

Scientific Advice



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

NICE National Institute for
Health and Care Excellence

The information needs for HTAs

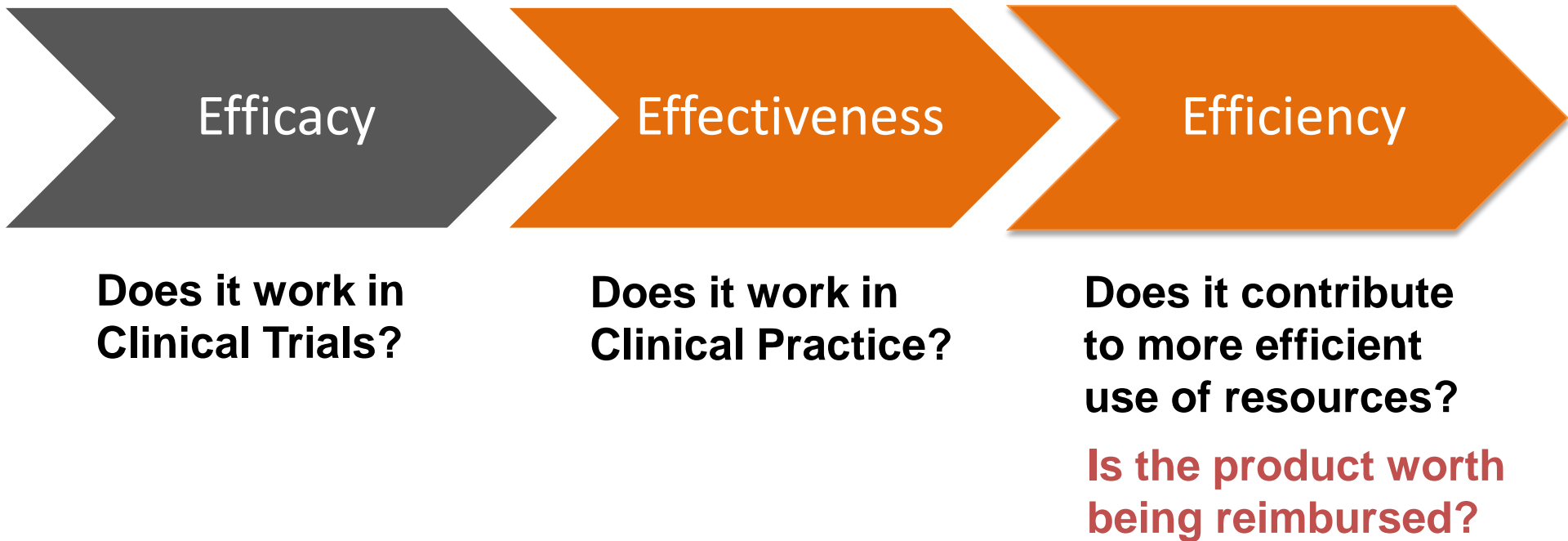
Dr. Leeza Osipenko
Senior Scientific Adviser

November 26, 2013

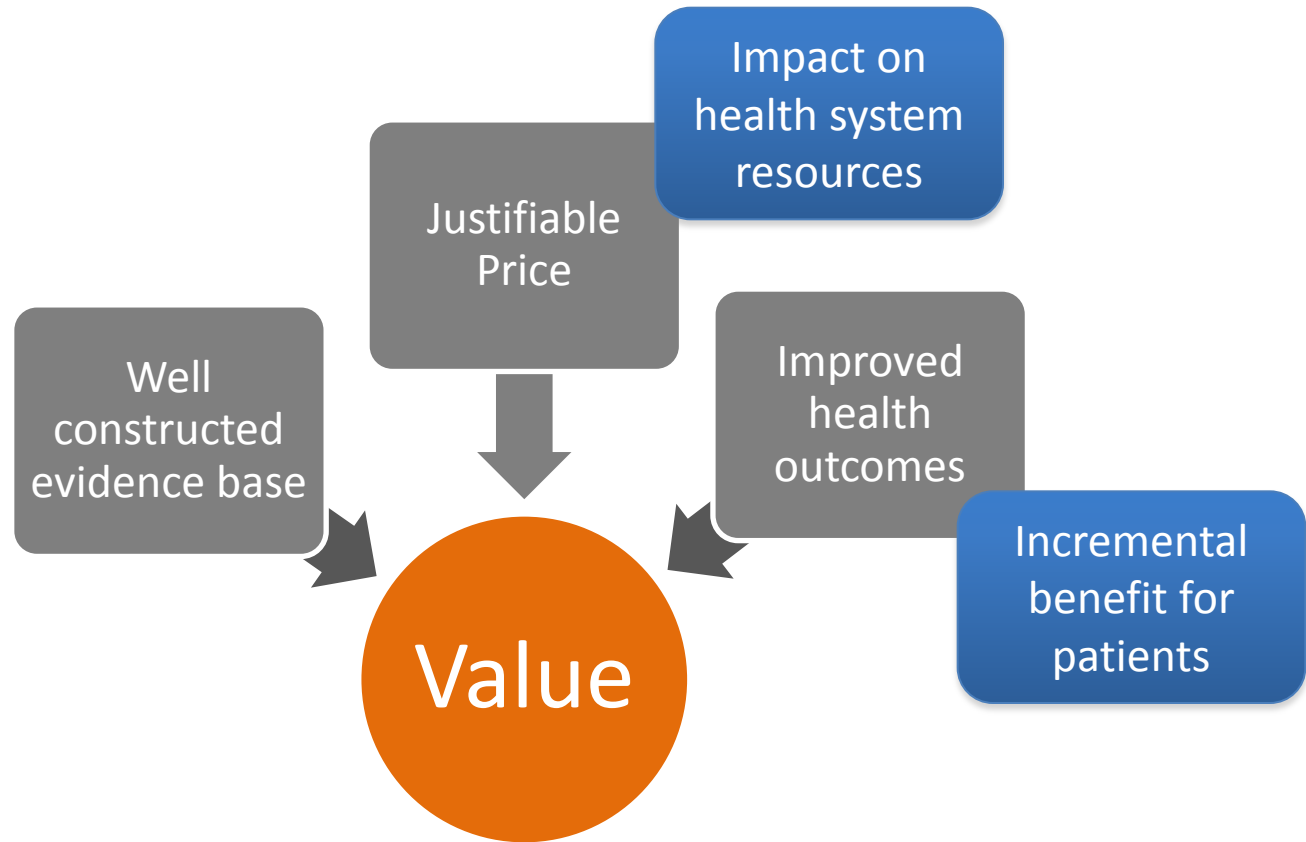
HTA is EASY



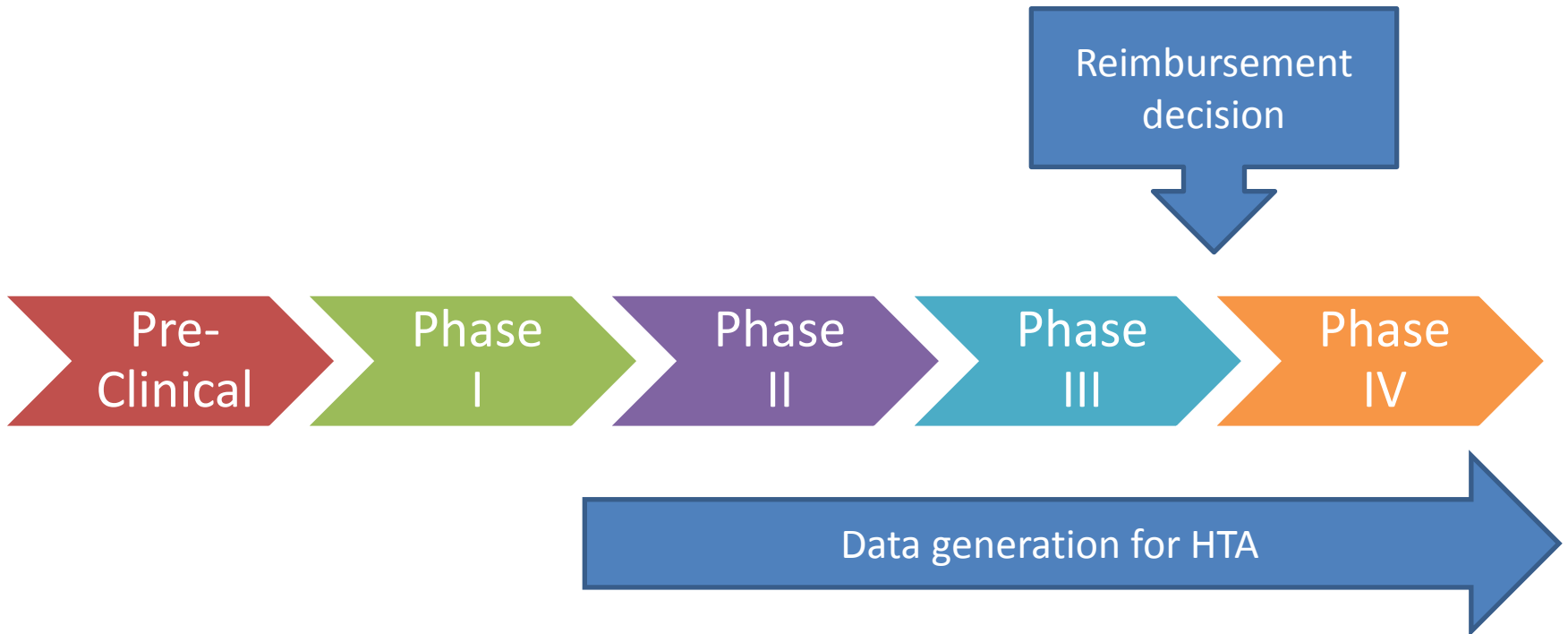
Triple E of Health Technologies



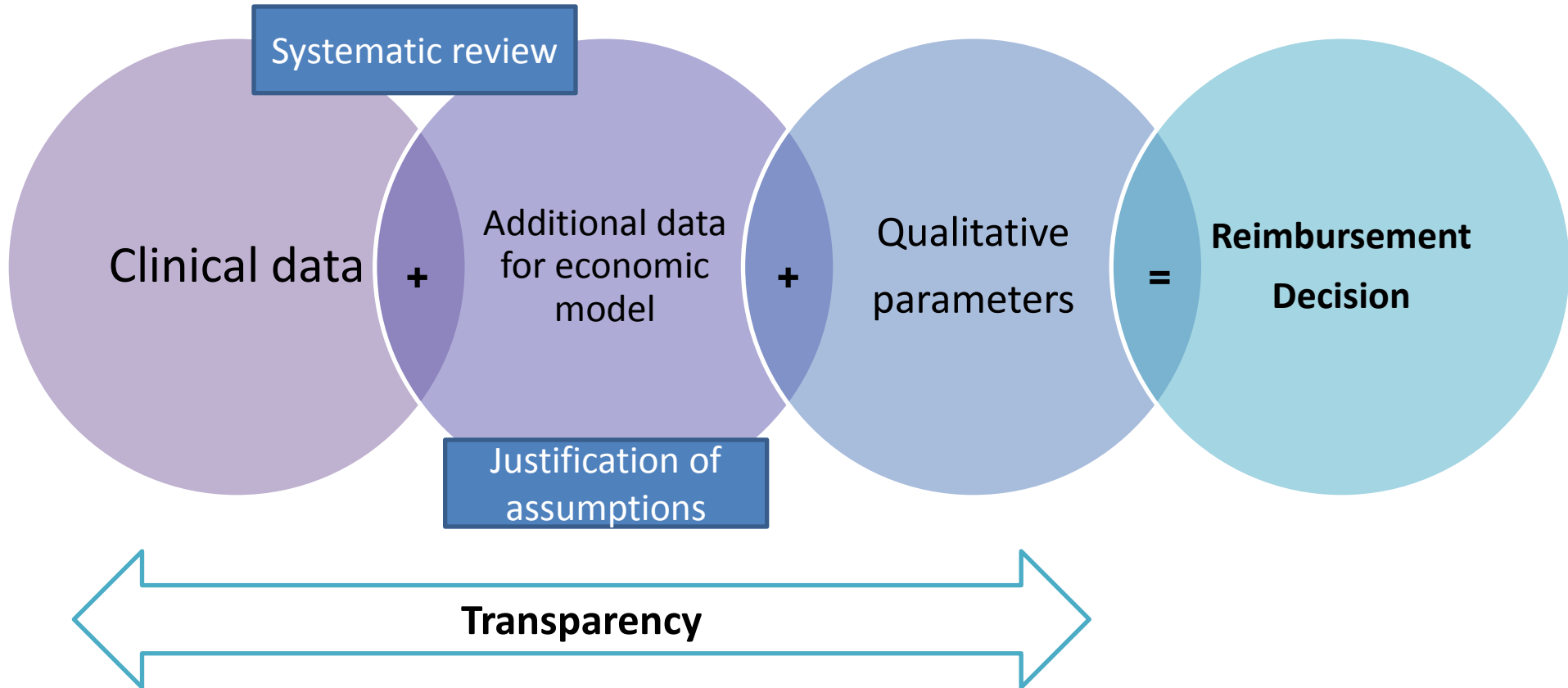
HTA & Value Proposition



Product Development



The HTA Case



Evidence Requirements

Population

Talk to local clinicians

- Establish if population in the trial is representative of patients treated in practice in the country of interest
- Identify biologically plausible subgroups if appropriate

Evidence Requirements

Talk to local clinicians

Comparator(s)

Explore off-licence use

- Identify **established practice** for managing condition in each country
 - how many relevant comparators?
- Study an active comparator if possible
 - mixed treatment/indirect comparisons can be used

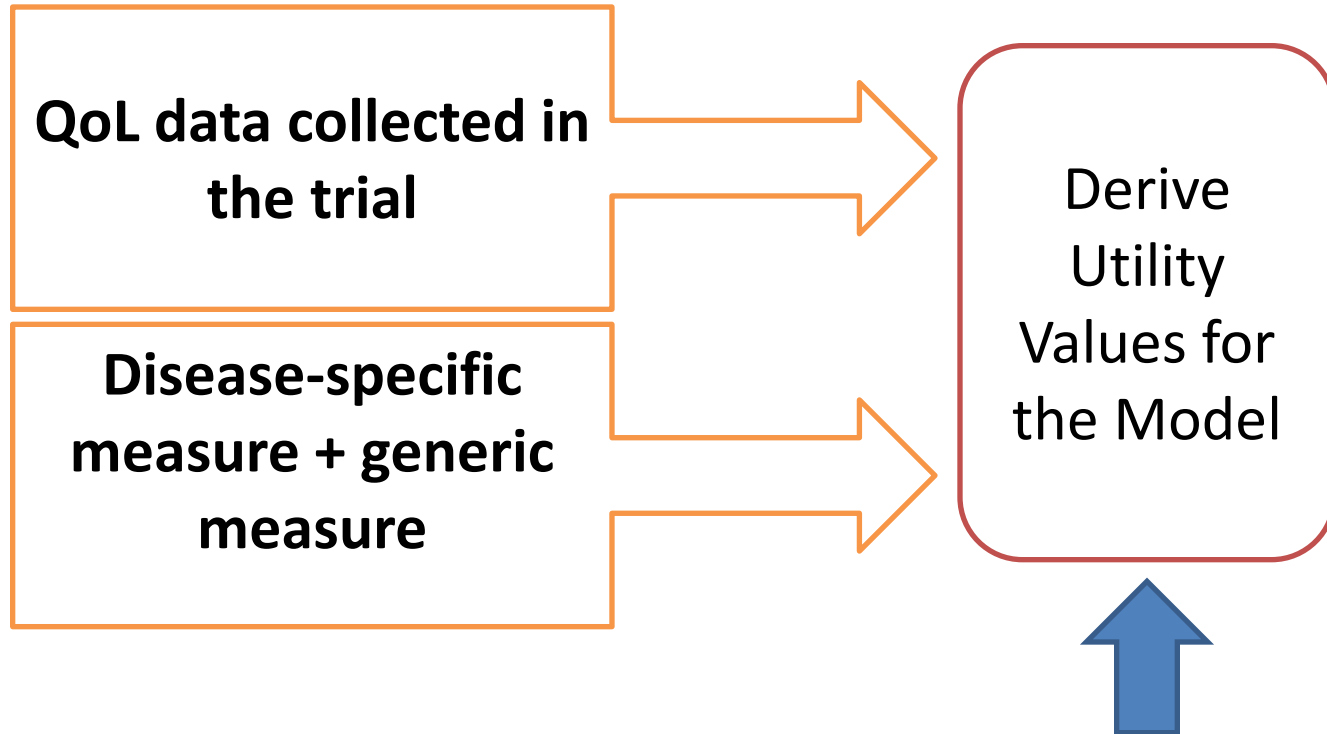
Evidence Requirements

Endpoints

Talk to patients

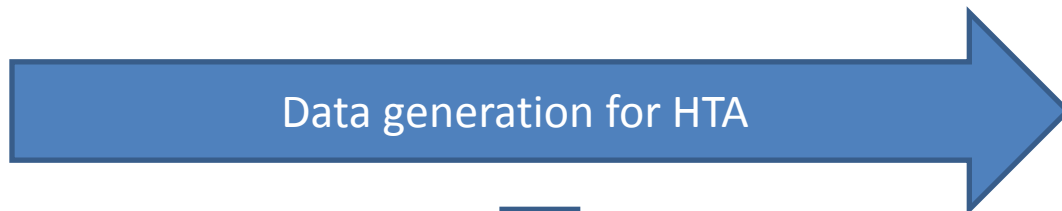
- Measure health benefits & AEs important to patients
 - impact on quality and duration of life
- Prove surrogate-to-final outcome relationship

Quality of Life

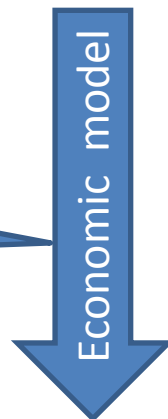


For HTA :

- QoL data for important events needs to be captured
- Frequency of QoL data collection matters



Non-trial data



Costs & Resources

Perspective of the decision-maker determines which costs and resources are relevant



Cost entire pathway of care

Capture:

big cost drivers in the trial

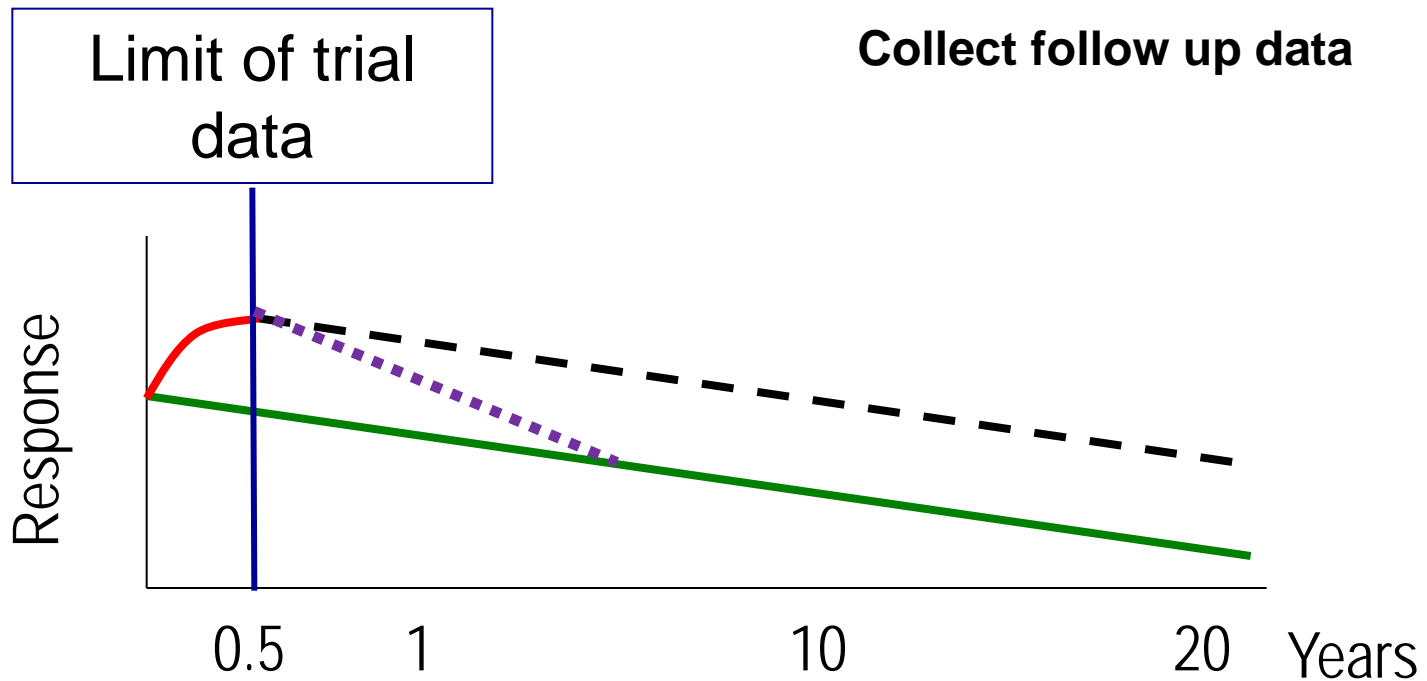
costs of dosing and administration

costs & utilities associated with discontinuation



Collect country-specific data

HTA needs to know what happens in the end...



Other data sources are frequently needed to extrapolate to the longer term

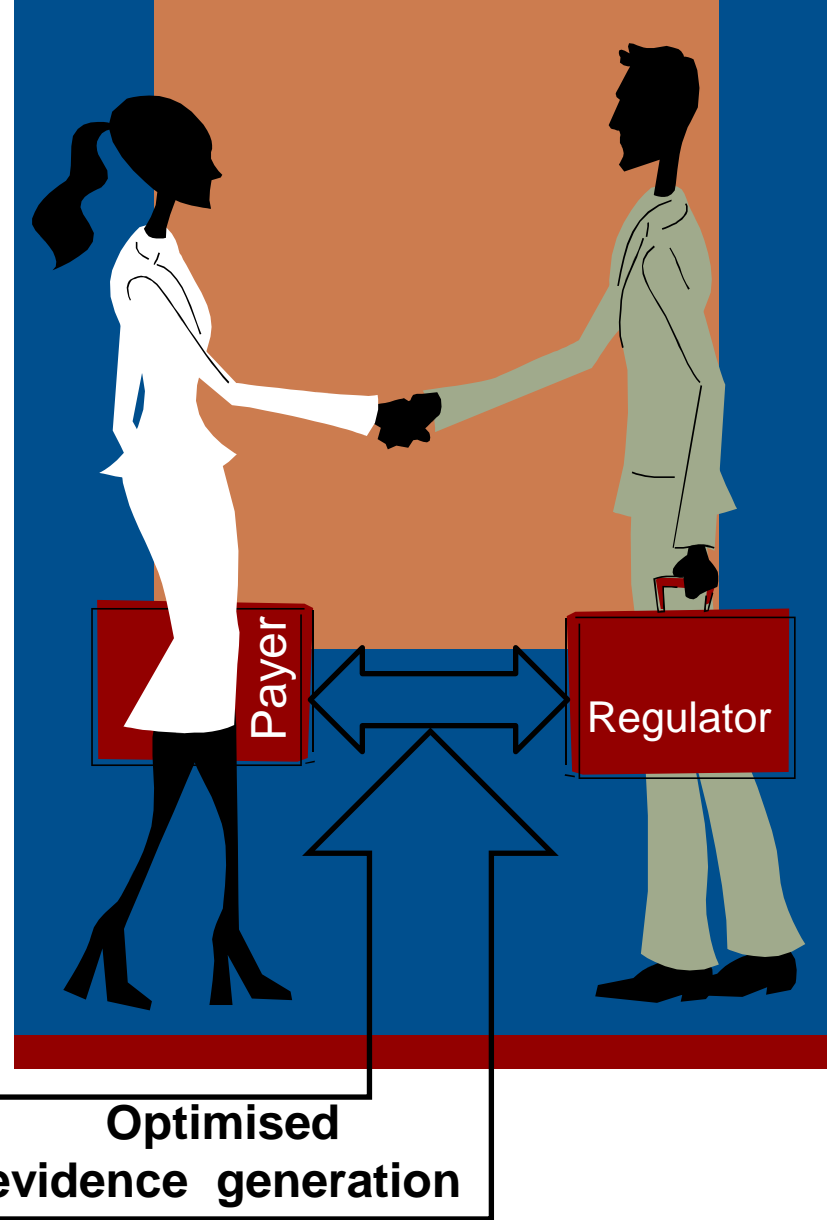
Decisions

The 'value' of the product will vary depending on:

- use in the pathway of care
- population subgroup
- dosing
- background therapy
- etc

Each decision problem requires separate evidence

Collaboration + Communication =
Understanding of Requirements



www.nice.org.uk/scientificadvice

Leeza Osipenko

leeza.osipenko@nice.org.uk