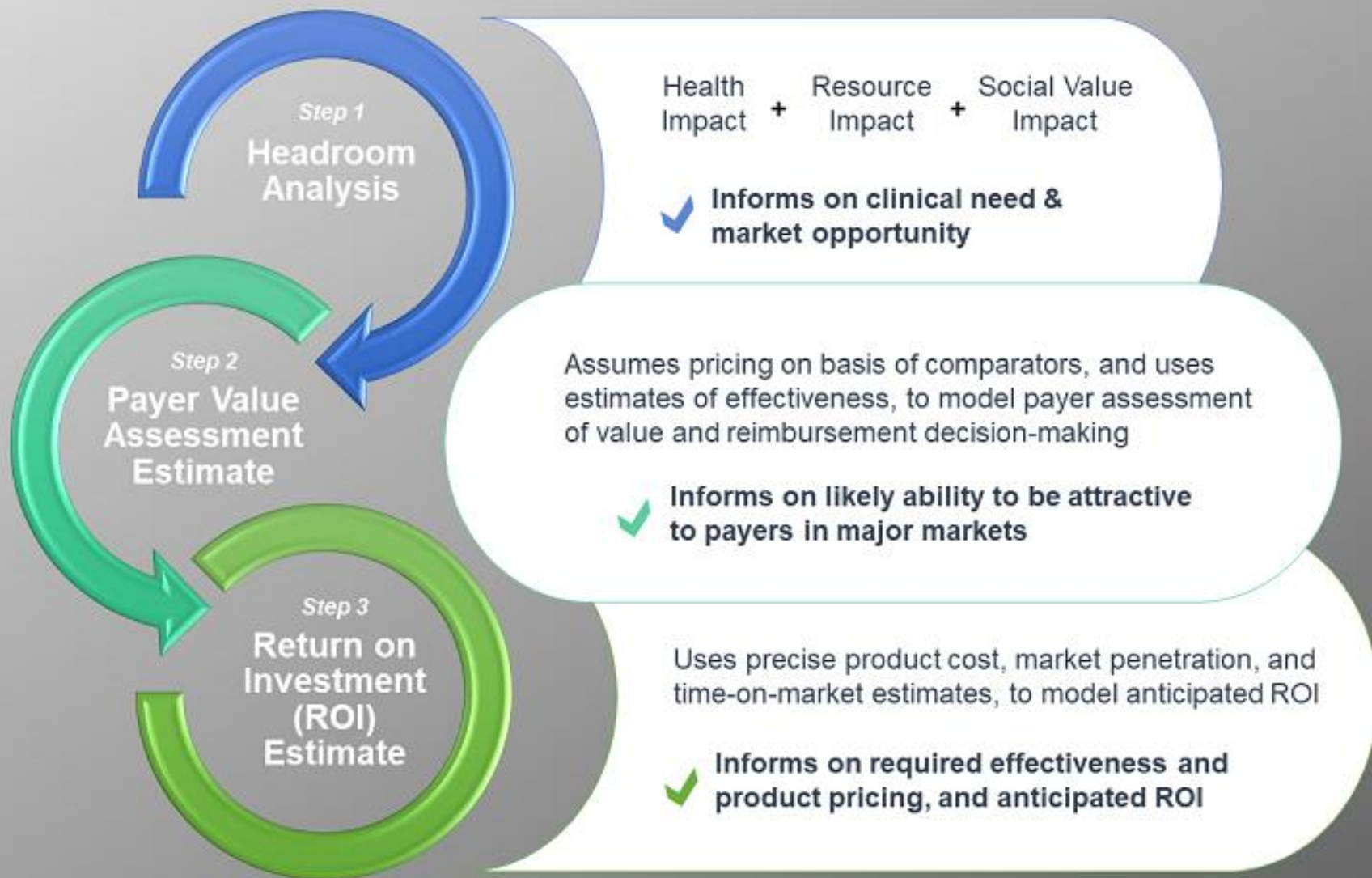
**November 30, 2018
Edmonton, Alberta**

IHE Early Stage Assessment Service

VALUE-ENGINEERED TRANSLATION (VET)

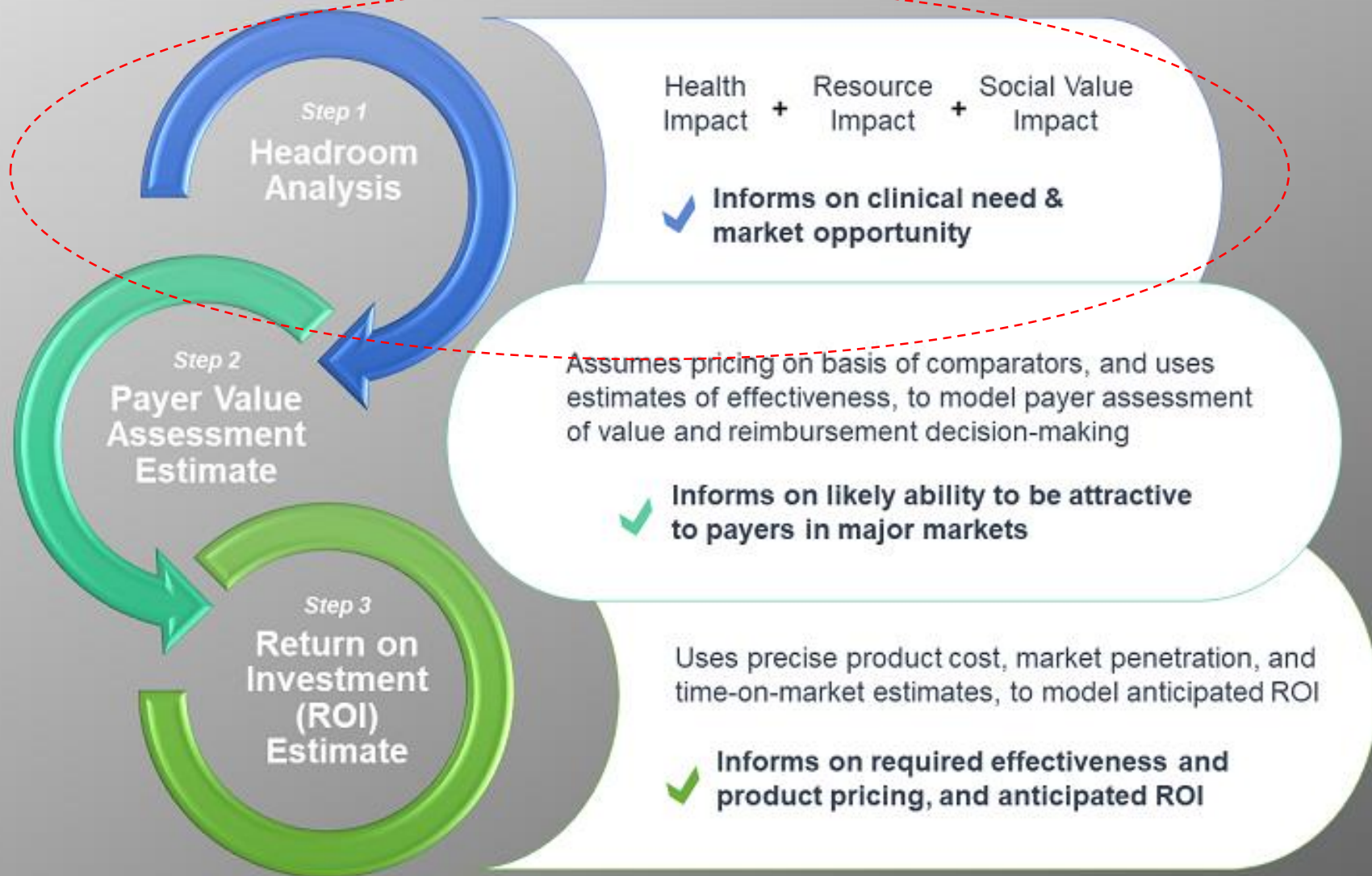


IHE Early Stage Life Sciences Technology Assessment

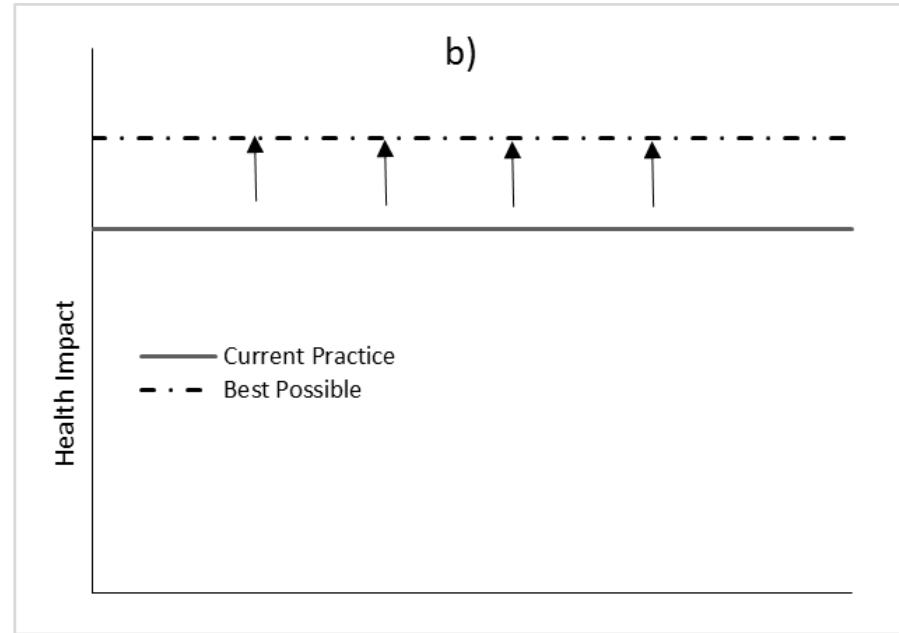
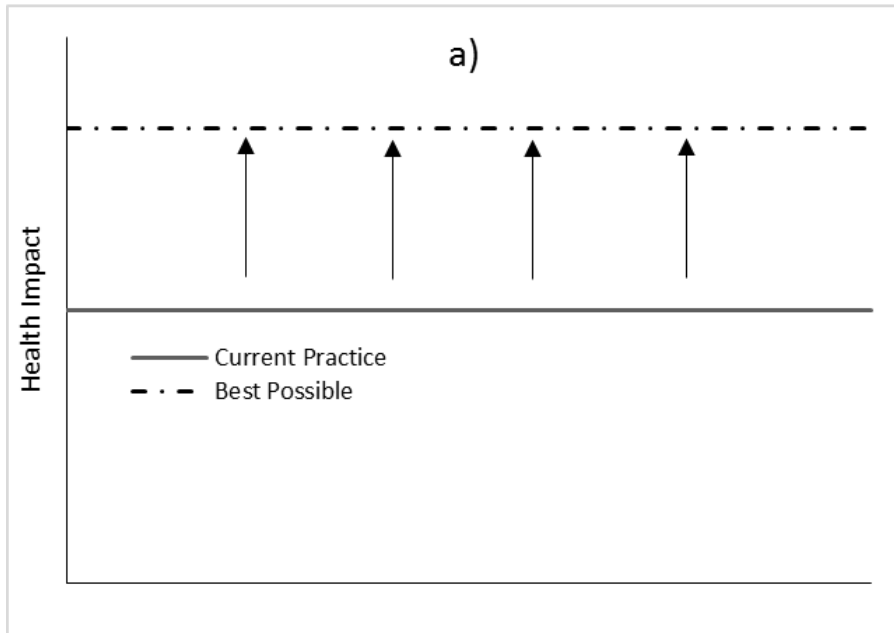


- In the development of early life sciences technology, it is critical to understand whether healthcare organizations are likely to purchase your innovation -> provide a return on investment (ROI)
- Healthcare organizations make purchase decisions based upon clinical and *economic (value for money)* considerations
- The IHE early stage technology assessment service:
Helps to provide an understanding of the conditions under which a technology may be considered attractive to those who eventually pay for it

IHE Early Stage Life Sciences Technology Assessment



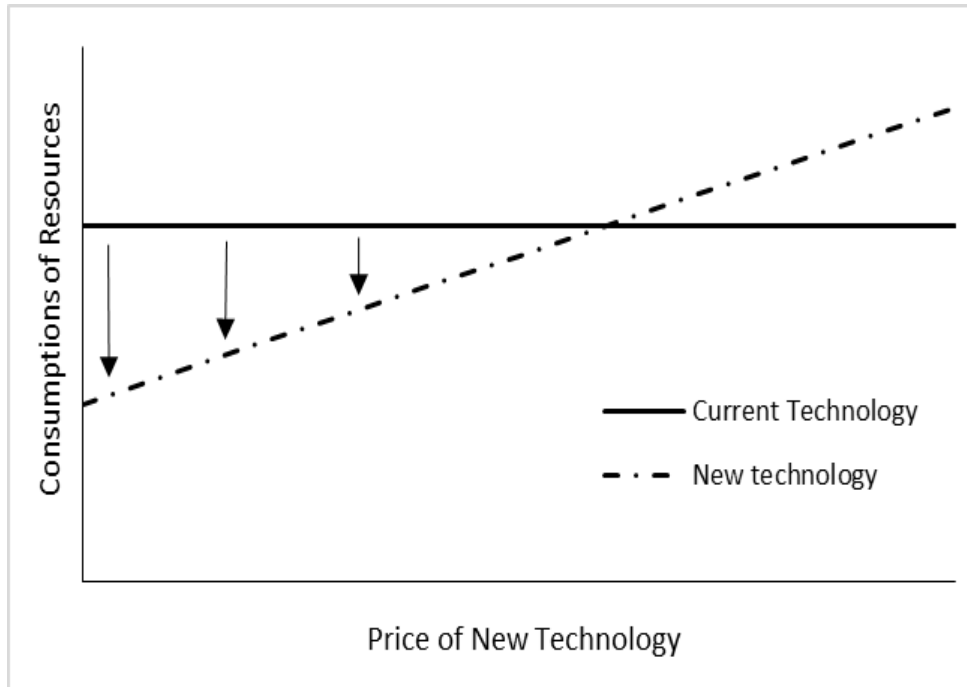
Headroom Analysis: Health Impact



a) Lots of potential headroom to have a health impact on patient population

b) Less potential headroom to have a health impact on patient population

Headroom Analysis: Resource Impact



Comparisons can be made with currently used technologies, or the technologies that are anticipated to be used at time of market entry.

Technologies can be valuable to health system if they provide the same health benefits for less money

Health impact and resource impact headroom analyses bring together information necessary to address cost-effectiveness questions later.

Headroom Analysis: Social Value Impact

Disease	Technology	Population	Socio-economic
Prevalence	Evidence of effectiveness	Distribution of health	Socio-economic policy objectives
Severity	Evidence of safety	Distribution of access to care	Industrial policy objectives
Identifiability	Magnitude of benefit		Legal considerations
Life-threatening	Social impact of Tx		
Availability of alternative Tx	Impact of Tx on distribution of health		
	Innovative		

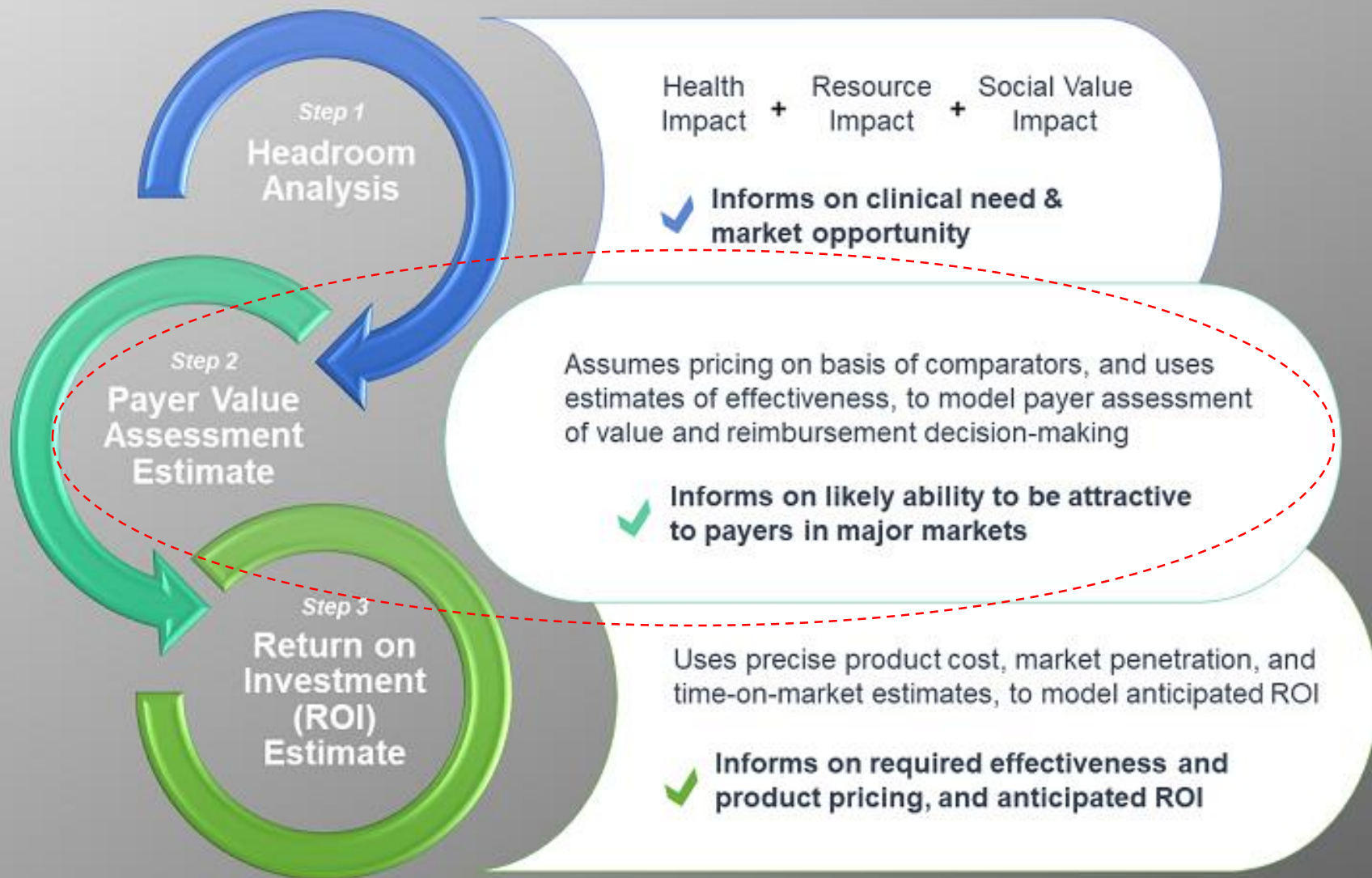
Helpful for consideration of the social value arguments that might be advanced for 'paying more' for a technology.

Would any apply that would mean that 'headroom' is valued more highly?

Understand the Technology and Clinical Landscape

- To understand the headroom that is likely to be available in the future, need to identify:
 - advanced competitors
 - fast follower technologies
- Technologies in either category likely to reduce the headroom for the candidate innovation
 - Hence commercial risk needs to be considered when deciding whether to invest in new technology
- (Might have to apply over-confidence bias adjustment to potential resource impact of unproven technologies)

IHE Early Stage Life Sciences Technology Assessment



Payer Value Assessment Estimate

- Assuming that headroom assessment concludes that there is sufficient headroom (in total) to justify developing the innovative technology
- Conduct 'back-of-the-envelope' assessment to assess whether candidate technology can clear value hurdles (be cost-effective) in sufficient markets
- Informs:
 1. On likely ability of innovation to be attractive to payers in major markets
 2. Whether investors can make commercial return on the necessary investment

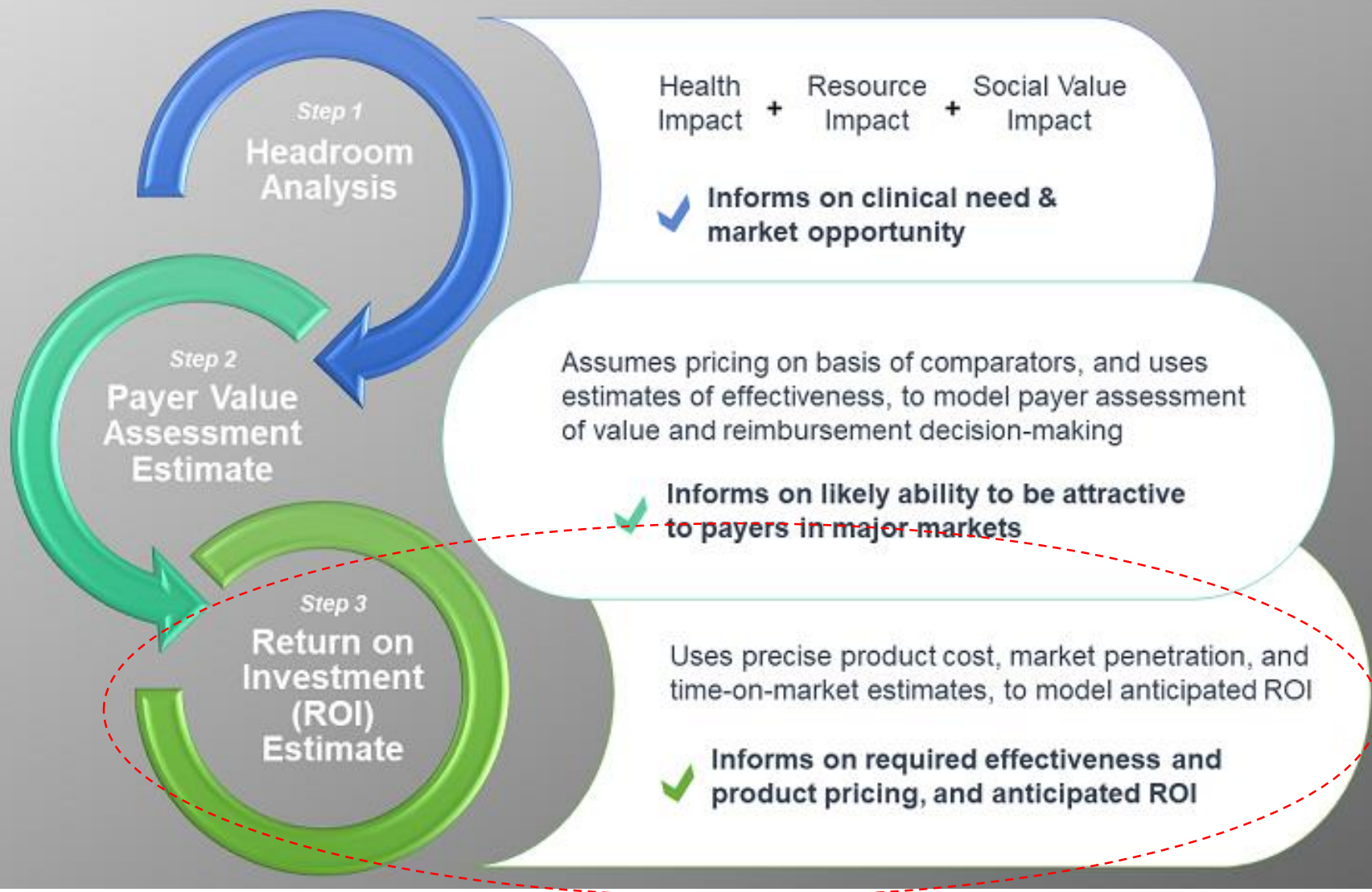
Payer Value Assessment Estimate (*cont'd*)

- Have to make assumptions:
 - Assume technology can be delivered to market at current 'innovative technology' prices
 - Obtain expert estimates (Bayesian elicitation) on expected effectiveness of the technology
- Also consider number of markets required to support commercial proposition – depends on prevalence of condition

Payer Value Assessment Estimate (*cont'd*)

- Possible outcomes:
 - Technology found not likely to be good enough to clear value hurdle – stop development
 - Identify issues need to be addressed to clear value hurdle (cost of goods, location of technology on care pathway, etc.)
 - Technology has high potential value, moves to next step of assessment pathway

IHE Early Stage Life Sciences Technology Assessment



Return on Investment (ROI) Estimate

- Gain detailed understanding of the cost drivers for the development of the technology:
 - Regulatory pathways – identify these pathways, and costs that these will incur
 - Intellectual asset management – whether IP will have to be licensed for technology or the processes required for its manufacture
 - Alternative manufacturing models
 - Scale-up and scale-out models (big-pharma vs. laboratory test)

Return on Investment (ROI) Estimate (*cont'd*)

- Obtain detailed information on size of patient population in target markets (US, UK, France, Germany, and Japan considered to be default markets)
 - Informs number of treatments per year that will be sold
- Consider likely patent life left (based upon regulatory analysis) – insights into how many patients treated before generic competition arrives

Return on Investment (ROI) Estimate (*cont'd*)

- Combine information to construct alternative manufacturing models:
 - > Provide stochastic cost of goods estimates, which can then be included in a micro cost-effectiveness analysis
- Explore range of assumptions based on expected proportion of market that might be captured
- Possibly inform the design of a clinical trial
- Finally feed into any further go-no-go investment decision

Summing Up

- Aim of the IHE Early Stage Life Sciences Technology Assessment is to de-risk any large late stage investment decisions
- By conducting these analyses early in the translation process we:

Can avoid investing time, money, and intellectual resources in technologies that are unlikely to be commercially successful



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