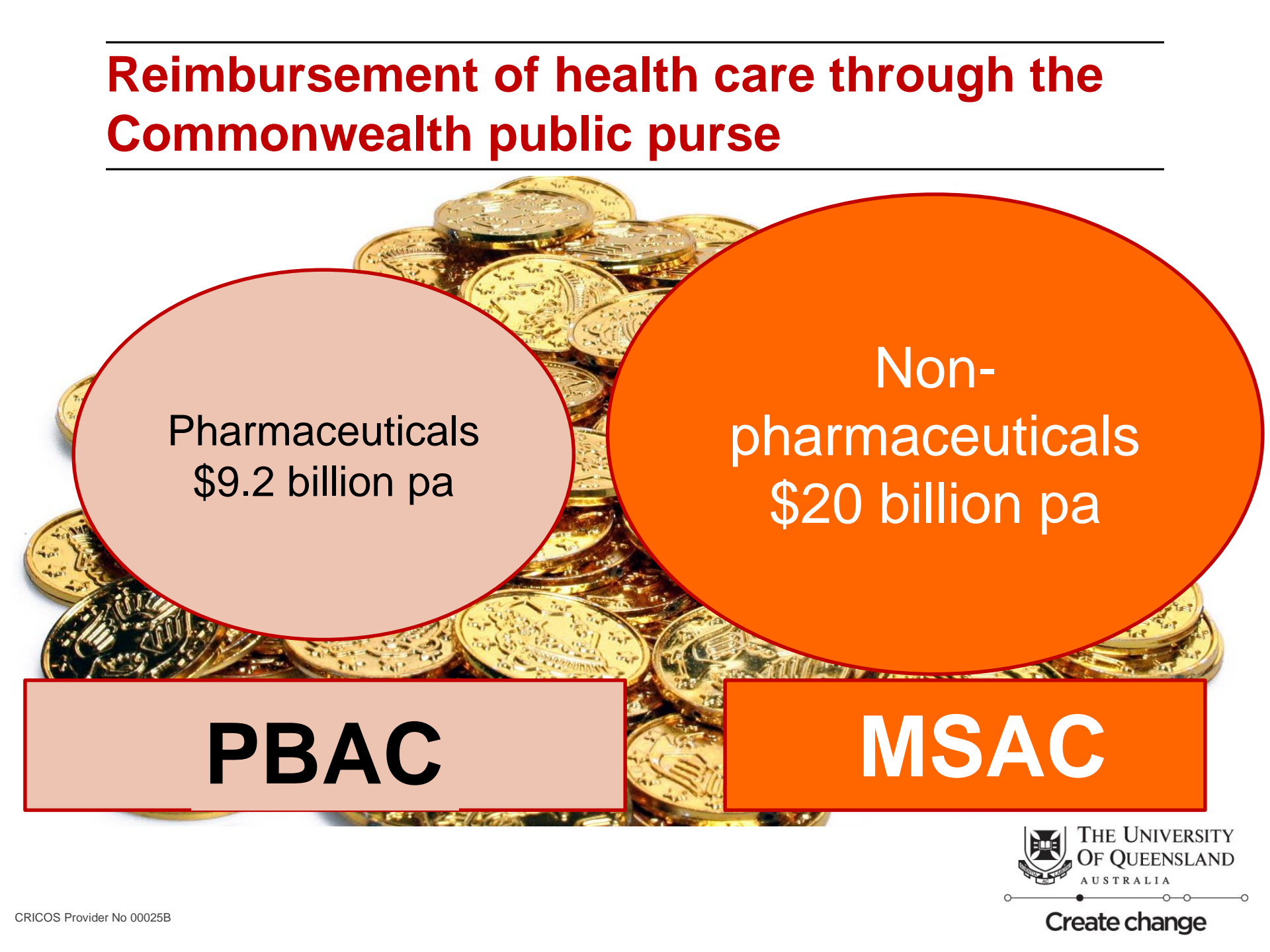

Getting omics into healthcare -what's for sale and why aren't governments buying?

Disclaimer: Member of the PBAC and Chair of MSAC
Personal views not those of the committees or the Commonwealth

Reimbursement of health care through the Commonwealth public purse



Pharmaceuticals
\$9.2 billion pa

PBAC

Non-
pharmaceuticals
\$20 billion pa

MSAC

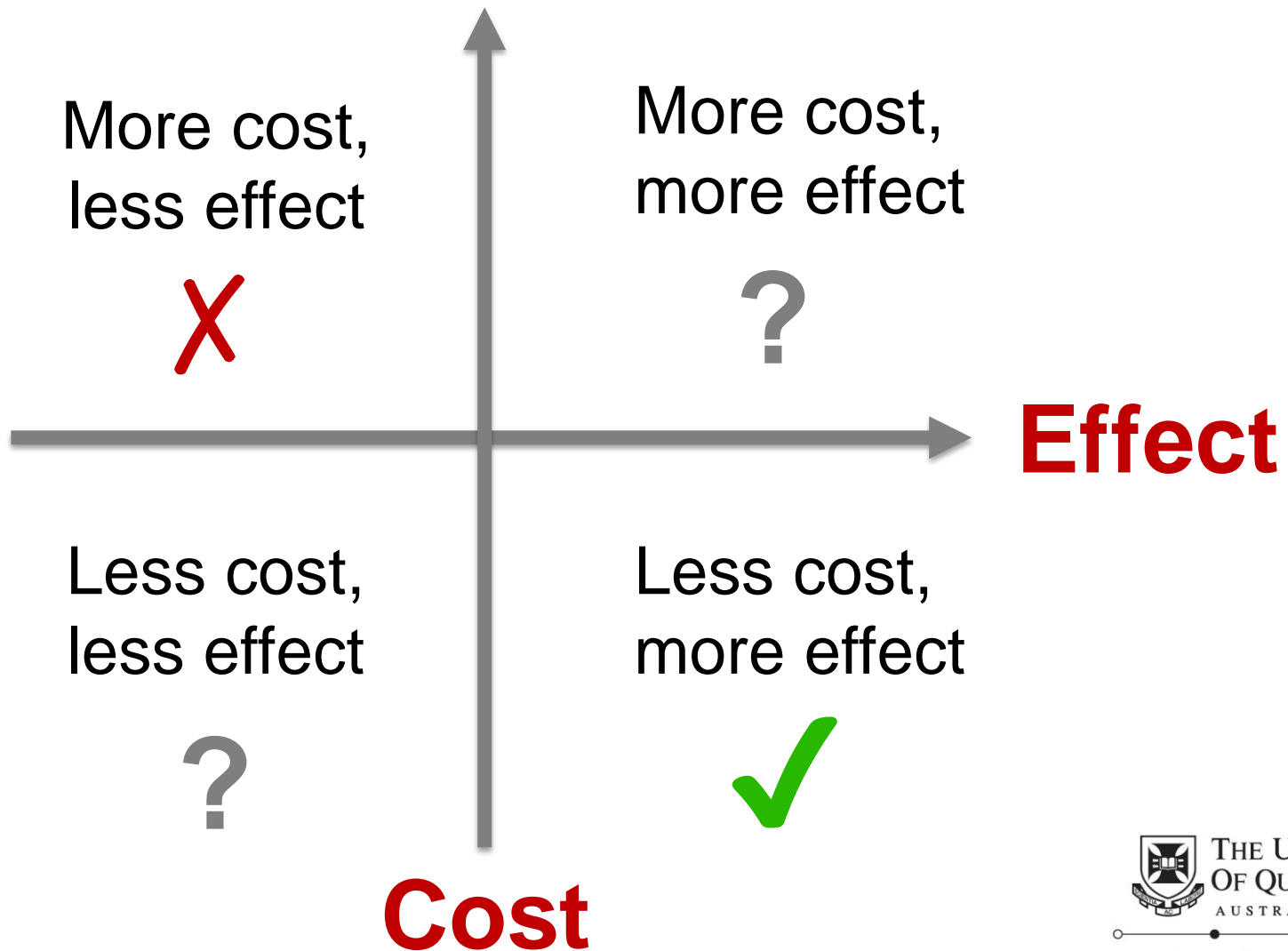
The ICER value framework

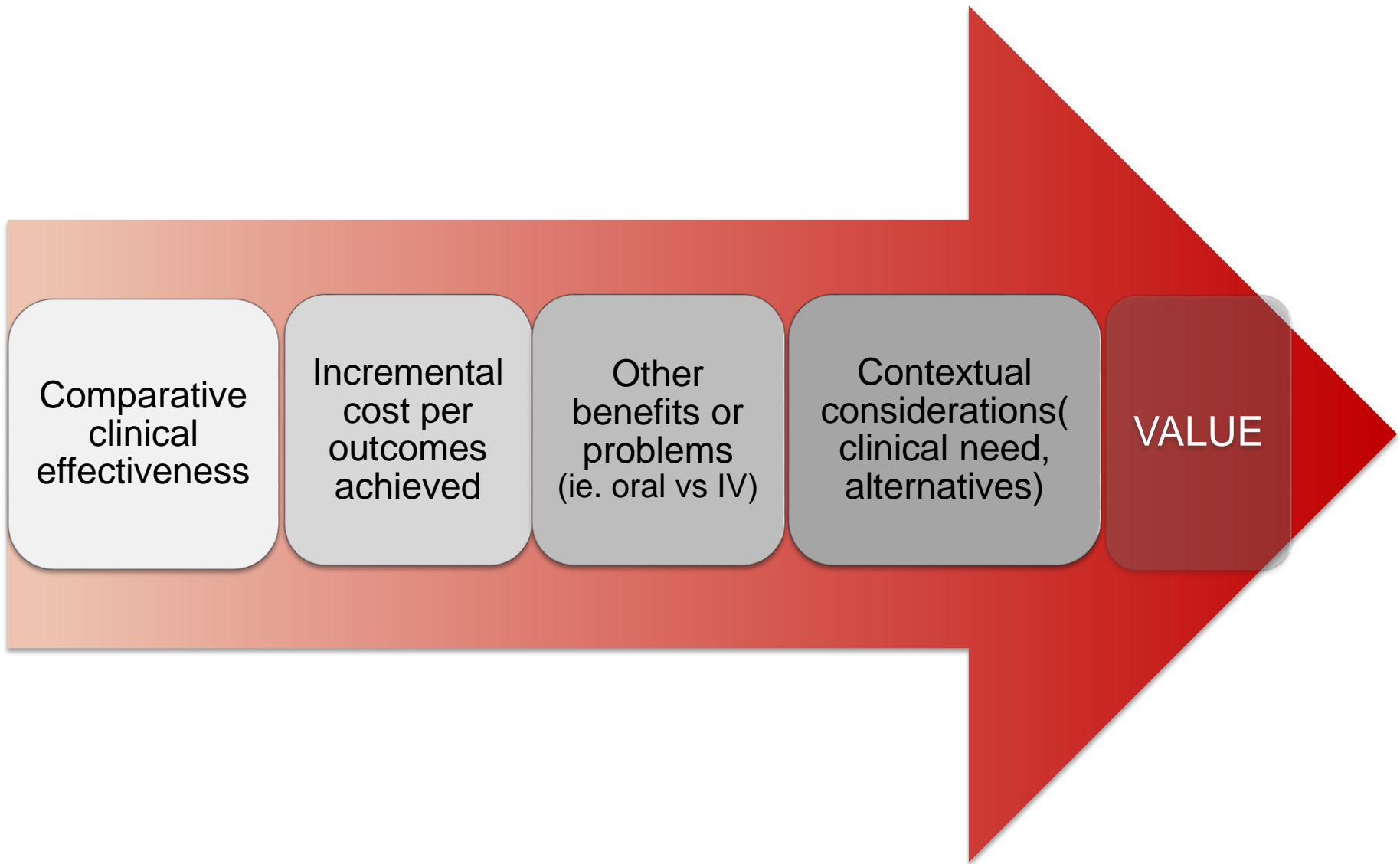
(Incremental cost-effectiveness ratio)

$$\text{ICER} = \frac{\text{Net costs A} - \text{net costs B}}{\text{Net effects A} - \text{net effects B}}$$

Effects = Life years gained (LYG) or
Quality adjusted life years gained (QALYG)

Cost effectiveness and decisions





Financial implications for government health budgets - Affordability

- Drugs + tests + imaging + services + XX + XX
- Over a 5 year period
- Estimates of patient numbers
- Proportions of current population being treated
- Patient preferences
- Setting - primary care or specialist
- Likelihood of new tests/medicines or treatments
- Uptake pattern – unmet demand or latent populations

Who is selling and who is buying?

PBS (drugs)

- Single seller – pharma
- Single buyer - commonwealth
- Single negotiation on payment mechanisms
- Manage risk of leakage or excessive expenditure (risk share and price volume arrangements)

MBS (non-drugs)

- Multiple sellers
- Multiple buyers
- Often no negotiation – pay the asking price
- Uncontrolled risk of excess expenditure

Genomics a lever to bend the (healthcare) cost curve?



Sources of uncertainty for buyers?

- Evidence base is sparse
- Evidence is not fit for purpose
- ICERs often high but low total financial cost if only used in rare groups
- Gatekeepers poorly defined
- High risk of use outside reimbursement conditions
- Paying for test results that aren't ordered
- Assessing “value” of a “black box”

What is a black box?

- “assay composed of or derived from multiple molecular measurements and interpreted by a fully specified computational models to produce a clinically actionable result” ETO-IOM, 2012
- Re-stated: Multiple inputs, processing by predictive algorithm, probabilistic outputs
- Black boxes appear black to all except those who develop and operate them – source of uncertainty and suspicion from regulators and payers

Current framework for evaluation is not sufficient

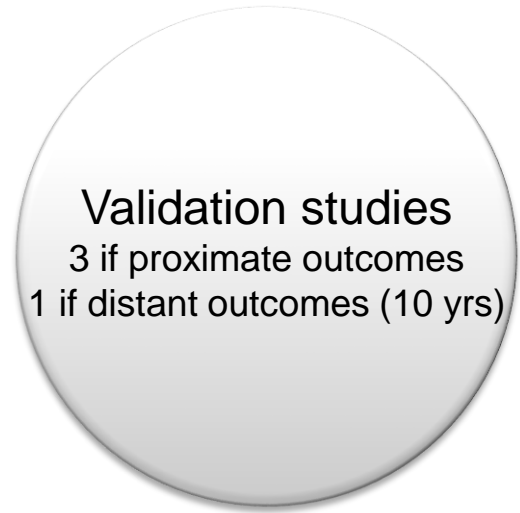
Standards	Definition	Big data nuances
Analytical validity	Test ability to measure accurately and reliably the analyte	++
Clinical validity	Ability to predict the disorder	++++
Clinical utility	Ability to improve patient outcomes	++++++++



- Inputs
- Computer algorithm
- Reporting



- Independent samples
- Use the black box without re-optimisation



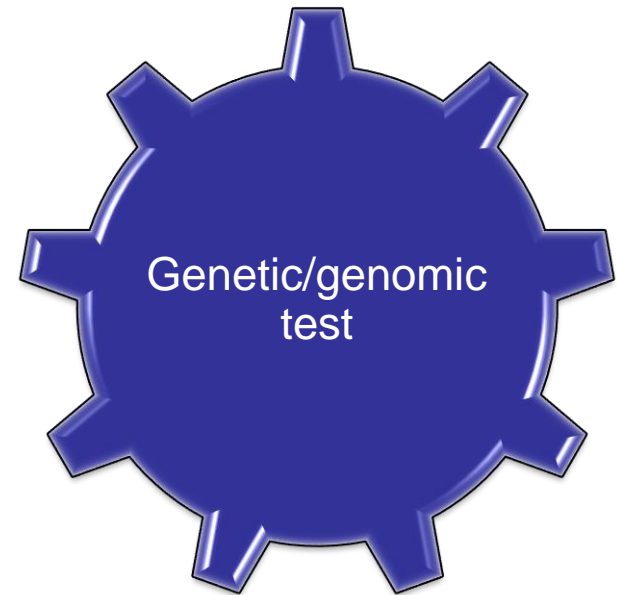
- Analytical validity
- Clinical validity
- Clinical utility
- Prognostic value
- Predicting treatment effect

Independent assessor

- Assess development pipeline
- Adherence to quality control
- Complete separation of discovery and validation
- Description of confounders in the validation data set
- Standard HTA assessment of quality and scientific rigor
- Similarities of participants in discovery/validation with proposed reimbursed population
- Variability over time – must show alterations don't affect results

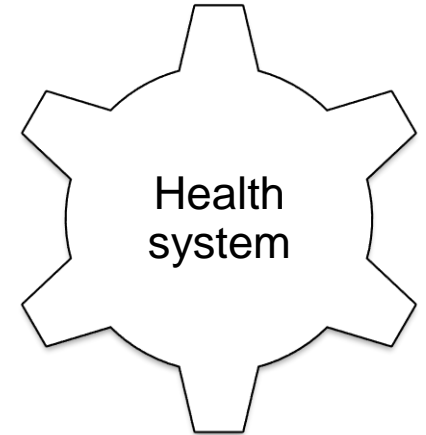
Reactive approach: traditional HTA assessment (value based assessment)

- Evidence
- Cost of test
- ICER
- Financial cost



Proactive approach: integration at health system level

- Identify sector needs
- Facilitate technology development process
- Clinical utility of genetic testing for sectors of community
- Cost of genetic/genomic testing
- Demand for genomic testing



Innovative approach: integration with broader economy

- Best **outcome** for the population as a whole
- Deliver major **economic outcomes**:
 - shared gain/shared risk*
 - new industries in health/science/education -*
 - based on knowledge not sophisticated manufacturing*



Approach	Outcome	Challenges
<p>Reactive: Fee for service for individual tests</p>	<ul style="list-style-type: none"> • Economic incentive for oversupply • Inequity in access • Fragmentation of care delivery 	<ul style="list-style-type: none"> • Current state • Increasingly unsustainable
<p>Proactive: Sourcing tests that a health system needs</p>	<ul style="list-style-type: none"> • Avoids fragmentation • Coordinated service delivery 	<ul style="list-style-type: none"> • Identify needs • Political cooperation – state & commonwealth • Preparedness to prioritise
<p>Innovative: Creating publically owned research</p>	<ul style="list-style-type: none"> • Shared reward for taxpayers and patients and local industry 	<ul style="list-style-type: none"> • Build partnerships between academia and industry • Redesign research workforce training